FACTORS ASSOCIATED WITH ANTIRETROVIRAL THERAPY ADHERENCE UNDER OPTION B+ STRATEGY AMONG BREASTFEEDING MOTHERS AT MZUZU HEALTH CENTRE, MALAWI

MASTER OF SCIENCE (MIDWIFERY) THESIS

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Factors Associated with Antiretroviral Therapy Adherence under Option B+ Strategy among Breastfeeding Mothers at Mzuzu Health Centre, Malawi

Master of Science (Midwifery) Thesis

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Declaration

I, Beatrice Kanyimbo hereby declare that this thesis is completely the result of my own original work and has not been submitted for any other awards at the University of Malawi or any other University for similar purposes. The work of other people used in text has been acknowledgement appropriately.

BEATRICE KANYIMBO

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Signature

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Date

Certificate of Approval

The undersigned certify that this thesis represents the student's own work and has been submitted with our approval.

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Dr. Ursula Kafulafula (main supervisor)

Signature _____ Date_____

Mrs. Bertha Chakhame (second supervisor)

Dedication

To my beloved husband Raston Mkandawire and my parents Mr and Mrs Kanyimbo for their love, encouragement and endless support throughtout my studies. I really honour you with profound gratitude.

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List of Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
COMREC	College of Medicine Research and Ethics Committee
EFV	Efavirenz
EMTCT	Elimination of Mother to Child Transmission
HIV	Human Immunodeficiency Virus
LTFU	Lost to follow up
MCH	Mzuzu Central Hospital
MHC	Mzuzu Health Centre
MoH	Ministry of Health
MTCT	Mother to Child Transmission
PMTCT	Prevention of Mother to Child Transmission
TDF	Tenofovir
UNAIDS	United Nations Program on HIV/AIDS
WHO	World Health Organization
3TC	Lamivudine

Operational Definitions

Adherence

The mother's ability to take prescribed medications correctly corresponding with recommendations from the health care provider, whether retained in care or not.

Adherence rate

Describes the degree to which a client correctly follows medical advice and prescribed doses over a period of time. In this study, the Malawi clinical management of HIV in children and adults recommendations will be used which recommends ART adherence rate of ≥ 95% to achieve optimal benefits.

Anti-retroviral drugs (ARV)

Are drugs for the treatment of infections by retroviruses, primarily HIV.

Anti-retroviral therapy

Is referred to the treatment given to people with HIV infection that act on different stages of HIV life cycle to stop the multiplication of the virus and reduce the risk of MTCT. The therapy contains a combination of three ARV drugs which are TDF/3TC/EFV (5A).

Associate

Refers to a relationship between factors and how an HIV positive breastfeeding mother adheres to her ART.

Expert clients

They are health workers who help in the follow-up of HIV sero-positive mothers on ART who have missed appointments and those who have defaulted.

Factors

A factor refers to anything that is associated with how an HIV positive breastfeeding mother adheres to her ART.

Breastfeeding mother

Any woman 18 years and above who is HIV positive, on ART, breastfeeding from 6 weeks to 24 months and attends ART, under-five or family planning clinics at Mzuzu Health Centre (MHC).

Abstract

ART adherence among breastfeeding mothers is very essential in the PMTCT. Standard adherence rate of ≥ 95% sufficiently suppresses the virus and brings much more desirable outcomes, thus; it improves maternal health and reduces rate of vertical transmission of HIV. However, PMTCT remains a challenge after childbirth, with inadequate adherence among the breastfeeding mothers which needs greater attention. The aim of the study was to investigate factors associated with ART adherence by specifically determining social-demographic factors, assessing patient related factors, identifying the therapy related factors, assessing condition related factors, determining health care system factors associated with ART adherence and determining ART adherence rate among breastfeeding mothers on option B+ strategy at Mzuzu Health Centre Malawi.

A quantitative cross-sectional descriptive study was conducted among all HIV positive mothers on ART with children breastfeeding from 6 weeks to 24 months, 18 years and above at Mzuzu Health Centre, Malawi in May to June 2019. Data were collected using a structured questionnaire (face to face interviews). A Statistical Package for Social Sciences (SPSS) version 23.0, bivariate and multivariate logistic regression was used for data analysis.

A total of 323 participants were recruited in the study. The overall ART adherence rate among the breastfeeding mothers under option B+ strategy was 55.1%. The study showed that, forgetfulness ***[AOR 0.08; 95% CI :(0.44, 0.14)],*** religious beliefs ***[AOR 0.49; 95% CI :(0.24, 1.0)]***, accessibility to ART clinic ***[AOR 2.53; 95% CI :(1.13, 5.68)]*** and ART appointment dates ***[AOR 4.73; 95% CI :(1.50, 14.98)]***, were significantly associated with ART adherence under patient related factors and health care system related factors respectively.

The study showed that forgetfulness was the most significant variable which had the greatest effect on ART adherence rate. Therefore, efforts to improve ART adherence rate should focus on promoting strategies for reminders such as cell phones, alarm clocks and family members and other factors which showed significant association in ART adherence.

Key words: ART**,** Adherence, Breastfeeding mothers, Factors, Option B+.

CHAPTER ONE

Introduction and Background

Introduction

Globally, mother to child transmission (MTCT) of human immunodeficiency virus (HIV) remains one of the major causes of new HIV infections among children under the age of 15, and it also causes indirect maternal and neonatal morbidity and mortality. According to World Health Organization (WHO) 2010, MTCT accounts for 25% of new HIV infections in children and in Malawi, it is the second major cause of HIV transmission. Prevention of MTCT (PMTCT) of HIV is one of the strategies that has been put in place to reduce the vertical transmission of the virus. Malawi currently is using option B+ strategy, where pregnant and breastfeeding women are tested and initiated on Antiretroviral Therapy (ART) as soon as possible if tested HIV positive regardless of CD4 count and WHO clinical staging criteria. Implementation of option B+ started in 2011. Some of the reasons why Malawi adopted and is still implementing Option B+ are to; increase access to ART for HIV-positive pregnant or breastfeeding women in a setting that has limited access to CD4 testing, improve mothers' health and reduce post-partum mortality, reduce stigma resulting from restraining breastfeeding and malnutrition among infants (WHO, 2014). It is also one of the standard care which aims to eliminate MTCT in order to achieve an HIV and Acquired Immuno-deficiency Syndrome (AIDS) free generation. In addition, this addresses sustainable development goal number 3 which was set to ensure health and promote wellbeing for all at all ages and target 3.3 which aims to end the epidemics of AIDS by 2030 (Osborn, Cutter, & Ullah, 2015).

The approach implemented in Malawi was a modification of WHO option B policy. ART adherence by pregnant and breastfeeding mothers is very essential in the PMTCT of HIV. According to (MoH, 2018b), adherence rate of ≥ 95% sufficiently suppresses the virus and brings much more desirable outcomes, thus; it improves maternal health, reduces rate of vertical transmission of HIV in current pregnancy and future pregnancies, prevents horizontal transmission and prevents drug resistance (WHO, 2014, 2016; MoH, 2013] .

The implementation of option B+ in the country has resulted in increased availability, accessibility and utilization of PMTCT services, such that between 2011 and 2015, the proportion of women with HIV who were diagnosed increased from 49 to 80%, and the proportion of those who were virally suppressed jumped from 2 to 48% (UNAIDS, 2016). Despite the above results, PMTCT remains a challenge after childbirth, with inadequate adherence among the breastfeeding mothers. Nachega et al., (2012), found an adherence rate of 73.5% during pregnancy and 53% during the breastfeeding period (p=0.005). In addition, according to the recent Global Plan report, half of the new HIV infections in children occur during the breastfeeding period due to internal and external factors like poor health system on follow-up of HIV positive mothers during breastfeeding

period thus, lost to follow-up (LTFU) and poor retention in care (UNAIDS, 2015, 2016). However, this influence ART adherence negatively. Correspondingly, low levels of ART adherence leads to virologic failure, increased risk of MTCT and high risk of drug resistance that may require a change to more expensive second line regimens at early stage (Tsegaye, Deribe, & Wodajo, 2016). Henceforth, the study seeks to explore factors associated with Antiretroviral

Therapy (ART) adherence under option B+ strategy among breastfeeding mothers at Mzuzu Health Centre, Malawi.

Background

HIV and AIDS remain a global challenge. According to UNAIDS, (2016); and WHO, (2010, 2016), MTCT is one of the major causes of new HIV infections among children below the age of 15 and without treatment the likelihood of MTCT is 15 to 45%. Nevertheless, ART and other effective PMTCT interventions have reduced the risk of transmission to below 5% and 2% to breastfeeding and non-breastfeeding population respectively. MTCT is an entry point of ART for life in pregnancy and breastfeeding period regardless of ones CD4 count and WHO clinical staging. Globally in 2016, 36.7 million people were living with HIV, and 1.8 million had new HIV infections of which 160,000 were children. Over the same period, about 5,000 new HIV infections occurred per day and 64% happened in sub-Saharan Africa. About 400 happened among children under the age of 15 and almost 43% were among women. Every year in 21 Global plan priority countries in sub-Saharan Africa, 110 000 children get newly infected with HIV infection. More than half of these new HIV infections in children occur during the breastfeeding period (UNAIDS, 2016). In 2016, Malawi had HIV adult prevalence rate of 9.2% which was high in women 11.2% than in men 7.1%. Among 1.0 million people who were living with HIV, 36,000 had new HIV infections of which 4,300 happened in children due to MTCT. However, globally ART coverage provided to pregnant women who are HIV positive has rose from 47% to 76%, and over the same period HIV new infections among children declined by 47% since 2010. In Malawi, coverage of pregnant women living with HIV accessing ART almost quadrupled from 21% in 2009 to 84% in 2016 (National Statistical Office (NSO)

[Malawi] & ICF, 2017; UNAIDS, 2016). Even though there has been an increase in the initiation of ART in most of the African countries including Malawi, adherence to these Antiretroviral (ARV) drugs has remained a challenge and it needs greater attention.

Option B+ strategy comprises, initiation of ART to all HIV positive pregnant and breastfeeding women, regardless of their CD4 count and WHO clinical staging. This approach in Malawi was a modification of WHO option B policy and was pioneered by Malawi's MoH in 2011 (WHO, 2014). It aimed to simplify the implementation of ART for prevention of vertical transmission and for the health of the mother, as well as preventing horizontal transmission. Its implementation led to a seven-fold increase in women starting ART in the first year alone, and hoped that women who are initiated on ART will adhere to their treatment and remain in care. Under Option B+, HIV infection is diagnosed in many women during routine testing during antenatal care when they are asymptomatic, and these women start treatment soon after they have tested HIV positive. They receive a triple ART regimen once daily containing Tenofovir, Lamivudine, and Efavirenz (TDF/3TC/EFV) called 5A and the newborn is given Neverapine syrup for six weeks after birth (MoH, 2013; Mulamba et al., 2017; WHO, 2016).

WHO, (2010) recommends optimal ART and infant feeding practices as two main strategies to reduce the risk of HIV MTCT and improve HIV free survival of the exposed infants. It recommends that HIV-positive women should exclusively breastfeed their infants until 6 months and continue breastfeeding until 12 months. However, Malawi modified the guidelines to extend breastfeeding to 24 months due to the poor social economic status and cultural aspects of the country. Correspondingly, the recent updated WHO HIV and infant feeding guidelines have adopted the same extended period of breastfeeding (WHO & UNICEF, 2016). In 2014, sub-

Saharan Africa 21 priority countries managed to reduce MTCT rate by half from 28% in 2009 to 14% in 2014. This achievement happened due to quick roll out of option B+ policy, the countries provided ART to additional 55, 000 pregnant women living with HIV in 2014. The data from this report also suggested that low ART adherence and lost to follow-up (LTFU), especially during breastfeeding continue to leave infants vulnerable of acquiring HIV. Nevertheless, it did not achieve the Global plan of reducing MTCT rate of < 5% and < 2% among breastfeeding and the non-breastfeeding populations respectively. On the other hand, the 21 priority countries managed to achieve the overall target of MTCT of 5% at six weeks in 2016, however it rose from 4.7% at six weeks to 8.9% at the end breastfeeding period (UNAIDS, 2015, 2016).

In Malawi the implementation of option B+ has increased the uptake of ART for HIV positive pregnant and breastfeeding women in a setting that has limited access to CD4 testing. It has resulted in a steep reduction of MTCT rate form 27% in 2009 to 9% in 2015 including the breastfeeding period, and the drastic decline of new HIV infections in children from 16,000 in 2010 to 4,300 in 2016. This was due to increased coverage of mothers receiving ART from 23% to 84% over the same period. Despite the quadruple coverage of women who receive ARVs to prevent new HIV infections among children, MTCT during breastfeeding remains a challenge. In 2015, MTCT rate during the final period of breastfeeding was 9%, which did not manage to achieve the Global plan of Elimination of Mother to Child Transmission (EMTCT) of <5% among the breastfeeding infants. Hence it calls for more strategies, so as to achieve the Global goal. (Adetokunboh & Oluwasanu, 2016; UNAIDS, 2015, 2016, 2017). On the other hand, Malawi integrated HIV report first quarter (2018) showed that, a total of 9,220 clients were registered in ART clinics on option B+, and at 24 months survival and retention rate was 68%

and 26% were defaulters. Over the same period Mzimba north as a district registered 323 clients and survival and retention rate at 24 months was 51% and default rate of 29%. While, Mzuzu Health Centre, registered a total of 133 clients at ART clinic on option B+, and at 24 months survival and retention rate was 50% and 37% were defaulters while 13% were transferred out (MoH, 2018). The data from previous and recent reports has shown that Mzuzu Health Centre registers had many clients compared to any health facility in Mzimba north.

Despite the effective interventions and prevention strategies from WHO, the government and non-governmental organizations on PMTCT, HIV transmission remains a global problem. The concern remains that women with asymptomatic HIV infections may not be retained and adhere poorly to treatment and most LTFU women continue to breastfeed after stopping ART because they consider breastmilk to be an important source of nutrients for the child hence, increasing the risk MTCT of HIV. Regardless of the benefits in an infant's health, PMTCT cascade recommends breastfeeding in resource poor countries and yet, it remains a major weakness to EMTCT of HIV (Flax et al., 2017; UNAIDS, 2011, 2015, 2016; WHO, 2014). Evidence from several studies have highlighted the challenges in the implementation of option B+ strategy in regards to poor retention in care and early and high LTFU during the breastfeedingperiod. For instance, in a systematic review of ART adherence during pregnancy and breastfeeding which was done in low, middle and high income countries in 2012 it was found that, during pregnancy there was adherence rate of 73.5%, compared to 53% during the breastfeeding period (p=0.005) (Nachega et al., 2012). By the same token, in a study done in Uganda by Decker et al., (2017) the results showed that 76.5% of the women breastfed for greater than 12 months, however, no woman adhered completely for 18 months. In Malawi, a

study done by Haas et al., (2016) showed adequate ART adherence rate of 73% during pregnancy compared to 66% in the first three months breastfeeding, however only 30% maintained adequate adherence at each subsequent visit. A nationwide facility level data analysis study in Malawi found that, under option B+ LTFU rate was 24% and happened in the first 6 months in high patient volume facility with most losses occurring in the first 3 months of ART initiation. Women who started ART during pregnancy were five times more likely than women who started due to their own health to never return after their initial clinic visit (odds ratio 5.0, 95% CI 4.2-6.1). While breastfeeding women were twice as likely to miss their first follow up visit (odds ratio 2.2, 95% CI 1.8-2.8) (Tenthani et al., 2014). Similarly, Tweya et al., (2014), found a significant LFTU of women within the first year of ART initiation which accounted for 47%, and these women only received drugs once and never returned to refill the drugs.

Evidence has shown that HIV treatment can dramatically extend the lifespan of people living with HIV and effectively prevent HIV transmission. Malawi's option B+ roll out has been very successful, in achieving up to 84% coverage (UNAIDS, 2016). Despite the success on the implementation of option B+ in the country, there are still high rates of lost to follow-up and default rate from option B+ especially during the breastfeeding period. This leads to sub-optimal ART adherence increasing the risk of MTCT of HIV (Tweya et al., 2014). Yet ART adherence rate of >95% sufficiently suppress the virus and brings much more desirable outcomes (MoH, 2018b). Therefore, there is need for healthcare workers to explore factors influencing ART adherence.

According to Chesney (2000), before implementing measures to improve ART adherence, it is vital to identify the main factors that contribute to the inability of patients to take

their medications as expected. The critical factors that influence adherence fall into five main categories; socioeconomic factors, treatment related factors, patient related factors, disease related factors and healthcare delivery system related factors (Chesney, 2000; Sabaté & WHO, 2003). Growing evidence has shown that many factors influence adherence positively as well as negatively.

Although there is free decentralized provision of ART in facilities, literature have documented several factors associated with ART adherence, LTFU and retention in care under option B+ strategy. For example, in some studies done in Nigeria, Tanzania and Uganda the main motivation to ART adherence was to protect the unborn and have an HIV free baby. In addition, support from male partners as well as peers, family and support groups enhanced good adherence. However, once the baby is born most women stop taking medications especially if they have experienced side effects (Buregyeya et al., 2017; Ekama et al., 2012; Ngarina, Popenoe, Kilewo, Biberfeld, & Ekstrom, 2013). On the other hand, same day diagnosis and treatment, younger age, parity, poor understanding of option B+, denial to disclose the HIV status, poor socioeconomic status, poor treatment from service providers, heavy workload and staff shortages, negative health worker attitude, medicine shortages and detrimental health facility policies are some of the factors associated with low ART adherence. At community level stigma was key a factor (Decker et al., 2017; Dube, 2016; Ekama et al., 2012; Haas et al., 2016; Hodgson et al., 2014; Ngarina et al., 2013; Tenthani et al., 2014; Tsegaye et al., 2016; Hoffman et al., 2017). However, majority of these studies have combined pregnant and breastfeeding mothers. In Malawi, most of the studies reviewed by the researcher have shown that they were

conducted in the central and southern part of the country, while the problem is cross cutting among the women hence the purpose of this study.

Problem statement

Currently in Malawi, ART adherence rate among breastfeeding mothers is sub-optimal. Evidence has shown that there is low ART adherence during breastfeeding (66%) compared to pregnancy (73%) period (Haas et al., 2016). Further evidence reveals that only 30% maintained adequate adherence at each subsequent visit, yet ART adherence rate of >95% is required for optimal viral suppression and treatment success in breastfeeding mothers to improve maternal health, prevent HIV MTCT during the breastfeeding period as well as to prevent drug resistance (MoH, 2018b). This poses a greater risk of HIV MTCT during breastfeeding. Despite good initiation of ART, adherence calls for more attention because it is the most complicated and dynamic issue influenced by internal and external factors. Many of the studies reviewed by the researcher have combined pregnant and breastfeeding mothers on the factors associated with ART adherence, hence the study.

Justification of the study

This study is significant because it will assist to determine the factors associated with ART adherence among breastfeeding mothers. The findings from this study will contribute the understanding of the local situation in different settings, which may influence the program managers to evaluate policies and make recommendations to address the problem. The findings may also inform healthcare workers in anticipating non-adherence and assist in promoting adherence. The study results will also help to identify possible solutions and develop strategies,

to facilitate better drug adherence among these women and improve retention in care as well as prevent the LTFU. This will help to achieve the goal of eliminating MTCT of HIV infections among children to <5% by 2020 (UNAIDS, 2011). It will help the health care providers to identify the key focus areas in the PMTCT service context, and will also act as a base for further research studies in the same area. The results will also influence policy makers to place as much emphasis on the breastfeeding period and ensuring adherence to antiretroviral therapy following birth, as they do with pregnancy period. In addition, the need to develop better methods to measure adherence, especially at the national level (UNAIDS, 2016).

Broad objective

To investigate factors associated with ART adherence among breastfeeding mothers under option B+ strategy at Mzuzu Health Centre

Specific objectives

1. To determine ART adherence rate among breastfeeding mothers on option B+
2. To determine social-demographic factors associated with ART adherence among breastfeeding mothers on option B+
3. To assess patient related factors associated with ART adherence among breastfeeding mothers on option B+
4. To assess the condition related factors associated with ART adherence among breastfeeding mothers on option B+

5. To identify the therapy related factors associated with ART adherence among breastfeeding mothers on option B+
6. To determine health care system factors associated with ART adherence among breastfeeding mothers on option B+

CHAPTER TWO

Literature review

Introduction

"Literature review is a written summary of the state of evidence on a research problem" (Polit & Beck, 2010, p. 192). The review covers key concepts and available information relating to the researcher's understanding of the topic. It also provides comprehensive background for understanding current knowledge and highlights the significance of the new study (Polit & Beck, 2017). The main aim of this chapter is to present an analytical appraisal of the recent work by determining what is already known about the topic and to identify gaps within findings of similar studies conducted elsewhere.

An extensive search of articles from electronic databases and search engines such as Science Direct, BioMed Central, and Google Scholar, Malawi Medical Journal, Journal of the International AIDS Society, HINARI, Wiley online library and PubMed was done. Besides, websites for international organizations like WHO, UNICEF, and UNAIDS were also searched for relevant publications and information. The keywords used to search for literature included; breastfeeding mothers, lactating women, factors associated with, ART adherence, assessing adherence, retention in care, ART, Option B+, PMTCT, international, Sub- Saharan Africa and Malawi. The researcher screened the identified literature for relevance and only included peer reviewed articles, articles published in English and papers published from 2008 to 2019. However, some old literature has been cited because it contained important information from

primary source for the study. This chapter will be guided by the objectives as well as the conceptual framework.

Conceptual Framework

Adherence to long-term therapies: Evidence for action

This conceptual framework is mainly focused on **adherence**, which is defined as the "extent to which a person's behavior of taking medication, following diet and/or executing lifestyle changes, corresponds with the recommendations from a healthcare provider" (WHO, 2003 p. 3). It was developed by the WHO to study and improve adherence of therapies to chronic conditions like: mental disorders, non-communicable and communicable diseases (Diabetes, Asthma, Epilepsy, Cancer, Depression, Hypertension, HIV/AIDS and Tuberculosis). The concept of adherence is a better way of capturing dynamic and complex changes required of many players over long periods to maintain optimal health in people with chronic conditions. Initially the patient was thought to be the source of the problem with adherence. However, later the role of the health care providers was also addressed, and currently, system approach is acknowledged.

Adherence is a multidimensional phenomenon determined by the interplay of five sets of factors. In this framework the factors are also termed dimensions of which patient related factors are just one of the determinants. With a common belief that patients are solely responsible for their own treatment, it is misleading and most often reflect a misunderstanding of how other factors affect people's behavior and capacity to adhere to treatment. Other dimensions include; social and economic factors, health care/system factors, therapy related factors and condition

related factors. These factors exert positive and negative influence on the long-term therapies. However, health systems and providers need to develop means of accurately assessing not only adherence, but also those factors that influence it. Similarly, the developed strategies targeting adherence must be tailored according to particular condition.

Patient related factors, such as forgetfulness, anxieties about possible adverse effects, low motivation, inadequate knowledge about the disease and treatment, lack of self-perceived need for treatment, negative beliefs regarding the efficacy of the treatment, non-acceptance of the disease, hopelessness, lack of support, status disclosure issues and stigma of the disease have reported to affect adherence. **Social-economic factors,** these are factors like; poor socioeconomic status, poverty, illiteracy, low level of education, unemployment, lack of effective social support networks, long distance from treatment centre, high cost of transport and medication, unstable living conditions, culture and lay beliefs about illness and treatment. **Social-demographic factors** (gender, marital status, age, educational level and health status) have shown effects on adherence but it differs from one setting to another. **Health care/system related factors**, a good patient-provider relationship may improve adherence, however, there are several factors that have a negative effect and these include; poor medication distribution systems, overworked health care providers, lack of incentives and feedback on performance, weak capacity of the system to educate patients and provide follow-up, inability to establish community support and self-management capacity, lack of knowledge on adherence and of effective interventions for improving it.

Therapy related factors, most notable ones are; complexity of the treatment, duration of treatment, the immediacy of beneficial effects, previous treatment failures, frequent changes in

treatment, side-effects, and the availability of medical support. **Condition related factors,** represent particular illness and related demands faced by the patient. Some of the factors include; severity of symptoms, level of disability, rate of progression and severity of the disease and the availability of effective treatment.

The conceptual framework illustrated below has been developed and adapted from Adherence to long-term therapies: Evidence for action WHO, (2003). The study will operationalize some of the concepts from the framework (**figure 1**).

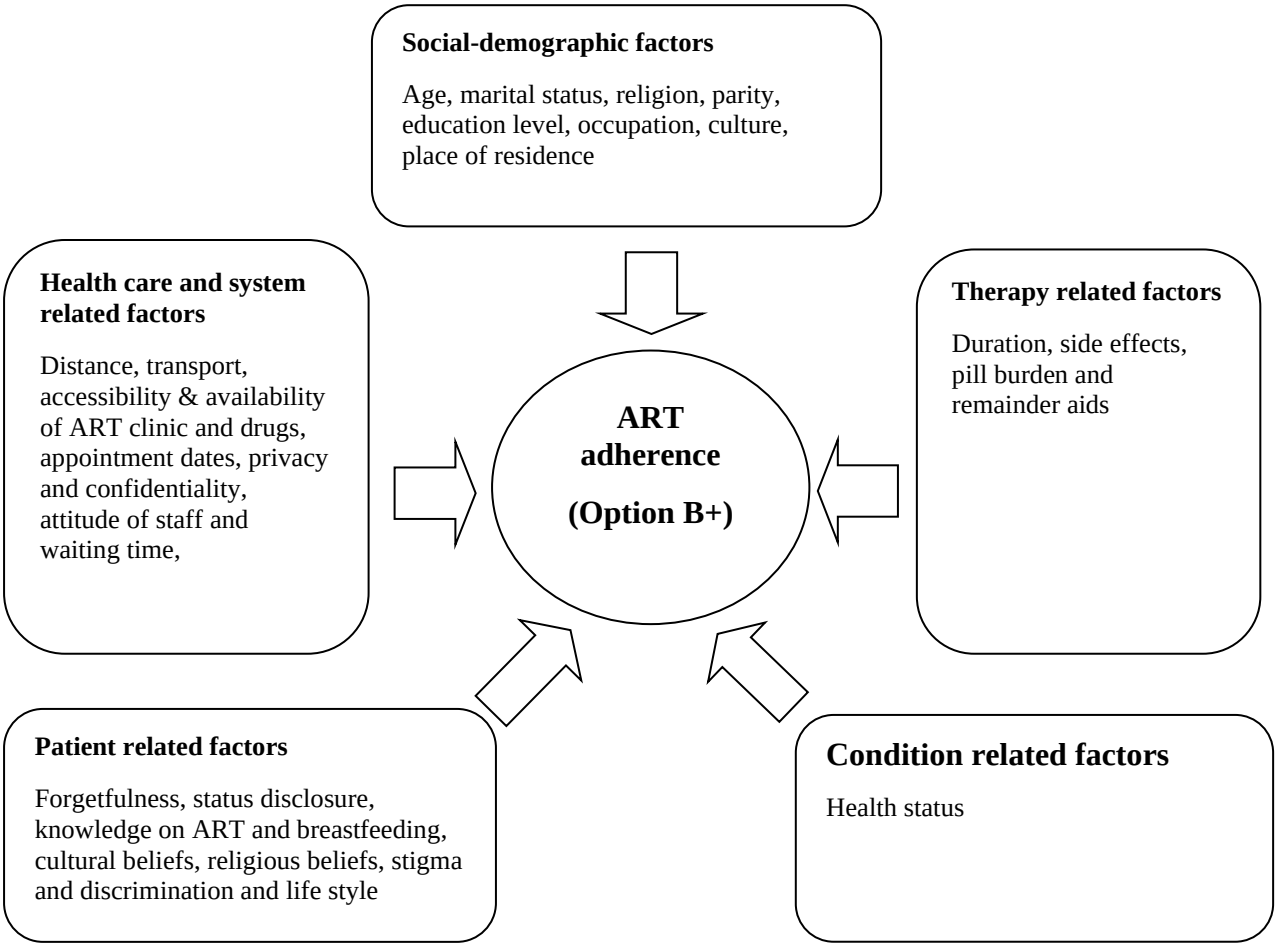

Figure 1: Conceptual framework on ART adherence (option B+)

Source: Adapted from the WHO framework for adherence to long-term therapies

ART adherence during breastfeeding period

The introduction of ART has enabled HIV positive women to pursue motherhood. However, the success of ART in decreasing morbidity and mortality in mothers, as well as reducing perinatal infections is dependent on adherence to treatment. On the other hand, sub-optimal adherence to ART can counteract its benefits. Evidence has shown that ART adherence declines among HIV infected women from pregnancy to breastfeeding period despite increased risk of morbidity and mortality during this period, as a result of increased immunosuppression (Bardeguez et al., 2008; Boehem et al., 2014).

According to literature, postpartum adherence on Option B+ is generally low. In studies conducted in Tanzania and Nigeria on ART adherence during postpartum period, most women reported a motivation to take their medication while pregnant in order to protect their child. However, once the child was born, most women felt they could stop taking their medication, especially if they had experienced negative side-effects (Ekama et al., 2012; Ngarina et al., 2013). In contrast, other women do not take ART even while pregnant as well as breastfeeding for fear of harming the baby (Ferguson & WHO, 2013). Similarly, in Uganda, young women initiated on Option B+ reported stopping treatment as soon as they gave birth because health workers were targeting to save the baby from HIV vertical transmission (Webb & Cullel, 2013). Correspondingly, in a nationwide facility level data analysis study in Malawi, it was found that, women who started ART during pregnancy were five times more likely never to return after their initial clinic visit than women who started due to their own health [Odds Ratio (OR) 5.0, 95% CI 4.2-6.1]. Furthermore, breastfeeding women were twice as likely to miss their first follow up visit (OR 2.2, 95% CI 1.8-2.8) (Tenthani et al., 2014). Therefore, LTFU and poor retention of

women during breastfeeding period has generally been a challenge in many countries implementing option B+ strategy.

Magnitude of ART adherence among breastfeeding mothers

ART adherence rate of ≥95% is required for optimal viral suppression and treatment success in breastfeeding mothers, to improve maternal health, prevent HIV MTCT during the breastfeeding period as well as to prevent drug resistance (MoH, 2018b). However, evidence has indicated that there is low ART adherence during breastfeeding compared to pregnancy period, which poses a risk of MTCT transmission during breastfeeding period. In a systematic review on ART adherence during pregnancy and breastfeeding which was done in low, middle and high income countries in 2012 found that, adherence rate during pregnancy was 73.5% compared to 53% during the breastfeeding period (p=0.005) (Nachega et al. 2012). By the same token, in a study done in Uganda by Decker et al. (2017) the results showed that 76.5% of the women breastfed for greater than 12 months. However, no woman adhered to ART completely for 18 months. Similarly, in a retrospective study conducted in Johannesburg South Africa, there was an increased risk of non-adherence during the breastfeeding period with relative risk (RR) of 1.46, 95% Confidence Interval (CI), compared to pregnancy itself with RR 0.95, 95% CI (Henegar et al., 2015).

Correspondingly, in a Malawi study done by Haas et al. (2016) revealed adequate ART adherence rate of 73% during pregnancy compared to 66% in the first three months breastfeeding, however only 30% maintained adequate adherence at each subsequent visit. In a nationwide facility level data analysis study it was found that, under option B+ LTFU rate was

24% and happened in the first 6 months in high patient volume facility with most losses occurring in the first 3 months of ART initiation. Such that women who started ART during pregnancy were five times more likely never to return after their initial clinic visit than women who started due to their own health (OR 5.0, 95% CI 4.2-6.1). On the other hand, women who started treatment while breastfeeding were twice as likely to miss their first follow up visit (OR 2.2, 95% CI 1.8-2.8). In addition, the study found a significant LFTU of women within the first year of ART initiation which accounted for 47%, and these women only received drugs once and never returned to refill the drugs (Tenthani et al., 2014). This further shows that when a woman has given birth, their ability to continue ART adherence is reduced.

Measuring patient ART adherence

Recommended adherence rate of ≥ 95% sufficiently suppress the virus and brings much more desirable outcomes, thus; it improves maternal health, vertical transmission of HIV in current pregnancy and future pregnancies, prevents horizontal transmission and prevents drug resistance (WHO, 2014, 2016; MoH, 2013). However, Lam & Fresco, (2015) shows that after decades of research, there is very little guidance for health professionals and researchers to choose the most suitable adherence measures. Adherence to therapy is difficult to measure accurately, and evidence has shown that there are no gold standard methods for measuring adherence (Chesney, 2000). The methods of measuring adherence are categorized into two: direct methods (therapeutic drug monitoring and directly observed treatment) and indirect methods (self-report, pill count, pharmacy refill records and medication event monitoring system), these methods have their advantages and disadvantages. Direct methods are the most accurate however, expensive and difficult to perform because it requires to monitor the process

and carry out tests. On the other hand, indirect methods measures are subjective and their most advantage is that they can provide explanations for client's non-adherence (Chesney, 2000; Jimmy & Jose, 2011; Krousel-Wood, 2015; Lam & Fresco, 2015).

Self-report

It is the most commonly used method to measure adherence in clinical and research setting. Self-report method has low costs, takes little time and is flexible to design (questionnaire suit different language abilities). It also has low staff and respondent burden. In addition, self-report data is easy to collect and while discussing, it can help determine the reasons why the patient has missed the doses. It can also help distinguish between intentional and unintentional reasons as well as discussing for potential solutions. Nevertheless, it tends to overestimate adherence because the self-report reflects only on short term or average, and also it has non standardized questions. Another setback is that patients underreport the non-adherence to avoid disapproval from the health care providers. Regardless of the limitations, evidence has shown that this measure of adherence has high degree of correspondence with other measures like pill count and electronic medication monitoring (Chesney, 2000; Evan & Fox, 2013; Lam & Fresco, 2015). For instance, Bailey et al., (2014); Decker et al., (2017); Kreitchmann et al., (2012); Tsegaye et al., (2016) used this method assess adherence in their studies.

Pill count

Pill count involves counting the remaining doses of medication and assuming that the return of excess pills provide tangible evidence of non-adherence. The clients are asked to bring the pill container for the health care providers to physically count the remaining pills. This method is simple and inexpensive. However, it is time consuming and prone to errors.

Furthermore, the clients may inadvertently discard the pills or pill sharing prior to the clinic visit which may lead to over estimation of adherence. In addition, it does not explain if the patient took the medication at the correct time with the appropriate good dietary requirements (Chesney, 2000; Evan & Fox, 2013; Jimmy & Jose, 2011). Despites the above mentioned setbacks of this method, Gertsch et al., (2013); Tsegaye et al., (2016) studies used this method to assess adherence.

Pharmacy refill records

Pharmacy refill records is based on the objective estimate calculated from routinely collected pharmacy records. Adherence rates from pharmacy refill records are determined by comparing the actual with expected refill dates. It is commonly used in settings where medications are provided and financed in a single location especially in a closed pharmacy. Equally important, pharmacy refill records can generate a refill list and flag the patients who are not coming for the refills. However, it cannot be easily implemented for routine data collection on adherence since it depends on information technology which is not universally available in most resource limited countries. It requires the patient to use the same pharmacy each time which is a setback if patients are mobile. Also the wrong assumption that patients collecting medications regularly on the due dates are adhering to treatment (Jimmy & Jose, 2011; Lam & Fresco, 2015). Despite the limitations, Haas et al., (2016) used this method to assess ART adherence among women receiving care in Malawi under option B+ program.

Therapeutic drug monitoring

Therapeutic drug monitoring is considered to measure the medication adherence which is feasible in clinical and research (trial) settings. It measures the drug or its metabolite

concentration in body fluids like blood and evaluation of the presence of a biological marker given with the drug. Besides, the method measures only the recent doses. (Chesney, 2000; Lam & Fresco, 2015). However, this method is often impractical because it is expensive and not easily accessible and available in many resource limited settings. In addition, some tests are difficult to perform, and some can be very invasive which may cause pressure and anxiety in patients. Furthermore, the drug-food and drug-drug interaction may hinder the accuracy, and also tends to over-estimate the adherence because some patients may take the medication prior to clinic visit for the upcoming tests (Evans & Fox, 2013; Lam & Fresco, 2015). One of the studies which have used this method was on, adherence to antiretroviral treatment decreases during postpartum compared to pregnancy: A longitudinal electronic monitoring study by Gertsch et al., (2013).

Directly Observed Treatment (DOT)

DOT is the objective method of measuring adherence, it is where health care providers administer medicine directly to the patients. It also confirms the adherence since the healthcare providers observe the patients taking the drugs. On the other hand, this method can predispose patient to stigma, uncovers patients' privacy, and it is expensive for a life-long ART treatment (Jimmy & Jose, 2011; Lam & Fresco, 2015). Therefore, this methods is mostly used to patients who need intermittent administration and hospitalization.

Factors associated with ART adherence among breast feeding mothers

There are many factors which influence ART adherence. According to Chesney, (2000); WHO, (2003), the critical factors that influence adherence fall into five main categories; socioeconomic factors, therapy related factors, patient related factors, disease related factors and

healthcare delivery system related factors. These factors exert positive and negative influence on the long-term therapies including ART. Therefore it is essential to identify the main factors before implementing measures to improve adherence.

Social-demographic factors

Evidence has indicated that social-demographic factors generally do not predict adherence behavior. However, some literature have revealed that factors like age, parity, level of education, place of residence, occupation, marital status, culture and religion can influence adherence (Hoffman et al., 2017). Similarly, Sabaté & WHO, (2003) highlighted that some factors reported to have a significant effect on adherence, for instance; poor socioeconomic status, poverty, illiteracy, low level of education, lack of effective social support networks, long distance from treatment centre, high cost of transport, changing environmental situations, culture and lay beliefs about illness and treatment which will lead to stigma.

Literature has revealed that, women reported that the overwhelming demands of everyday life, poverty, work conflict and lack of empowerment posed significant barriers to ART adherence. Low level of education (primary level) has also been reported as a setback because women with primary education reported having little or no income which was related to the cost of transport, prescription, diagnosis and food. On the other hand, completion of primary school was significantly associated with retention in care (OR 3.06) (Clouse et al., 2014; Ngarina et al., 2013; Tweya et al., 2014). Age has been reported to be associated with adherence, Hoffman et al., (2017), has shown that odds retention and ART adherence was significantly higher among women whose age was >25 years (OR 2.44), compared to those who were 18 to ≤ 25years (OR 1.00). Correspondingly, in studies done in Malawi and Uganda younger age ($p<0.01$) and lower

parity lower parity ($p = 0.04$) were cited as significant obstacles in ART adherence (Decker et al., 2017; Haas et al., 2016). However, Tsegaye et al., (2016) showed that women who received in-hospital treatment and lived in rural areas, were at a greater risk of poor adherence to the treatment.

Patient related factors

Patient beliefs and behaviours play an important role in adherence and is a critical link between a prescribed regimen and treatment outcomes. Patient related factors represent the resources, knowledge, attitudes, beliefs, perceptions and expectations of the patient, and are the major contributor of ART adherence (Sabaté & WHO, 2003). Evidence has shown that the most common patient related factors that affect adherence include: forgetfulness, status disclosure, knowledge, cultural beliefs, feeling stigmatized, life style, psychosocial support, motivation, lack of self-perceived need for treatment and hopelessness (WHO, 2003).

Some studies have cited that, the main facilitator for most women to initiate and adhere to ART during breastfeeding period was the desire to have an HIV free child and improve their health. However, once the child is born, and have been successfully protected and weaned, women felt they could stop taking their medication, especially if they had experienced negative side-effects. In addition, some variables which motivated women to ART adherence were: knowledge of the health benefits of ART, social support from male partners, peer and family support groups as well as encouragement from community health workers, self-efficacy, side effects subsiding, poor in health status and fear of future sickness (Buregyeya et al., 2017; Ekama et al., 2012; Gertsch et al., 2013; Gugsa et al., 2017; Kim et al., 2016; Ngarina et al., 2013). Furthermore, Hoffman et al., (2017), reported statistical significance between HIV status

disclosure to the primary sex partner and ART adherence among women retained in care than those who defaulted care (100% versus 78%, $p < 0.001$). Consequently, the above mentioned factors enhanced good ART adherence among women under option B+ strategy.

On the other hand, despite free decentralized provision of ART, evidence has shown that obstacles to ART adherence among mothers initiated on option B+ still exist. To begin with, several studies have revealed that starting ART with option B+ strategy face challenges in treatment adherence. It often leaves very little time for women to process their diagnosis, because ART is initiated on the same day they are diagnosed HIV positive (test and treat policy). This, together with the natural power imbalance between health providers and patients, women report feeling pressured to accept treatment with inadequate information on side effects, the commitment required for life-long treatment and without adequate support and referral pathways for adherence (Buregyeya et al., 2017; Haas et al., 2016; Kim et al., 2016; Matheson et al., 2015; Tsegaye et al., 2016). Forgetfulness on when to take ART medication, has been cited in the studies as one the setback on ART adherence (Ebuy, Yebyo, & Alemayehu, 2015; Kreitchmann et al., 2012; Sabaté & World Health Organization, 2003). Further evidence shows that 92.3% respondents reported forgetfulness as one of the common reason of not adhering to the treatment in Ethiopia (Ebuy et al., 2015). Fear of HIV status disclosure to partners or significant others has also been cited as one of the major obstacles in ART adherence among breastfeeding women. This leads to poor social support from partners and family as well as poor male involvement, hence poor ART adherence among postpartum women. In addition, fear to stigma and discrimination from the community if status has been disclosed to family members has also been associated with poor ART adherence (Buregyeya et al., 2017; Clouse et al., 2014; Flax et al.,

2017; Mulamba et al., 2017; Ngarina et al., 2013). Nevertheless, economic stability have been proved to improve ART adherence and retention mostly when clients have disclosed their HIV status, because of the association with support from primary male partner and family (Hoffman et al., 2017). Conversely, health service providers must always respect a client's choice. Ekama et al., (2012), highlighted that fear to be identified as HIV positive (stigma and discrimination) was the common reason for non-adherence which accounted for 63.6% in Nigeria.

Kreitchmann et al., (2012); Nachega et al., (2012) reported that, a decrease in ART adherence during breastfeeding period is associated with alcohol and tobacco use. In South America, competition with other issues including family obligation and hectic lifestyle were the most frequently cited barriers to adherence (Gertsch et al., 2013). Similarly, Ngarina et al., (2013) reported that being over whelmed with demands of everyday life, feeling healthy, and feeling hopelessness, were associated with poor ART adherence during breastfeeding period. Emotional stresses, depression especially during postpartum period, poor understanding of HIV, ART, & PMTCT, and difficulty in managing practical demands of ART were also cited as setbacks for ART adherence among breastfeeding mothers (Hodgson et al., 2014; Nachega et al., 2012).

Therapy related factors

Having ARVs with less complex regimen can improve ART adherence. However, there are a number of therapy related factors that pose as stumbling blocks to ART adherence. Most notable ones are those related to the complexity of the treatment, duration of treatment, the immediacy of beneficial effects, side-effects, and the availability of medical support to deal with them (Sabaté & WHO, 2003). At the outset, the occurrence of or fear of side-effects while on

ART treatment has been identified in the literature as a significant barrier to adherence, especially where there is inadequate counselling and poor understanding of these side-effects (Merten et al., 2010). In a study on attrition rates and adherence for women initiated onto option B+ in Malawi, 10% of the women reported non-adherence due to side-effects (Tweya et al., 2014). Although side effects tend to disappear with time, increased patient load and poor quality counselling may result in patients not receiving adequate information about side effects, which impacts adherence (Merten et al., 2010). Studies done in Malawi and Uganda have revealed that side effects were the commonly cited barriers to ART initiation and adherence. Further evidence shows that, 50% of the women stopped ART due to experiencing multiple side effects at once. Other women also cited the big size of the tablet as one of the obstacle to ART adherence. However, subsiding of side effects was reported as a facilitator for restarting ART (Buregyeya et al., 2017; Kim et al., 2016). In addition, a qualitative study done in Swaziland found that, women felt overwhelmed by the lifetime commitment of ART, feeling healthy when asked to initiate ART, preference for short course prophylaxis and fear of side effects (body changes) (Katirayi et al., 2016).

Condition related factors

On condition related factors evidence has shown that the severity of symptoms, level of disability and rate of progression and severity of the disease is associated with adherence (Sabaté & WHO, 2003). Practically initiation of ART under option B+ strategy leaves very little time for women to think over their diagnosis. Literature has revealed that, initiating women on lifelong ART on the same day that they are diagnosed with HIV was associated with poor adherence, due to women being asymptomatic during ART initiation. Furthermore, evidence shows that 60% of

those who were diagnosed with HIV 74% were less likely to adhere to treatment (Tsegaye et al., 2016). Conversely, some studies have also found that, being initiated earlier on ART while still asymptomatic and feeling healthy were barriers to ART adherence (Kim et al., 2016; Ngarina et al., 2013; Tsegaye et al., 2016; Tweya et al., 2014). In contrast, feeling hopeless of the disease, decline in health and fear of future sickness were cited as facilitators to ART adherence (Kim et al., 2016; Ngarina et al., 2013; Tweya et al., 2014).

Health care and system related factors

Health workers are the key drivers for strengthening PMTCT program information management in the health facilities. Nevertheless, unapproachability of health services providers has been well documented as a setback to uptake of health services across a wide range of perspectives (Kumwenda et al., 2018). Good patient-provider relationship may improve ART adherence, although they are many negative factors that affect adherence which include; poor medication distribution systems, burnout of health care providers, lack of incentives and feedback on performance, weak capacity of the system to educate clients and provide follow-up care, inability to establish community support and lack of knowledge on adherence (Sabaté & WHO, 2003). Correspondingly, in a study done in Zimbabwe by (Dube, 2016) it was reported that, negative health worker attitudes, shortages of medicine, heavy workload, shortage of staff and detrimental health facility policies posed a risk to poor ART adherence.

Many studies have drawn much attention to counseling as being positive and useful for clients in ART adherence and retention in care. However, poor quality counselling as a result of health worker shortages, poor communication skills as well as the inadequate information given out during counselling has a negative impact on adherence. In Malawi, women receiving

PMTCT reported that they did not perceive long-term ART as part of PMTCT, suggesting health workers could not have expressed this point adequately during counselling (Ferguson & WHO, 2013). The type of workers providing counselling is important in terms of quality of counselling. In resource poor settings lay counsellors are used to provide pre and post-test HIV counselling in order to alleviate the burden for health workers. However, lay counsellor training is often poor and they may end up only providing information, rather than recognizing and changing a patient's behaviour such as inadequate adherence (Kagee et al., 2011).

In a study done by the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) on the acceptability of Option B+ in Malawi, most women reported that they were unable to obtain adequate information about the program because health workers were rushed and the women could not ask questions. In addition, women reported feeling vulnerable when accessing services due to health workers being harsh, threatening and lacking respect (Ferguson & WHO, 2013). Similarly in a cross section study done in Uganda by Buregyeya et al., (2017) it was found that, a number of women felt that counselling was inadequate and had questions about taking ART for life. In Uganda, 33% of women accessing PMTCT services reported that health workers were rude and displayed generally unacceptable behaviour (Duff et al., 2010). Health workers have also been accused by the women of being discriminatory towards HIV positive women. A multi-country study on maternal health worker's attitude conducted in Africa, Asia, Latin America and the Middle East found that heavy workload, long working hours, inadequate supervision, poor salaries and lack of equipment were all self-reported by health workers as contributing to negative health worker attitude (Mannava, Durrant, Fisher, Chersich, & Luchters, 2015).

A study done in Malawi by Cataldo et al., (2017) showed that, patients identified fear regarding the breach of privacy and confidentiality as a barrier contributing to LTFU of women initiated under the Option B+. In another study done in Swaziland, it was reported that before ART initiation nurses preferred to determine on an individual basis number of counseling appointments the woman needed, adequate community sensitization about HIV and ART, as well as the need to educate men about HIV and ART. Hence, understanding women's concerns will aid in developing effective counseling messages, and designing appropriate counseling structures. In addition, providing appropriate support during ART initiation and also knowing who to target in the community (Katirayi et al., 2016).

Summary

This chapter reviewed literature related to ART adherence globally, in Sub-Saharan Africa as well in Malawi. Literature on ART adherence during breastfeeding period, the magnitude of ART adherence among breastfeeding mothers and concluded with factors associated with ART adherence (option B+). It is anticipated that study results may help to inform program managers identify possible solutions and develop strategies, to facilitate better drug adherence among the women on option B+ and improve retention in care as well as prevent the LTFU. In addition, it will contribute evidence to the body of knowledge. The next chapter will discuss the methodology to be used in the study.

CHAPTER THREE

Methodology

Introduction

This chapter gives an overview of the research methodology used for the study. It describes the study design, setting, population, sample size, sampling method, inclusion and exclusion criteria, data collection instrument , data collection process, validity and reliability of the instrument, data management, data analysis and ethical consideration

Study design

This was a quantitative cross sectional descriptive study which was guided by the WHO framework for adherence to long-term therapies. The use of quantitative methods in this study aimed at measuring the factors associated with ART adherence. The design involves collecting data at one point in time and is appropriate for describing the status of relationships among phenomena at a fixed point (Polit & Beck, 2010; Schmidt & Brown, 2012).

Study setting

According to Polit & Beck, (2010), " a setting is the physical location and conditions in which data collection takes place in a study" (p.568). The study was conducted at Mzuzu Health Centre, Malawi. It has a catchment population of 220,649 square kilometers. This site was chosen because it is the busiest health centre in the city, and acts as district hospital (Mzimba North District Hospital Office) because the city does not have the district hospital. It also provide ART services to all eligible clients including pregnant and breastfeeding mothers.

Study population

The study population included all HIV positive breastfeeding mothers with children from 6 weeks to 24 months under option B+ strategy, at Mzuzu Health Centre ART, under five, postnatal and family planning clinics. The above mentioned service care points are where the researcher accessed the study population and achieved the sample size. The inclusion from 6 weeks is supported with a study conducted by Decker et al., (2017), which showed effect on the postpartum adherence on option B+ in Uganda.

Sample size

Sample size for this study was calculated based on the ART adherence rate among women on option B+ program from a study conducted in Malawi by Haas et al., (2016). They found that the adherence rate was 70% for both women who started ART during pregnancy and breastfeeding within the first two years. The Cochran formula was used to calculate the sample size because it allows the researcher to calculate the ideal sample size given, the marginal error (level of precision), the estimated proportion of the attribute (adherence rate) present in the population and the desired level of confidence (Lemeshow & World Health Organization, 1990).

$$n_0 = \frac{Z^2 pq}{e^2}$$

In the formula:

n_0 Is the desired sample size (n) of breastfeeding mothers on option B+

Z =Z^2 is the Z value associated with 95% level of confidence, and from the normal distribution table the Z is 1.96

p is the estimated proportion of ART adherence rate of option B+ mothers expressed in decimal, where ART adherence rate was 70%, therefore p = 0.7.

q=1-p and e^2 is the desired level precision or margin of error of the study expressed in decimal, which was set at 5% that is e = 0.05.

Therefore, substituting the figures in the formula sample size was 323, which was adequate to produce results with good statistical power.

n= [(1.96^2) (0.7) (1-0.7)] / 0.05^2

n=323

Sampling method

The researcher used simple random sampling method, because it is one of the probability sampling methods and involves randomly selecting subjects from the accessible population. Simple random sampling methods ensure that all the subjects (breastfeeding mothers on option B+) have equal chance of participating in the study and there is low risk of bias (LoBiondo-Wood & Haber, 2014; Schmidt & Brown, 2012).

Inclusion and exclusion criteria

The study included women who were HIV positive, on ART, breastfeeding children from 6 weeks to 24 months, 18 years and above and attending ART, under five and family planning clinics as well as postnatal clinic at Mzuzu Health Centre. Furthermore, those who had missed the appointment dates, had history of defaulting and those who gave consent and agreed to participate in the study after the explanation. However, those below 18 years and those who refused to give a consent were excluded from the study.

Data collection instrument

An instrument is a structured formal and written document used to measure variables in a study and for self-report data collection. The questionnaire (appendix 1) was used for data collection, because it is presented in a structured and consistence manner and provides less opportunity for bias, and also greater perceived anonymity (Creswell, 2012; Polit & Beck, 2010). Data collection was done through face to face interviews using a structured questionnaire to ensure consistency in asking questions. The researcher paraphrased some questions because they were adapted from the tools used in two different studies by (Chigova, 2016; Steel, Nwokike, & Joshi, 2007) appendix 1.

A structured questionnaire was developed based on adapted questions, guided by the objectives of the study and the conceptual framework. The questionnaire had three parts: section A covered social-demographic factors, section B asked information on patient, condition, therapy and health care system related factors and section C assessed the level of ART adherence among HIV infected breastfeeding mothers using four questions (appendix 1, section C) which were

adapted from a standardized Multi-Method ART Adherence Tool from South Africa experiences, designed to measure ART adherence in resource constrained setting (Steel et al., 2007). Since it was designed, some authors have used the same tool to measure ART adherence rate in their studies for instance, Ebuy et al., (2015) and Zacharius et al., (2019) in Ethiopia and Tanzania respectively.

The questionnaire was translated into Chichewa (appendix 2) then an independent translator was used to translate back the questionnaire to validate meaning. The interviews were done by the researcher and a research assistant who was trained by the researcher on data collection process, how to perform the simple random sampling technique, how to obtain consent from participants before starting interviews and how to handle data after the collection of data on a daily basis.

Data collection process

HIV and AIDS is a very sensitive issue to discuss with clients in public, so for privacy and confidentiality, anonymity was applied. The brief description of the study was made every morning at the ART clinic where some of the participants were recruited. For the under-five and family planning clinics where the researcher also accessed some of the participants to collect data, the researcher was checking in mothers health passport booklets to check for their HIV status and if they qualify to participate in the study. The participants (n=323) were recruited from mentioned areas. The researcher was working hand in hand with **'expert clients'** to recruit and interview the clients who had missed their appointment dates. The researcher wrote numbers on

a small papers and placed them in a bowl according to the participants available on daily basis. Only those who picked odd numbers were recruited in the study.

The researcher explained in detail the purpose and procedures of the study, obtained verbal consent, ensured confidentiality of all participants. Those who agreed to participate were asked to give a written consent (appendix 4). Then face to face interviews were done in a private room at the facility for the participant's privacy and confidentiality and the interview lasted for a maximum of **30 minutes**, so that the clients should go back home in good time. Data collection lasted for a period of eight weeks from May to June 2019.

Data management

Data management is the process that involves preparing and organizing data for analysis, and this in quantitative research consists of scoring the data, creating code book, determining which scores to use, selecting which computing program to use, inputting the data and clearing the data (Creswell, 2012). To achieve this, electronic data like consent forms, letters to different departments were written and the questionnaire was kept ready and safe in the computer with a secrete password during and after the study and the data were backed up. All the files in the computer were named according to content, to avoid a mix up of information and contaminating data. Names of study participants were not recorded to ensure anonymity, instead, unique identification numbers were used for purposes of data analysis. The data collected was checked for completeness and accuracy at the end of each interview. The completed questionnaire (appendix 1) and signed consent forms (appendix 4) was kept under lock and key for safety and

confidentiality reasons. The data access was restricted to others except for researcher and the assigned supervisors.

Data analysis

It is defined as the process of choosing methods of systematic organization of raw data and synthesis of research data, as well as analyzing and interpreting data in order to elicit meaning (Creswell, 2012; Fain, 2015; Polit & Beck, 2017). The data analysis was guided by the research questions as outlined in chapter one. Face to face interviews using a structured questionnaire was used for data collection which had three sections (appendix). **Section A** covered social-demographic factors, while **section B** focused on patient, condition, therapy and health care system related factors. **Section C** assessed respondent's level of ART adherence using Multi- Method ART Adherence Tool. The items on the questionnaires was coded for easy data entry.

Data were verified daily for completeness, cleaned and entered into Microsoft Excel database and imported into SPSS version 23.0 for data analysis. Descriptive statistics was used and presented using frequency distribution tables, percentages. Inferential statistics, bivariate analysis using Chi-Square test was used to describe the relationship between variables ($p<0.05$) at 95% Confidence Interval (CI). Furthermore, the researcher used multivariate logistic regression model to describe the strength of significance relationship between adherence (dependent variable) and social-demographic factors, patient, therapy, condition and health care system related factors (independent variables).

Validity and reliability

Validity is the degree to which an instrument measure what it is supposed to measure (Schmidt & Brown, 2012). Since the researcher adapted questionnaire (appendix 1). To ensure validity, the questionnaire was reviewed by the experts in the field and the supervisors who made an input based to their experience in the clinical practice and the method used in the study. This helped in refining the questionnaire for meaning and clarity within the Malawian context, hence construct validity was achieved.

Reliability, refers to the accuracy and consistency of information obtained in the study (Polit & Beck, 2010). Steel et al., (2007), found that Multi-Method ART Adherence Tool took an average of 5 minute with a 9% CI of 3-8 minutes to administer however, with times decreasing as users gained experience. The tool was validated against viral load and Medication Event Monitoring System (MEMS). Self-reporting as on the component in the multi method tool showed the highest correlation with viral load and MEMS ***(r=0.53)***. The multi method approach also provided the best estimate of adherence relative to MEMS with a strong correlation **(*r=0.73, 95% CI 0.5-0.85)***. Therefore, the tool was recommended and included in the 2010 national ART guidelines as standard of care for assessing adherence in all the nine province of South Africa.

In addition, pre-test of the questionnaire (appendix 1) was done after COMREC approval on twenty seven breastfeeding women who met the inclusion criteria at Mzuzu Central Hospital (Rainbow clinic) before the actual data collection of the main study at Mzuzu Health Centre. The pre-test was done so as to estimate the time for completion of the questionnaire, identify ambiguous questions and for the researcher to familiarize with the natural flow of the interview.

Furthermore, it was also done to ensure the reliability of the data collection instrument. The amendments which were made after the pre-test of the questionnaire were as follows; Section A of the questionnaire, question A8 the researcher added one option on the already existing options (appendix 1). Section B of the questionnaire, question B15 the researcher paraphrased the question and then changed the options and removed question B17 which was a follow-up question (appendix 1). On the same section question B28 was also paraphrased from close ended to open ended question and question B29 was removed (appendix 1). Question B33, the options for this question changed from dichotomous to multiple (appendix 1). Question B40 was also paraphrased from close ended to open ended question and question B41 was removed (appendix 1).

Ethical consideration

The proposal was approved by College of Medicine Research and Ethics Committee (COMREC) P.03/19/2620 (appendix 13). Permission and clearance were sought from Mzimba North District Officer (appendix 9&10), ART coordinators, in charges from under-five and family planning clinics as well as Mzuzu Central Hospital (appendix 11&12). Written informed consent (appendix 4) was obtained from all study participants who were sampled and agreed to participate in the study.

According to Polit & Beck, (2017), the principle of beneficence imposes a duty on researchers to minimize harm and maximize benefits. The participants were guaranteed confidentiality and anonymity by not asking them their names during the interviews and not including their names on any of the study materials except the consent forms. The participants

were recruited voluntarily and they were informed that they were free to withdraw from the study at any time. The participants were informed about any foreseeable physical harm (risks), and also in cases of any emotional or psychological harm the participants were to be counselled accordingly. Signed consent forms and completed questionnaires were kept in a locked safe place and computer with a secret password to ensure the privacy and confidentiality of data.

Dissemination of results

The study results will be presented to healthcare providers working at Mzuzu Health Centre and academic staff at KCN during research seminars, published through peer reviewed nursing journals and presented at conferences both national and international. The report will be given to Mzimba North District Health officer, coordinator for ART at the facility and COMREC and other copies will be submitted to KCN library and Ministry of Health.

CHAPTER FOUR

Results

Introduction

The results are being presented in this chapter according to the objectives of the study. Demographic characteristics/factors, patient related factors, therapy related factors, condition related factors and health care system related factors associated with ART adherence among breastfeeding mothers on option B+ and ART adherence rate among breastfeeding mothers on option B+.

ART adherence rate among breastfeeding mothers under option B+ strategy

The level of adherence was measured using Multi-Method ART Adherence Tool which was designed to measure ART adherence in resource constrained setting (appendix 1 section C), and was adapted to this study. The level of adherence was measured using four measurement questions. The questions on the tool had bivariate responses (Yes=1 and 0=No). Total score for each participant was computed using SPSS version 23.0. Adherence rate was determined by cutoff points. A participant was determined to have good adherence if she responded to "**no**" to all four questions and if she responded "**yes**" to at least one question she was determined to have poor adherence. Good adherent participants were identified with the score of 4 on the tool, while poor adherers with a score of <4. Thus; ≥95% represent good adherence and <95% represent poor adherence (Ministry of Health, 2018b; Steel et al., 2007).

ART adherence rate was computed from the same scores to percentages. The study revealed that out of 323 participants, more than half 178 (55.11%) had an adherence rate of ≥95% while 143 (44.89%) had <95%.

Social-demographic characteristics/factors of the respondents

A total of 323 participants were planned to be interviewed and the overall response rate was 100%. Age of the respondents ranged from 18 to 49 years. The mean age was 29 years with a standard deviation (SD) of 6 years. Most 89 (27.6%) of the respondents were between the age of 25-29 years. On parity (number of children) 214 (66.3%) of the respondents were multiparous (2-4 children). Majority 268 (83%) of the respondents were married. On level of education, about 153 (47.4%) had attained secondary education. Almost half 163 (50.5%) of the respondents belonged to Tumbuka tribe followed by Chewas 85 (26.3%). Majority 304 (94.1%) respondents were not employed. On the other hand, 50.6% of their spouses were unemployed and 49.4% were employed. More than half 168 (52%) of the respondents were from the semi-urban setting. Furthermore, the study results revealed that most 100 (31.0%) of the respondents belonged to Pentecostal churches (Table 1).

Table 1: Social-Demographic characteristics/factors (n=323)

Variable	Frequency (%)	Variable	Frequency (%)
Age (years)		**Tribe**	
<20	16 (5.0)	Chewa	85 (26.3)
20-24	68 (21.1)	Ngoni	25 (7.7)
25-29	89 (27.6)	Tumbuka	163 (50.5)
30-34	79 (24.5)	Ngonde	14 (4.3)
35-39	57 (17.6)	Tonga	19 (5.9)
>40	14 (4.3)	Lambiya	16 (5.0)
Parity		Other	1 (0.3)
Primiparas	72 (22.3)	**Occupation**	

Multiparous	214 (66.3)	Employed	19 (5.9)
		Unemployed	304 (94.1)
		Spouse occupation	
Grand-multiparous	37 (11.5)	Employed	136 (50.2)
		Unemployed	133 (49.8)
		Religion	
Marital status		CCAP	72 (22.3)
Single	8 (2.5)	Roman Catholic	43 (13.3)
Married	268 (83)	Seventh Day	33 (10. 2)
Divorced	36 (11.1)	Islam	22 (6.8)
Widow	11 (3.4)	Pentecostal churches	100 (31.0)
Education level		New apostolic	29 (9.0)
Never been to school	10 (3.1)	African	16 (5.0)
Primary	143 (44.3)	Other	8 (2.5)
Secondary	153 (47.4)	**Place of residence**	
Tertiary	17 (5.3)	Urban	76 (23.5)
		Semi-urban	168 (52)
		Rural	79 (24.5)

Patient related factors of the respondents

The results presented in this section cover the patient factors associated with ART adherence among breastfeeding mothers under option B+ strategy. The respondents were asked questions on; knowledge, stigma and discrimination, cultural beliefs, religious beliefs, financial status, forgetfulness, HIV status disclosure, life style and support.

Knowledge

The results revealed that there was variations in respondents' level of knowledge HIV/AIDS and ART adherence (table 2). Majority of the respondents 85.4% (n=276) reported that HIV infected women can transmit the virus to the babies during breastfeeding. In addition, 95.4% (n=308) reported that adhering to ART reduces the risk of HIV transmission to the baby. Furthermore, the results indicated that nearly all the respondents 96.3% (n=311) knew that ART was beneficial to them as well as their child.

Table 2: Respondents knowledge about HIV and ART adherence

Statement	Category	Frequency	Percentage
Can HIV infected women transmit the virus to the babies during breastfeeding	Yes	276	85.4
	No	47	14.6
Does adhering to ART reduce the risk of HIV transmission to the baby	Yes	308	95.4
	No	15	4.6
Is ART beneficial to you and your child	Yes	311	96.3
	No	12	3.7

Stigma and Discrimination

Out of 323 participants, 118 (36.6%) respondents reported that they felt comfortable taking ART in the presence of others. While nearly all 307 (95%) of the respondents reported not to avoid friend and relatives because of their HIV sero status however, a few 16 (5%) reported to avoid friends and relatives because of their HIV sero status.

Cultural beliefs

The results of the study revealed that all the respondents 100% (323) reported that cultural beliefs affected their ART adherence positively, it allowed them to take ART without any restrictions.

Financial status

Majority 280 (86.7%) of the respondents reported that financial status did not affect the consistency of their ART treatment however, a few 43 (13.3%) reported that it affected the

consistency of their ART treatment. Of the respondents who were affected 9.3% was due to cost of transport to reach to the ART clinic while 5.5% with the overwhelming demands of everyday life.

Forgetfulness

The results showed that 127 (39.3%) respondents reported that they missing their ART in the past month (28 days) due to different reasons like cost of transport to the facility, failing to take drugs in presence of other people and side effects just to mention a few. Of those who missed their doses, majority 64 (19.8%) reported that they took the drug the moment they remembered, 57 (17.6%) took their drug the next day while 6 (1.9%) did not take the drug. This happened due to above mentioned factor.

HIV status disclosure

The results of this study revealed that nearly all 321 (99.4%) the respondents reported to have disclosed their HIV sero status to friends, relatives, spouse and neighbours. Out of 321 respondents 39.5% disclosed to their spouses, 39.2 % disclosed to relatives, 6.9% disclosed to their neighbours and 13.5 % disclosed to their friends while 1 % disclosed to others like pastor at church and boyfriends.

Religious beliefs

More than half 267 (82.7%) reported they did not believe in religious powers to treat HIV without ART medication, However, a few 56 (17.3%) believed in religious powers to treat HIV and this was regardless of the denomination they belonged to.

Life style

All the respondents 323 (100%) denied smoking behavior, and nearly all 320 (99.1%) respondents denied taking alcohol, while a few 3 (.9%) accepted the behavior of taking one to five bottles of alcohol per week.

Social and family support

Majority 286 (88.5%) of the respondents reported to receive support from spouse, relatives and friends. 89.2% reported that the support they received helped them to adheree to ART medication. Out of these 89.2%, 61% were helped with remainder aids to take ART, 57% were supported financially while 67.2% were encourage in taking ART medication.

Therapy related factors of the respondents

Under this section the respondents were asked questions on duration of ART medication, side effects of ART, pill burden as well as remainder aids.

Duration of ART medication

Out of 323 participants, majority 301 (93.2%) reported that duration of ART medication for life did not affect their ART medication. Out of the 301 respondents, nearly half of them 141 (46.8%) attained high ART adherence, 112 (37.2%) attained medium ART adherence while a few 48 (15.9%) attained low ART adherence.

Side effects

The study results revealed that 148 (44.5%) respondent's experienced side effects however, only 9.5% reported that the side effects affected their ART treatment. Out of 148,

59.3% went to the hospital, 9% stopped taking ART and 81.4% continued taking ART while 2.1% did nothing.

Pill burden

Majority 275 (85.1%) of the respondents reported that the tablets were easy for them to take while 48 (14.9%) reported to have pill burden. Out of the 14.9%, three quarters 40 (12.4%) of the respondents reported that the tablet was big, 2.2% and 0.3% reported that the tablets were tiresome to take every day and only one said the tablet was bitter respectively.

Reminder aids

Nearly all 315 (98.1%) of the respondents reported that remainder aids (mobile phone, alarm clock and family members) helped them in adhering to ART treatment.

Condition related factors of the respondents

The results of this study revealed that, nearly half 160 (49.5%) of the respondents reported that being healthy encouraged them to continue taking ART so that they should remain healthy, while 137 (42.4%) reported that either of the health status (being sick or health) did not affect their ART adherence, 22 (6.8%) reported that being sick encouraged them to continue taking ART, while 3 (0.9%) and only 1 (0.3%) respondent being health discouraged them to take ART medication and being sick discouraged her to take ART respectively.

Health care system related factors of the respondents

The study results on health care system related factors; distance to ART clinic, transport to the clinic, accessibility of ART clinic, availability of staff at the clinic, waiting time to be

assisted, privacy and confidentiality during consultation, health workers attitude, appointment dates and adequacy of the information during ART initiation will be presented in this section.

Distance to ART clinic

According to the results of this study distance ranged from 1.4 to 88 Kilo Meters (KM). The mean distance was 7 KM with a SD of 9.3 KM. Almost half of the respondents 260 (80.5%) were living within a distance of 8 KM to the ART clinic. Nevertheless some respondents lived at a distance of as far as 88 KM to reach to the ART clinic because of stigma and discrimination in their area, so they preferred to be collecting drugs from a distant ART clinic.

Transport to ART clinic

The study results revealed that majority 303 (93.8%) of the respondents used spent money for transport to reach at the ART clinic from their homes, while 20 (6.2%) reported not to use transport money because the facility was at a walkable distance and also some could not manage to find transport money. On transport affordability, out of 303 who spent money on transport to reach the ART clinic 24.1 % reported to always find transport, 45% could usually find the transport and 23.9% occasionally find transport.

Accessibility of ART clinic

According to the results of this study, majority 279 (86.4%) of the respondents reported that the ART clinic was easily accessible. Out of 279 respondents 162 attained good adherence while 117 attained poor adherence.

Availability of staff and drugs

Nearly all 317 (98.1%) of the respondents reported that staff (health care providers) at the ART clinic were always available. In addition, nearly all 318 (98.5%) of the respondents reported that drugs were always available.

Waiting time before being assisted

Waiting time of the respondents before being assisted ranged from 15 minutes to 6 hours. The mean time with a SD was 1.8±0.99. Majority 115 (35.5%) of the respondents were assisted within a period time of 2 hours which was close to average time.

Appointment dates

Majority 299 (92.6%) reported that the appointment dates to the ART clinic were convenient, while a few reported that the appointment dates were not convenient due to; being given different appointment dates for the baby and the mother and closeness of the appointment dates to refill the drugs. Out of 299, more than half 176 respondents attained a good ART adherence rate while 126 reported to have attained poor ART adherence.

Privacy and Confidentiality

The results of this study revealed that majority of respondents 266 (82.4%) reported to have privacy and confidentiality during the consultation time, however a few respondents 57 (17.6%) reported not to have privacy during consultation. Out of those who reported to have privacy and confidentiality, 152 attained good adherence rate and 114 attained poor adherence rate.

Health workers attitude

The results of this study revealed that majority 233 (72.1%) of the respondents reported that health workers good attitude encouraged them to continue taking ART and remain adherent to ART, 66 (20.4%) reported that health workers attitude whether good or bad does not affect their ART adherence however, a few 3 (0.9%) respondents reported that bad attitude of health workers discourages them and at times they think of never returning to the ART clinic.

Factors associated with ART adherence using bivariate and multivariate logistic regression analysis

In this segment, associations between dependent (adherence rate) and independent variables [social-demographic factors (age, parity, marital status, level of educational, occupation, spouse occupation and place of residence), patient related factors (knowledge, stigma and discrimination, cultural beliefs, financial status, forgetfulness, HIV status disclosure, religious beliefs, life style and social and financial support), therapy related factors (duration of ART, side effects, pill burden and reminder aids), condition related factors (health status) and health care system related factors (distance to ART clinic, transport to ART clinic, accessibility of ART clinic, availability of staff at the ART clinic, waiting time to be assisted, availability of drugs at the ART clinic, privacy and confidentiality, health workers attitude, appointment dates and adequate information during ART initiation] will be presented.

All single variables under each factor were analyzed using bivariate analysis (Chi-Square test) with dependent variable. Then all variables with a p-value of <0.05 were included in the multivariate logistic model, which was conducted at 95% CI and 5% confidence level 2-tailed to

establish the significant relationship between variables. This was done so as to control the effect of other covariates.

Table 3*:* Bivariate analysis (Chi-Square test) between Social-Demographic Factors, Patient Related Factors, Therapy Related Factors, Condition Related Factors and Health Care System Related Factors and ART adherence rate.

Variable	Chi-Square	df	p-value	Variable	Chi-Square	df	p-value
Social-Demographic Factors				**Therapy Related Factors**			
Age	2.471	3	0.480	Duration	0.864	1	0.353
Marital status	3.819	3	0.82	Side effects	1.385	1	0.239
Education Level	2.811	3	0.422	Pill burden	1.960	1	0.161
Parity	0.255	2	0.880	Reminder aids	0.328	1	0.567
Occupation status	0.489	1	0.484	**Condition Related Factors**			
Spouse's Occupation	0.425	1	0.515	Health status	28.775	20	0.092
Place of Residence	0.344	2	0.842	**Health Care System Related Factors**			
Patient Related Factors				Distance to ART clinic	3.341	2	0.188
Knowledge	0.849	1	0.357	Transport to ART clinic	1.967	1	0.161
Stigma and	0.852	1	0.356	Accessibility of ART	**7.235**	**1**	**0.007**

discrimination				clinic			
Cultural beliefs	N/A	N/A	N/A	Appointment dates	**14.955**	**2**	**0.001**
Financial status	0.010	1	0.92	Availability of staff at ART clinic	0.064	1	0.800
Forgetfulness	**96.297**	**1**	**0.000**	Availability of drugs at ART clinic	2.53	1	0.112
HIV status disclosure	0.021	1	0.884	Waiting time	2.814	2	0.245
Religious beliefs	**5.396**	**1**	**0.020**	Privacy and confidentiality	2.522	1	0.112
Alcohol use	N/A	N/A	N/A	Health workers attitude	42.119	31	0.088
Smoking cigarettes	0.164	1	0.686	Adequacy of information during ART initiation	7.487	3	0.058
Social and financial support	0.022	1	0.881				

Table 4: Multivariate analysis (Binary logistic regression test) for all significant factors associated with adherence rate

Variable	**Adjusted Odds Ratio (AOR)**	**p-value**	**Confidence Interval (CI)**
Forgetfulness	0.0773196	0.000	0.044063-0.1356705
Religious beliefs	0.4893397	0.048	0.2406213-0.9951472
Accessibility of ART clinic	2.533641	0.024	1.130932-5.670148
Appointment dates	4.7333555	0.008	1.496248-14.97515

In bivariate analysis (Chi-Square test), the results revealed that forgetfulness ***(p<0.001),*** religious beliefs ***(p=0.020),*** accessibility to ART clinic ***(p=0.007)*** and ART appointment dates ***(p=0.001),*** were significantly associated with ART adherence under patient related factors and health care system related factors respectively.

In multivariate analysis (binary logistic regression); forgetfulness ***[AOR 0.08; 95% CI :(0.44, 0.14)],*** religious beliefs ***[AOR 0.49; 95% CI :(0.24, 1.0)],*** accessibility to ART clinic ***[AOR 2.53; 95% CI :(1.13, 5.68)]*** and ART appointment dates ***[AOR 4.73; 95% CI :(1.50, 14.98)],*** were also significantly associated with ART adherence under patient related factors and health care system related factors respectively.

Table 5 shows the results from the regression model which revealed that the four variables forgetfulness, religious beliefs, accessibility to ART clinic and appointment dates to ART clinic explained approximately 34% (***R^2=0.342***, ***p<0.001***) of the variation in ART adherence rate. However, further studies should be done to explore others factors associated with ART adherence among the breastfeeding mothers at Mzuzu health centre, Malawi which contributes to the unexplained 66% of variation on ART adherence rate.

Table 5: Summary of the multivariate regression model for all significant factors

R	R_2	Adjusted R_2	Std. Error of the Estimate	F	P-value
0.585	0.342	0.0334	0.406	41.403	0.000

CHAPTER FIVE

Discussion

Introduction

This chapter presents a discussion of the study results and the interpretation, in relation to what previous researchers have found and objectives which guided the study. The discussion focuses on the factors that were associated with ART adherence after doing the bivariate and multivariate logistic regression analysis. ART adherence rate among breastfeeding mothers on option B+ will be discussed first, then social-demographic characteristics/factors associated with ART adherence, patient related factors associated with ART adherence, therapy related factors associated with ART adherence, condition related factors associated with ART adherence and health care system factors associated with ART adherence among breastfeeding mothers on option B+. Finally a conclusion of the discussion will be made and will be followed by limitation of the study and the recommendations.

ART adherence rate among breastfeeding mothers under option B+ strategy

The results of this study showed that, 55.11% (178) respondents attained an adherence level of ≥95% and 44.89% (145) respondents attained <95%. This shows that among the breastfeeding mothers under option B+ strategy at Mzuzu health centre, 55.1% attained optimal ART adherence while 44.9% had sub-optimal ART adherence. In contrast, the adequate ART adherence rate in this study was lower than in the study done by Haas et al., (2016)in same country (Malawi) which revealed that 66% of women during breastfeeding period achieved adequate ART adherence rate in the first three months, however only 30% maintained adequate

adherence at each subsequent visit. This contrast may be because the study designs were different, the population was drawn from 13 large health facilities (sample space) and used different methods for measuring ART adherence level. This furthers shows that there is need for developing appropriate interventions to improve ART adherence rate among breastfeeding mothers. The evidence based interventions should focus on the factors which are statistically significant.

Nevertheless, the adherence level in this study was higher than the findings reported in a systematic review study done by Nachega et al. (2012) on ART adherence during pregnancy and breastfeeding in low, middle and high income countries, where ART adherence rate during postpartum period was 53%. Correspondingly, in a study done in Uganda by Decker et al. (2017) the results showed an adherence rate of 51% at six months breastfeeding period. At the same time, 76.5% of the women breastfed for greater than 12 months. However, no woman adhered to ART completely for 18 months. On the other hand, in a retrospective study conducted in Johannesburg South Africa, showed an increased risk of non-adherence during the breastfeeding period with relative risk (RR) of 1.46, 95% CI, compared to pregnancy with RR 0.95, 95% CI (Henegar et al., 2015). This is due to different tools they used for measuring adherence level and also the methods used. For instance, Decker et al. (2017) combined self-report and amount of drug refill visits to measure adherence level.

Patient related factors associated with ART adherence

Forgetfulness

The study results showed that forgetfulness had a significant association with ART adherence ***[AOR 0.08; 95% CI :(0.44, 0.14)].*** This means that the breastfeeding women who reported to have missed some ART doses were 99.9% less likely to attain good ART adherence than those who reported not missing any dose. This was statistically significant with a p-value less than 0.05 ***(p<0.001).*** This corresponds with the study done by Ebuy at el (2015), which showed that 92.3% respondents reported forgetfulness as one of the common reason for not adhering to ART treatment in Ethiopia. Furthermore, some studies have cited that forgetfulness was one of the setback in ART adherence (Ebuy et al., 2015; Kreitchmann et al., 2012; Sabaté & WHO, 2003). This highlights the relevance of emphasizing remainder aids and the importance of ART adherence to the mother as well as the infant to prevent vertical transmission during counselling and education hence, helping to achieve the goal of eliminating MTCT of HIV infections among children to <5% by 2020 (UNAIDS, 2011).

Religious beliefs

Religious beliefs also showed a significant association ***[AOR 0.49; 95% CI :(0.24, 1.0)],*** with ART adherence. This shows that the women who reported to have believed in religious powers to heal HIV without taking ART were 99.5% less likely to adhere to ART than those who did not believe hence, the stronger the beliefs the lower the ART adherence rate. This was statistically significant with a p-value less than 0.05 ***(p=0.048)***. Furthermore, the study revealed that according to denomination, majority 100 (31%) of the respondents go to Pentecostal

churches which also has an impact of believing in religious powers instead of being adherent to ART treatment nowadays. This may be so because some religious beliefs discourages the use of ARV medications on the basis that one has been healed. However, it was not statistically significant ***p=0.15.*** These results are in line with a study done by Sariah et al., (2019), where religious faith was mentioned as one of the reasons that made participants stop taking ART medication. Similar results in Nigeria by Omonaiye, Kusljic, Nicholson, & Manias, (2018), revealed that religious belief was reported to be one of the set back to ART adherence. This highlight the importance of engaging faith and religious sectors in HIV services, thus the need of counselling to combine religious beliefs (prayers) with ART to prevent vertical transmission. However, study done by Kim et al, (2016), showed that religious beliefs did not affect adherence rate.

Health care system related factors associated with ART adherence

Accessibility to the ART clinic

Accessibility to the ART clinic was statistically significant with ART adherence rate ***[AOR 2.53; 95% CI :(1.13, 5.68)].*** These results showed that breastfeeding mothers who reported to access the ART clinic easily were 2.5 times more likely to attain good ART adherence than those who reported to have difficulties to access ART clinic. This was statistically significant with a p-value less than 0.05 ***(p=0.024).*** Furthermore, the study has revealed that almost half of the respondents 260 (80.5%) were living within a distance of 8 KM to the ART clinic. This is consistent with the Ministry of Health recommendation of a travelling distance to clinics of 5 to 8 km, however only 46% of the population lives within 5 km while 20% lives within 25 km of a health facility (Government of Malawi, 2015).

In contrast, the study done by Tweya et al. (2014), showed that 16% of the participants who stopped taking ART lacked transport money to reach the ART clinic. Likewise, some authors have reported that lack of transport money to refill the drugs was cited as a barrier to ART adherence (Boehme et al., 2013; Buregyeya et al., 2017; Flax, Yourkavitch, et al., 2017). Correspondingly, a study done by Decker et al., (2017) found that higher travel costs to the hospital was significantly associated with ART adherence (p=0.024). Therefore, accessibility to the ART clinic was significantly associated with ART adherence may be because majority 260 (80.5%) of the respondents were staying within a distance of 8 KM to the ART clinic. Nevertheless some respondents lived at a distance of as far as 88 KM to reach to the ART clinic and because of stigma and discrimination in their area, some participats preferred to be collecting drugs from a distant ART clinic.

Appointment dates to the ART clinic

In multivariate analysis, appointment date to ART clinic was associated with adherence rate ***[AOR 4.73; 95% CI :(1.50, 14.98)]***. The breastfeeding mothers who reported to have convenient appointment dates to ART clinic were 4.7 times more likely to attain adequate ART adherence rate than those who reported to have inconvenient appointment dates. This was statistically significant with a p-value less than 0.05 ***(p=0.008).*** The study results were in contrast with a study done by Buregyeya et al., (2017) which revealed that some women reported missing the scheduled clinic appointment dates due to lack of transport money and other social and family responsibilities. Similarly, a study done by Gugsa et al., (2017) at Bwaila Lilongwe in Malawi reported that most women who were not retained in care lacked designated guardians to assist them with medication refills or clinic appointments. The association of this variable

highlight emphasis of tracking the clients who have missed appointment dates according to the scheduled date on the master card. The tracing should be followed up within two weeks of missed appointment date with the help of expert clients (Karfakis & Kneehn, 2014). Also emphasis should be focused on different appointment ART clinic dates for the baby and the mother and closeness of the appointment dates to refill the drugs, because they are some of the reasons some participants expressed during data collection.

Study Limitations, Recommendations and Conclusion

Limitations of the study

Although the study used primary data and validated adherence measurement tool (Multi-Method ART Adherence Tool), the interpretation of results need a consideration of the following limitations. In this study adherence rate was measured using participants self-report which is one of the component in Multi-Method ART Adherence Tool. Although self-reporting is the most commonly used measure of adherence in a resource limited setting because it is easy to conduct in routine clinical practice and also helps to determine the reasons why the patient has missed the doses. The results of adherence rate might be subjected to recall bias because it reflects only on short-term or average adherence and often overestimate or underestimate. Because of the limitation the study might not have captured the actual adherence level of the respondents. However, the biases were minimized by using startegies such as, interviewing the participants in private rooms, also explaining to them the aim of the study and also the role of them partipating in the details.

In addition, selection bias occurred as only those breastfeeding mothers who were on ART at the time of data collection were included, whereas those who were lost to follow-up and defaulters were excluded. Age selection of those only above 18 years as one of the inclusion criteria was also a limitation, because some women attain motherhood below the age 18 years. The study results will not be generalized because the study was conducted at only one facility Mzuzu Health Centre since, it was for academic purposes and was to be finalized within the specified time. However the results can be applied to similar settings.

Recommendations

Based on the findings of the study, the researcher made recommendations for practice, research and policy.

Practice

Strengthen and emphasize proper counselling during ART initiation on the benefits of ART adherence to the mother and their infants at the time of HIV diagnosis, promote strategies for reminders such as cell phones, alarm clocks and family members in order to address the issue of forgetfulness as one of the factor which has a strong positive significant correlation with ART adherence among the breast feeding mothers.

According to the study results it showed that nearly all 98.1% of the respondents reported that reminder aids (mobile phone and family members) helped them in adhering to ART treatment. Therefore, collaborative work among the breastfeeding mothers, family and healthcare workers can improve ART adherence during the breastfeeding period. Improve on the number of follow-up visits if the mothers have missed their appointment dates for drug refill and tests of their infants' early infant diagnosis (EID). This can be well achieved if the expert client (lay counsellors) who usually do the follow-up are well supervised and work hand in hand with health care workers, hence multi-disciplinary team approach.

Education and counselling are important in ART programmes hence, they empower the patients to be part of the treatment process. As almost half of the respondents' attained sub-optimal adherence to ART, therefore, there is need for health care providers to focus their

counselling and education on the factors that have shown significant association with ART adherence to improve the ART adherence among the breastfeeding women.

Research

The researcher also recommends evidence based intervention study focusing on the factors that have shown significant association (forgetfulness, religious beliefs, appointment date to the ART clinic and accessibility to ART clinic) with ART adherence to improve the ART adherence among the breastfeeding mothers. Therefore, there is also need to conduct a reasech on assessing reasons why forgetfulness has contributed much on low ART adherence rate. Furthermore, conducting a reaserch on bottleneck analysis and strategies on the factors association with ART adherence with the same population of the study to improve ART adherence among the breastfeeding mothers. In addition, since the study showed a few factors being significant, there is need to conduct the similar study considering big sample space to determine other factors associated with ART adherence. Subsequently, the study used self-report as a method for measuring adherence level, the researcher recommends further study which should include both methods objective (blood tests) so as verify self-report.

Policy

Identify possible solutions and develop strategies, to facilitate better drug adherence among these women and improve retention in care as well as prevent the LTFU. This will help to achieve the goal of eliminating MTCT of HIV infections among children to <5% by 2020 (UNAIDS, 2011). Policy makers should place much emphasis on the postnatal period and ensuring adherence to ART following birth, as they do with pregnancy period. In addition, the

need to develop better methods to measure adherence level, especially at the national level (UNAIDS, 2016).

Conclusion

In this study the overall adherence rate among the breastfeeding mothers under option B+ strategy showed that at least half (55.1%) of the respondents had good adherence. However, almost half (44.9%) of the respondents did not adhere to taking their medications. The results of this study depict that forgetfulness, religious beliefs, appointment date to the ART clinic and accessibility to ART clinic were significantly associated with ART adherence. The overall study showed that forgetfulness was the most significant variable which had the greatest effect on ART adherence rate.

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APPENDICES

Appendix 1: Questionnaire English version

Study title: Factors associated with antiretroviral therapy (ART) adherence among breastfeeding mothers under option B+ strategy at Mzuzu Health Center, Malawi

Facility ……. Respondent ID ……..

Date of interview …….. Time …….....

Section A: Sociodemographic data

"I would like to start asking you some questions about yourself and background."

NUMBER	QUESTIONS	ANSWERS AND CODES
A1	How old are you? (**Write)**	…….. years
A2	How many children do you have? **(Write)**	…….
A3	What is your marital status? **(Circle one answer)**	a. Single [1] b. Married [2] c. Divorced [3] d. Widow [4]
A4	What is your level of education? **(Circle one answer)**	a. Never been to school [1] b. Primary [2] c. Secondary [3] d. Tertiary [4]
A5	What tribe do you belong to? **(Circle one answer)**	a. Chewa [1] b. Ngoni [2] c. Tumbuka [3] d. Ngonde [4] e. Tonga [5]

		f. Other specify [6]
A6	What is your occupation? **(Circle one answer)**	a. Teacher [1] b. Farmer [2] c. Housewife [3] d. Business [4] e. Other specify [5]
A7	What is your spouse's occupation? **(Circle one answer)**	a. Farmer [1] b. Not working [2] c. Business [3] d. Driver [4] e. Teacher [5] **f.** Other specify [6]
A8	What is your religion? **(Circle one answer)**	a. CCAP [1] b. Roman Catholic [2] c. Seventh Day [3] d. Islam [4] e. Pentecostal churches [5]

		f. Other specify [6]
A9	Where do you stay? **(Circle one answer)**	a. In town [1] b. Near the town [2] c. In the village [3]

Section B

"Now I will ask about factors associated with ART adherence (option B+) as you are breastfeeding."

NUMBER	**QUESTIONS**	**ANSWERS AND CODES**
	Patient related factors	
B1	Can HIV infected women transmit the virus to the babies during breastfeeding? **(Circle one answer)**	a. Yes [1] b. No [2]

B2	Does adhering to ART reduce the risk of HIV transmission to the baby? **(Circle one answer)**	a. Yes [1] b. No [2]
B3	Is ART beneficial to you and your child? **(Circle one answer)**	a. Yes [1] b. No [2]
B4	Do you feel comfortable to take ART in the presence of others? **(Circle one answer)**	a. Yes [1] b. No [2]
B5	Do you avoid friends and relatives because of your HIV status? **(Circle one answer)**	a. Yes [1] b. No [2]
B6	Does your cultural beliefs affects your ART treatment? **(Circle one answer),** if **YES** go to B7	a. Yes [1] b. No [2]
B7	How does it affects it? **(Circle one answer)**	a. Our culture allows us to take ART [1] b. Our culture does not allow to take ART [2] c. Our culture needs us to seek consent from husband/ elders

		[3] d. Our culture prefers traditional medicine [4]
B8	Does your financial status affects the consistency of your ART treatment? **(Circle one answer),** if **YES** go to B9	a. Yes [1] b. No [2]
B9	How does it affect you? **(You can circle more than one answer)**	a. Cost of transport to get to the health facility [1] b. Overwhelming demands of everyday life [2] c. Other specify [3]
B10	Do you sometimes forget to take your ART medication? **(Circle one answer),** if **YES** go to B11	a. Yes [1] b. No [2]
B11	What do you do if you have forgotten to take the drugs? **(Circle one answer).**	a. I took the drugs the moment I remembered [1] b. I took the drug the next day [2] c. I did not take it [3]

B12	Have you disclosed your HIV status to anyone? **(Circle one answer),** If **YES** go to B13	a. Yes [1] b. No [2]
B13	To whom? **(You can circle more than answer)**	a. Spouse [1] b. Relatives [2] c. Neighbours [3] d. Friends [4] e. Others specify [5]
B14	Do you think HIV infection can be treated with religious powers without ART medication? **(Circle one answer)**	a. Yes [1] b. No [2]
B15	How much alcohol do you take in a week? **(Circle one answer)**	a. One to five bottles [1] b. Five to ten bottles [2] c. More than ten bottles [3] d. You don't drink [4]
B16	How many cigarettes do you smoke in a day? **(Circle one answer).**	a. One to five cigarettes [1] b. Five to ten cigarettes [2] c. More than ten cigarettes [3]

		a. You don't smoke [4]
B17	Do you have any support from partner, relatives and friends? **(Circle one answer),** if **YES** go to B18	a. Yes [1] b. No [2]
B18	Does the support help you adhere to ART medication? If **YES** go to B19	a. Yes [1] b. No [2]
B19	How does it help you? **(You can circle more than answer).**	a. Aids in reminder of taking ART [1] b. Support financially [2] c. Encourage in taking ART treatment [3] d. Others specify [4]
	Therapy related factors	
B20	Does the duration of ART medication affect you? **(Circle one answer)**	a. Yes [1] b. No [2]
B21	Have you ever experienced any side effects? **(Circle one answer),** if **YES** go to B22	a. Yes [1] b. No [2]

B22	Did the side effects affected your ART treatment? **(Circle one answer),** if **YES** go to B23	a. Yes [1] b. No [2]
B23	What did you do after experiencing the side effects? **(You can circle more than answer)**	a. Went to hospital [1] b. Stopped taking ART [2] c. Continued taking ART [3] d. Did nothing [4]
B24	Are the tablets easy for you to take? **(Circle one answer).** If **NO** go to B25	a. Yes [1] b. No [2]
B25	If **NO** how? **(Circle one answer).**	a. Tiresome to take every day [1] b. Tablets are big [2] c. Tablets are bitter [3] d. Too many tablets [4]
B26	Does the reminders aid you in adhering to ART medication? **(Circle one answer)**	a. Yes [1] b. No [2]
	Condition related factors	
B27	How does your health status affect your	……..

	taking of ART medication? **(Write)**	…….
	Health care system related factors	
B28	How far is the health facility from your home? **Write**	……KM
B29	Do you use transport to reach at the health facility? **(Circle one answer),** If **YES** go to B30	a. Yes [1] b. No [2]
B30	How much money do you use for transport? **Write**	……
B31	Is the transport affordable for you? **(Circle one answer)**	a. Always [1] b. Usually [2] c. Occasionally [4] d. Not available [4]
B32	Is the ART clinic easily accessible? **(Circle one answer),** if **NO** go to B33	a. Yes [1] b. No [2]
B33	Are the appointment dates for HIV services including drug refill convenient for you? **(Circle one answer)**	a. Convenient [1] b. Inconvenient [2]

		c. Do not know [3]
B34	Are the staff available at the ART clinic? **(Circle one answer)**	a. Always [1] b. Usually [2] c. Occasionally [3] d. Not available [4]
B35	How long do wait for you to be assisted**?** **(Write)**	……Minutes/hours
B36	Are the drugs available at the ART clinic? **(Circle one answer)**	a. Always [1] b. Usually [2] c. Occasionally [3] d. Not available [4]
B37	Is their privacy during the consultation? **(Circle one answer)**	a. Yes [1] b. No [2]
B38	How does the health workers attitude affect your ART treatment? **(Write)**	……. ……
B39	Do you feel like you received adequate information during initiation of ART?	a. Very adequate [1] b. Adequate [2]

	(Circle one answer)	c. Not adequate [3] d. No idea [4]

Section C

Adapted Multi-Method ART Adherence Tool

Assessing levels of ART adherence among HIV infected breastfeeding mothers using Multi-Method ART Adherence Tool

NUMBERS	QUESTIONS	ANSWERS AND CODES
C1	Do you sometimes find it difficult to remember to take your medication? **(Circle one answer)**	a. Yes [1] b. No [2]
C2	When you feel better, do you sometimes	a. Yes [1]

	take a break from your medication? **(Circle one answer)**	b. No [2]
C3	Thinking back over the past 28 days, were there any days when you missed your doses? **(Circle one answer)**	a. Yes [1] b. No [2]
C4	Sometimes if you feel worse when you take the ART medication, do you stop taking it? **(Circle one answer)**	a. Yes [1] b. No [2]

End of questions **Thank you for your time!**

Appendix 2: Questionnaire Chichewa version

Mutu wa kafukufuku: Zinthu zomwe zimakhudzana ndi kamwedwe ka mankhwala otalikitsa moyo (ART) pakati pa a zimayi omwe akuyamwitsa ana (option B+) pa chipatala cha Mzuzu Health Centre, Malawi.

Malo……. Nambala ya wotenga mbali……

Tsiku la kafukufuku……. Nthawi……

GAWO LOYAMBA: Mbiri ya wotenga mbali

"Ndiyamba ndikukufunsani mafunso okhudzana ndi mbiri yanu"

NAMBALA	MAFUNSO	MAYANKHO
A1	Kodi muli ndi zaka zingati? **(Lembani)**	Zaka……
A2	Muli ndi ana angati? **(Lembani)**	……
A3	Kodi muli pa banja? **(Zungulizani yankho limodzi)**	a. Simunakwatiwepo [1] b. ndili pa banja [2] c. Banja lidatha [3] d. Bambo adamwlira [4]
A4	Munafika pati ndi maphunziro anu? **(Zungulizani yankho limodzi).**	a. Sindinaphunzireko [1] b. Pulayimale [2] c. Sekondale [3] d. Koleji [4]
A5	Ndinu mtundu wanji wa anthu? **(Zungulizani yankho limodzi?**	a. Mchewa [1] b. M'ngoni [2] c. Mtumbuka [3] d. M'ngonde [4] e. Mtonga [5] f. Wina tchulani……[6]

A6	Kodi mumagwira ntchito yanji? **(Zungulizani yankho limodzi?**	a. Uphunzitsi [1] b. Ulimi [2] c. Mayi wa pakhomo [3] d. Kugulitsa malonda [4] e. Zina atchulani…… [5]
A7	Kodi amuna anu amagwira ntchito yanji? **(Zungulizani yanhko limodzi)**	a. Ulimi [1] b. Samagwira ntchito [2] c. Kugulisa malonda [3] d. Kuyendetsa galimoto [4] e. Uphunzitsi [5] f. Zina tchulani……. [6]
A8	Kodi mumapemphera mpingo wanji? **(Zungulizani yankho limodzi)**	a. CCAP [1] b. Katolika [2] c. Chisilamu [3] d. A Seveni [4] e. A Pente [5] f. Wina tchulani…… [6]

A9	Kodi mumakhala kuti? **(Zungulizani yakho limodzi)**	a. Dera la kumudzi [1] b. Pafupi ndi dera la kutauni [2] c. Kudera la kutauni [3]

GAWO LACHIWIRI

“Pano ndikufunsani mfunso a zinthu zomwe zimakhudzana ndi kamwedwe ka makhwala otalikitsa moyo (ART) pamane mukuyamwitsa (option B+)”

NAMBALA	MAFUNSO	MAYANKHO
	Mbali yokhudzana ndi odwala	
B1	Kodi ndizotheka mzimayi amene ali ndi ka chilombo ka HIV kumupatsira mwana pathawi yomwe akuyamwitsa? **(Zungulizani yankho limodzi)**	a. Eya [1] b. Ayi [2]

B2	Kodi kutsatira kumwa makhwala otalikitsa moyo (ART) kukhoza kuchepetsa chiophyezo chomupatsira mwana kachilombo ka HIV? **(Zungulizani yankho limodzi)**	a. Eya b. Ayi	[1] [2]
B3	Kodi makhwala otalikitsa moyo (ART) ndi othandiza kwa mwana? **(Zungulizani yankho limodzi)**	a. Eya b. Ayi	[1] [2]
B4	Kodi mumamasuka kumwa makhwala otalikitsa moyo pamaso pa anthu ena? **(Zungulizani yankho limodzi)**	a. Eya b. Ayi	[1] [2]
B5	Kodi mumawapewa achibale ndi anzanu chifukwa chokuti munapezeka ndi chilombo ka HIV? **(Zungulizani yankho limodzi)**	a. Eya b. Ayi	[1] [2]
B6	Kodi zikhulupiliro za chikhalidwe chanu zimasokoneza kamwedwe ka makhwala otalikitsa moyo (ART). **(Zungulizani yankho limodzi),** ngati **eya** pitani B7	a. Eya b. Ayi	[1] [2]

B7	Zimasokoneza bwanji? **(Zungulizani yankho limodzi)**	a. Chikhalidwe chanthu chimalola kumwa makhwala otalikitsa moyo (ART) [1] b. Chikhalidwe chanthu chimafuna kutenga chilolezo kwa bambo/akulu akulu [2] c. Chikhalidwe chanthu chimakhulupilira makhwala a chikuda [3]
B8	Kodi nkhani ya za chuma imasokoneza ndondomeko yanu yamankhwala otalikitsa moyo (ART) **(Zungulizani yankho limodzi),** ngati **eya** pitani B9	a. Eya [1] b. Ayi [2]
B9	Nanga imasokoneza chani? **(Mutha kungulizani mayankho oposera limodzi)**	a. Mayendedwe okafikila ku chipatala [1] b. Zokhumba za moyo za tsiku ndi tsiku [2] c. Zina tchulani…….. [3]
B10	Kodi nthawi zina mumayiwala kumwa makhwala otalikitsa moyo (ART)?	a. Eya [1]

	(Zungulizani yankho limodzi), ngati **eya** pitani B11	b. Ayi [2]
B11	Ndiye mumatani mukayiwala kumwa makhwala? **(Zungulizani yankho limodzi)**	a. Ndimamwa makhwala ntahwi yomwe ndakumbukila [1] b. Ndimamwa makhwala mawa lake [2] c. Sindimwa [3] d. Zina tchulani…….. [4]
B12	Munayamba mwawuzapo muthu wina aliyense kuti munapezaka ndi kachilombo ka HIV? **Zungulizani yankho limodzi),** ngati **eya** pitani B13	a. Eya [1] b. Ayi [2]
B13	Munawuzapo ndani? **(Mutha kungulizani mayankho oposera limodzi)**	a. Mwamuna wanga [1] b. A chibale [2] c. A neba [3] d. Azizanga [4] e. Ena tchulani …….. [5]
B14	Kodi mukuganiza kuti ka chilombo ka	a. Eya [1]

	HIV kakhonza kuchizika ndi mphavu za uzimu osamwa makhwala otalikitsa moyo (ART)? **(Zungulizani yankho limodzi)**	b. Ayi [2]
B15	Kodi mowa mumamwa ochuluka bwanji patsiku? **(Zungulizani yankho limodzi)**	a. Botolo limodzi mpaka asanu [1] b. Mabotolo asanu mpaka khumi [2] c. Kupitilira mabotolo khumi [3] d. Simumwa mowa [4]
B16	Kodi mumasuta fodya/ndudu zingati patsiku? **(Zungulizani yankho limodzi)**	a. Ndudu imodzi mpaka zisanu [1] b. Ndudu zisanu mpaka khumi [2] c. Ndudu zopitilira khumi [3] d. Sindimasuta [4]
B17	Kodi mumalindira thandizo lina lililonse kuchokela kwa amuna anu, a chibale kapena azinzanu? **(Zungulizani yankho limodzi),** ngati **eya** pitani B19	a. Eya [1] b. Ayi [2]

B18	Kodi chithandizo cho chimakuthandizani mukamwedwe kanu ka makhwala? **(Zungulizani yankho limodzi),** ngati **eya** pitani B20	a. Eya [1] b. Ayi [2]
B19	Chimakuthandizani bwanji? **(Zungulizani yankho)**	a. Kundikumbutsa nthawi yomwera makhwala [1] b. Nkhani ya za chuma [2] c. Kundilimbikitsa kumwa makhwala [3] d. Zina tchulani……..[4]
	Zokhudzana ndi Makhwala	
B20	Kodi kutalika kwa nthawi ya kamwedwe ka makhwala otalikitsa moyo (ART) imakusokoneza kutsatira kumwa mankhwala? **(Zungulizani yankho limodzi)**	a. Eya [1] b. Ayi [2]
B21	Munayamba mwakumanapo ndi zotsatila zoipa kamba ka makhwala wa? **(Zungulizani yankho limodzi)**,	a. Eya [1] b. Ayi [2]

	ngati **eya** pitani B23	
B22	Kodi zotsatila zoipazi zinasokoneza kutsatila kumwa mankhwala a ART? **(Zungulizani yankho)**, ngati **eya** pitani B24	a. Eya [1] b. Ayi [2]
B23	Ndiye munatani? **(Mutha kungulizani mayankho oposera limodzi)**	a. Ndinapita ku chipatala [1] b. Ndinasiya kumwa makhwala ART [2] c. Ndinapitiliza kumwa makhwala ART [3] d. Sindipange chichonse [4]
B24	Kodi mapilitsi mumamwa mosavutikira? **(Zungulizani yankho limodzi)**, ngati **ayi** pitani B26	a. Eya [1] b. Ayi [2]
B25	Chifukwa chani? **(Zungulizani yankho limodzi)**	a. Mapilitsi amanditopetsa kumwa tsiku lina lililonse [1] b. Mapilisi ndi akulu akulu [2] c. Mapilisi amawawa [3]

		d. Mapilisi amakhala ambiri [4]
B26	Kodi kukumbutsani kumwa makhwala kumakuthazani kutsatira ndondomeko ya kamwedwe kamankhwala a ART? **(Zungulizani yankho limodzi)**	a. Eya [1] b. Ayi [2]
	Zokhudzana ndi Nthenda (HIV/AIDS)	
B27	Kodi thanzi lanu limasokoneza bwanji kutsatila ndondomeko ya kamwedwe ka mankhwala otalikitsa moyo (ART)? (**Lembani)**	…… ……
	Zokudzana ndi Kuchipatala	
B28	Kodi chipatala chinatalikilana bwanji ndi komwe mumakhala? **(Lembani)**	……KM
B29	Kodi mumagwiritsa ntchito ndalama kuti mukafike ku chipatala? **(Zungulizani yankho limodzi)**, ngati **eya** pitani B32	a. Eya [1] b. Ayi [2]

B30	Mumagwiritsa ntchito ndalama zingati? **(Lembani)**	……..
B31	Ndalama yoyendela mumakwanitsa kuyipeza? **(Zungulizani yankho limodzi)**	a. Nthawi zonse [1] b. Nthawi zina [2] c. Mwa apo ndi apo [3] d. Sindiyipez [4]
B32	Kodi chipatala chomwe mumakatengelako makhwala ndikosabvuta kufikako? **(Zungulizani yankho limodzi)**, ngati **ayi** pitani B35	a. Eya [1] b. Ayi [2]
B33	Kodi masiku amene mumakalandila chithandizo kuphatikizapo kutenga makhwala kuchipatala alibe bvuto kwa inu? **(Zungulizani yankho limodzi)**	a. Alibe bvuto [1] b. Ali ndibvuto [2] c. Sindikudziwa [3]
B34	Kodi madokotala amapezeka kuchipatala (ART clinic) **(Zungulizani yankho limodzi)**	a. Nthawi zonse [1] b. Nthawi zina [2] c. Mwa apo ndi apo [3]

		d. Samapezeka [4]
B35	Mumatenga nthawi yayitali bwanji kuti muthandizike? **(Lembani)**	…….minitsi/maola
B36	Kodi makhwala amapeza kuchipatala? **(Zungulizani yankho limodzi)**	a. Nthawi zonse [1] b. Nthawi zina [2] c. Mwa apo ndi apo [3] d. Samapezeka [4]
B37	Kodi pamasungidwa chinsinsi mukamawonana ndi a dokotala? **(Zungulizani yankho limodzi)**	a. Eya [1] b. Ayi [2]
B38	Kodi mkhalidwe wa anthu ogwira ntchito ku chipatala umasokoneza bwanji thandizo lanu la mankhwala a (ART)? **(Lembani)**	…… ……
B39	Kodi mukuwona ngati munalandila uphungu wokwanila nthawi yomwe mumayamba kulandila makhwala otalikitsa moyo (ART). **(Zungulizani**	a. Okwanila kwambiri [1] b. Okwanila [2] c. Osakwanila [3]

	yankho limodzi)	d. Sindikudziwa [4]

GAWO LACHITATU

Adapted Multi-Method ART Adherence Tool in Chichewa version

Kufufuza mulingo wa makhwala otalikitsa moyo pakati pa azimayi amene akuyamwitsa ana pogwiritsa Multi-Method ART Adherence Tool

"Chonde zungulizani yankho lokhuzana ndi inu"

NAMBALA	MAFUNSO	MAYANKHO

C1	Kodi nthawi zina mumayiwala kumwa makhwala otalikitsa moyo (ART)?	a. Eya [1] **b.** Ayi [2]
C2	Kodi nthawi zina mukapeza bwino, mumasiya kumwa makhwala otalikitsa moyo (ART)?	a. Eya [1] b. Ayi [2]
C3	Polingalira pa masiku 28 a m'mbuyomu, pali masiku ena omwe simunamwe makhwala anu otalikitsa moyo?	a. Eya [1] b. Ayi [2]
C4	Kodi nthawi zina ngati simunamve bwino, munayamba mwasiyapo kumwa makhwala anu otalikitsa moyo?	a. Eya [1] b. Ayi [2]

Mafunso athela apa **Zikomo chifukwa cha nthawi yanu!**

Appendix 3: Information Letter

Study title: Factors associated with ART adherence under option B + strategy among breastfeeding mothers at Mzuzu Health Centre, Malawi.

Dear participants

My name is **Beatrice Kanyimbo** and I am currently registered as a student at University of Malawi, Kamuzu College of Nursing for Master of Science degree in Midwifery. I am

conducting a research project on "**Factors associated with ART adherence under option B + strategy among breastfeeding mothers at Mzuzu Health Centre, Malawi**." I write this letter to ask you to participate in the study mentioned above. The aim of the study is to explore the factors associated with ART adherence under option B+ strategy among breastfeeding mothers at Mzuzu health centre.

Participation in the study is entirely voluntary. You may choose to participate or withdraw from the study at any time, which will not have any effects on the services that you are receiving from the health care providers in this hospital. Furthermore, the study does not have any foreseeable physical harm (risks). However, in cases of any emotional or psychological harm you will be counselled accordingly or you may forward your concern and complaints to the researcher at Kamuzu College of Nursing.

Please note that there will be no financial benefits or any immediate benefits for you participating in the study. However, you will be given a little money amounting to 1000 Malawi Kwacha to cover for the lost work time. The findings from this study will provide the insight of the local situation in different settings, which may serve as reference for the policy makers to evaluate policies. It will also help the health care providers to identify the focus areas for counselling in the PMTCT service context, and this will contribute to the development of retention strategies.

No reports in this study will identify you in any way and results of the study will be given to you should you so wish. If you agree to participate, I will ask you to sign a consent form or put a finger print on the space provided to indicate that you have accepted to be interviewed. It is anticipated that the interview will take a maximum of **30-40 minutes**. The interview will be

conducted at a time that is most suitable and convenient to you in a quiet environment to avoid any disturbances and also for privacy.

The study has been approved by College of Medicine Research and Ethics Committee (COMREC), which is a board that ensures the protection of research participants in Malawi. The permission has been sought from Mzimba District Office to conduct the study at Mzuzu health centre.

Thank you for taking time to read this information letter.

Should you require any further information regarding the study or your rights as study participant you are free to contact me, or my research supervisor or COMREC.

The Principal Investigator: Beatrice Kanyimbo

Postal address: University of Malawi
Kamuzu College of Nursing
Post Office Box 415
Blantyre.

Email address: kanyimbo2017beatrice@kcn.unima.mw

Cell: +265 884 003 196

First research supervisor: Dr. Ursula Kafulafula

Postal address: University of Malawi
Kamuzu College of Nursing
Post Office Box 415
Blantyre.

Email address: ursulakafulafuka@kcn.unima.mw

Cell : +265 888 878 290

The chairperson: College of Medicine Ethics Review Committee (COMREC)

Private Bag 360

Chichiri

Blantyre 3.

Email address: comrec@medcol.mw

Telephone number: +265 187 4377

Physical address: University of Malawi

College of Medicine

Mahatma Gandhi Campus

Postgraduate Building Ground Floor

Room number 822.

Thank you for taking time to read this information letter.

Appendix 4: Consent Form

Study title: Factors associated with ART adherence under option B + strategy among breastfeeding mothers at Mzuzu Health Centre, Malawi.

PLEASE READ AND SIGN THE FORM IF YOU ARE TAKING PART IN THIS STUDY

I…… (Name/ Thumb Print), voluntarily give permission to participate in the study.

I have read or have had another person read to me and understood the content of the information letter and I have been given the opportunity to ask questions, where deemed necessary, about the study.

I understand that the information I give will be kept confidential and will only be accessed by the researcher and/or those people who are directly concerned with the study.

I know that I do not have to suffer any injury or harm during the research process and the information that I will give to the researcher will not be used against me in future.

…… or ……

Participant's Signature Thumb print Date

....

Researcher's Signature Date

Should you have any further inquiries please contact: The Chairperson, COMREC Secretariat P/Bag 360, Chichiri, Blantyre 3 or you may call on +265 187 4377.

Appendix 5: Chichewa translation of information letter

Mutu wa kafukufuku: Zinthu zomwe zimakhudzana ndi kamwedwe ka mankhwala otalikitsa moyo (ART) pakati pa a zimayi omwe akuyamwitsa ana (option B+) pa chipatala cha Mzuzu Health Centre, Malawi.

Okondedwa otenga mbali,

Dzina langa ndine **Beatrice Kanyimbo**. Ndine ophunzira pa sukulu ya ukachenjede ya anamwino ndi azamba (Kamuzu college of Nursing) yomwe ili gawo la sukulu ya ukachenjede ya Malawi (University of Malawi) ndipo ndili mu chaka chachiwiri chomwe chili chomaliza pa maphunziro anga a kuzama pa nkhani za uzamba (Masters degree in Midwifery). Monga gawo la maphunziro ozama pa nkhani za uzamba, ndikuyenera kupanaga kafukufuku okhudzana ndi sukuluyi. Mutu wakafukufuku wangayu ndi **'Zinthu zomwe zimakhudzana ndi kamwedwe ka mankhwala otalikitsa moyo (ART) pakati pa a zimayi omwe akuyamwitsa ana (option B+) pa chipatala cha Mzuzu Health Centre, Malawi.'** Cholinga cha kafukufukuyi ndi kufufuza zinthu zomwe zimakhudzana ndi kamwedwe ka mankhwala otalikitsa moyo (ART) pakati pa azimayi amene aku yamwitsa ana (option B+) pa chipatala cha Mzuzu Health Centre.

Cholinga cha kalatayi ndi kukupemphani ngati mungalore kutenga nawo gawo pa kafukufukuyu. Kutenga nawo gawo ndi sikokakamiza ndipo mutha kusankha kukana kapenanso kusiyira panjira pa nthawi yomwe mwavomela kutenga nawo gawo pakafukufukuyu. Izi sizizasokoneza thandizo lomwe mungalandile pa chipatala pano. Moonjezera apo, kufukufukuyu alibe chiopsezo chomwe chingachitike kwa inu pamene mwatengapo nawo mbali, komabe ngati mungaone chiopsezo kapena kukumana ndi vuto lililonse, mudzalandira uphungu molingana ndi vutolo kapena muli omasuka kutumiza dandaulo lanu kwa mwini kafukufukuyu ku sukulu ya anamwino ndi azamba ya Kamuzu College.

Chinanso, chomwe mungadziwe ndi chokuti palibe ndalama kapena mphatso zilizonse zomwe mungalandire popeza mwatenga nawo mbali. Komabe, mudzalandila kandalama kochepa kokanila 1000 Malawi Kwacha ngati chipuputa misozi panthawi yomwe mwataya muli ndi ife. Komanso, mutha kuthandiza kuti zotsatira za kafukufukuyi zizawonetse cheni cheni chomwe

chimachitika mu zipatala zosiyana siyana, zomwe zingathandize kuti akulu akulu aboma la Malawi opanga malamulo okhudzana ndi nkhani za makhwala otalikitsa moyo ART awone pomwe angasinthe. Zotsatirazi, zidzathandizanso anthu ogwira ntchito mu zipatala (health service providers) kuona pamene pakufunika kumatsindika akamapeleka uphungu pa nkhani za kuteteza mwana kuka chilombo ka HIV (PMTCT), zomwe zingapangitse kupeza njira zina zomwe zingamapangitse kuti a zimayi amene akumwa mankhwala otalikitsa moyo komanso akuyamwitsa ana, azimwa mankhwalawa mwandondomeko komanso kulandila chithandizo moyenere. Zolemba zilizonse za kafukufuyu sizizawonetsa zina lanu, komanso zotsatira za kafukufukuyi zizapatsidwa kwa inu ngati mwafuna, chifukwa muzapatsidwa nambala yomwe idzagwiritsidwa ntchito mmalo mwa dzina lanu. Ndipo zomwe mudzayankhe zidzasungidwa mwa chinsisi ndipo amene anangadzafikile ndi omwe akupanga kafukufuku okha. Kafukufukuyu wavomerezedwa ndi a komiti yaikulu yoona za kafukufuku ndi ufulu ya College of Medicine (COM) komanso ofesi yayikulu ya pa chipatala cha Mzuzu Health Centre.

Ngati mwavomereza kutengapo mbali pa kafukufukuyi muzapemphedwa kusaina kalata kapena kisindikiza chala chanu ndiponso kuyankha **mafunso kwa nthawi ya mphindi makhumi atatu kapena anayi.** Komanso mukufuna kudziwa zambiri zokhuzana ndi kafukufukuyi, kapena muli ndi madandaulo panthawi ya kafukufukuyi ndinu woloredwa kutumiza dandaulo lanu kwa:

Mwini kafukufuku: Beatrice Kanyimbo

University of Malawi

Kamuzu College of Nursing

Post Office Box 415

Blantyre.

Email address: kanyimbo2017beatrice@kcn.unima.mw

Nambala ya foni: +265 884 003 196

Woyang'anira kafujufuku: Dr. Ursula Kafulafula

University of Malawi

Kamuzu College of Nursing

Post Office Box 415

Blantyre.

Email address: ursulakafulafuka@kcn.unima.mw

Nambala ya foni: +265 888 878 290

Wa pampando: College of Medicine Ethics Review Committee (COMREC)

Private Bag 360

Chichiri

Blantyre 3.

Email address: comrec@medcol.mw

Nambala ya foni: +265 187 4377

Komwe amapezeka: University of Malawi
College of Medicine
Mahatma Gandhi Campus
Postgraduate Building Ground Floor
Room number 822.

Zikomo potenga nthawi yanu kuwerenga kalatayi.

Appendix 6: Chichewa translation of consent form

<u>Mutu wa kafukufuku: Zinthu zomwe zimakhudzana ndi kamwedwe ka mankhwala otalikitsa moyo (ART) pakati pa a zimayi omwe akuyamwitsa ana (option B+) pa chipatala cha Mzuzu Health Centre, Malawi.</u>

Sainani dzina lanu kapena sindikizani chala chanu pamalo omwe mwapatsidwa ngati mwavomeraza kutengapo mbali pa kafukufukuyu.

Ine…… (Dzina/ Sindikizani chala) ndavomera kupeleka chilolezo mosaumilizidwa pakutengapo mbali pakafukufukuyu.

Ndawerenga/kuwerengeledwa ndipo ndamvetsetsa uthenga onse uli mukalata yokhudzana ndi kufukufukuyu, ndipo ndapatsidwa mwayi ofunsa mafunso pomwe pakufunika kutero. Ndamvetsestanso kuti zonse zomwe ndingafotokoze/kupereka zisungidwa mwa chinsisi ndipo amene ngazifikile ndi mwini kafukufuku yenkha kapena ene amene ali oyenera kutero. Ndawudzidwanso kuti sindikuyenera kukumana ndi chiopsezo cha mtundu wina uliwonse mu nthawi ya kafukufukuyi, ndipo uthenga omwe ndipereke kwa mwini kufukufukuyu suzagwilitsidwa ntchito mondiukila mtsogolo muno.

……kapena ……..

Posainila wotenga mbali Tsiku

…… Potsindikiza chala …….

Mwini kafukufuku Tsiku

Ngati pangakhale mafunso kapena nkhawa iliyonse yokhudzana ndi kafukufukuyu khalani omasuka kubweretsa madandaulo anu kwa: The Chairperson, COMREC Secretariat P/Bag 360, Chichiri, Blantyre 3 or mukhoza kuyimba pa foni nambala iyi: +265 187 4377.

Appendix 7: Tumbuka translation of the information letter

Mutu wa kafukufuku: Vinthu ivo vikukhwaskana na kamwelo ka mankhwala gha kutalikiska moyo (ART) pakati pa bamama awo bakuwokhyesya wana (option B+) pa chipatala cha Mzuzu Health Centre, Malawi.

Zina lane ndine **Beatrice Kanyimbo**. Ndine yumoza wa basambili pa sukulu ya yva unesi na uzamba (Kamuzu College of Nursing) iyo ili mugawo limoza la makolegi muno mu Malawi (University of Malawi), ndipo ine nili muchaka chachibiri icho ni chaka cha wumulilo mu masambilo ghane gha khani za uzamba (masters degree in Midwifery). Kwakulinga na gawo la masambilo ghane gha kuzama pa nkhani za uzamba, khwenela kupanga kafukufuku wakukhwaksana na sukulu yane. Mutu wakafukufuku wane uyu ni '**Vinthu ivo vikukhwaskana na kamwelo ka mankhwala gha kutalikiksa moyo (ART) pakati pa bamama awo bakuwokhyesya wana (option B+) pa chipatala cha Mzuzu Health Centre, Malawi.'** Chakulata cha kafukufuku uyu ni kufufuza vinthu ivo vikukhwaskana na kamwelo ka makhwala gha kutalikiska moyo (ART) pakati pa bamama awo bakuwokhyeska wana (option B+) pa chipatala cha Mzuzu Health Centre.

Chakulata cha kalata iyi ntcha kuti mukupemphekeka kuti mutolepo nawo gawo pa kafukufuku uyu. Kutola nawo chigaba mu kafukufuku uyu nkhwa kujipereka. Mungamanya kuleka kugzola mafumbo pa nyengo yiliyose kwambula kukumana na suzgo lililose pa wovwili

wa vyaumoyo uwo imwe mungapokela pa chipatala ichi. Mwakusagzilapo, palije chakofya chilichose icho mungakumana nacho ku umoyo winu chifukwa chakutolapo chigaba pa kafukufuku uyu, kweni pala mwasangana na chakofya chilichose, muzamupokela uphungu mwakulingana na sugzo ilo mwakumana nalo olo ndimwe waku masuka kutumigza dandawulo linu kwa mweneko kafukufuku ku sukulu ya yva unesi na uzamba ya Kamuzu College.

Chinyakhe mungamanya ntcha kuti, palije ndalama panji chawanangwa chilichose icho mupokenge chifukwa mwatola nawo chigaba pakafukufuku uyu. Kweni Pazamuba kandalama kachoko kakukwana 1000 Malawi Kwacha ako muzamulipirika nga chipuputa misozi pa nyengo iyo mwataya muli na ise. Kutolapo chigaba mukafukufuku uyu vizamuwovwila kuwona veneko veneko ivo vikuchitika muvipatala vakupambana pambana ivo vizamuwovwila kumanyiksa wumba wose wa banthu kweniso awo bakupanga malango gha vya makhwala gha kutalikiska moyo (ART) na awo bakwendeska ndondomeko za umoyo muno mu Malawi kuti bamanye kusintha apo mphakwenela kusintha. Ivo tivisangenge mu kafukufuku uyu viwovwilengeso wanthu awo wakugwira ntchito mu vipatala (health servise providers) kuwona apo pakukhumbika kudidimigzapo pakupeleka uphungu pa nkhani za nthowa za kuponoskela mwana ku kachubungu ka HIV (PMTCT), kweniso ivo vingapangiska kusanga nthowa zinyakhe izo zingapangiska kuti bamama awo wakumwa makhwala gha kutalikiska moyo kweniso waku wokhyeska wana wamwenge makhwala mwandondomeko, ndiposo kupokela wovwili mwakuyenera. Ivo tizamuvisanga mukafukufuku uyu vizamupasika kwa imwe pala mwakhumba.

Uthenga wose uwo mugabanenge nase uzamusungika mwa chisisi ndipo uzamugwiriskika ntchito pa kafukufu pela. Lipoti ilo lizamulembeka lizamugwiliska ntchito

mazgolo wose pamoza ndipo lizamuzunula panyakhe kuwululula mazina yayi panyankhe chilichose icho chingapangiska kuti banthu bamanye kuti uyo wakatipasa uthenga uwu ni njani, chifukwa muzamupasika nambala iyo muzamugwiriska ntchito mumalo mwa zina linu. Magzolo yinu ghazamusungika mwachisisi nakusungika pamalo ghakutetegzeke makola na loko ndipo ma kiyi ghakhe ghazamuperekeka kwa munthu waliyose chala kupatula awo bakupanga kafukufuku uyu pela. Kafukufuku uyu wazomelegzeka na ba komiti yikulu yakuwona vya kafukufuku na wanangwa ya College of Medicine (COM) kweniso ofesi yikulu ya chipatala cha Mzuzu Health Centre.

Pala mwazomela kutolapo chigaba pa kafukufuku uyu mukupempheka kusayina kalata panyakhe kusindikigza njobe yinu, kweniso kugzola mafumbo kutolenge ma minitsi pakati pa 30 na 40. Usange mukukhumba kumanya vinandi vakukhwaskana na kafukufuku uyu panyankhe muna dandawulo panyengo ya kafufuku ndimwe wakuzomelegzeka kutumigza dandawulo linu kwa:

Bakuyendeska kafukufuku: Beatrice Kanyimbo
University of Malawi
Kamuzu College of Nursing
Post Office Box 415
Blantyre.

Email address: kanyimbo2017beatrice@kcn.unima.mw

Nambala ya foni: +265 884 003 196

Wakuwonelera kafukufuku: Dr. Ursula Kafulafula
University of Malawi

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Nambala ya foni: +265 888 878 290

Wa pampando: College of Medicine Ethics Review Committee (COMREC)

Private Bag 360

Chichiri

Blantyre 3.

Email address: comrec@medcol.mw

Nambala ya foni: +265 187 4377

Uko bakusangika: University of Malawi
College of Medicine
Mahatma Gandhi Campus
Postgraduate Building Ground Floor
Room number 822.

Yewo chomene pakutola nyengo yinu kuwerenga kalatayi.

Appendix 8: Tumbuka translation of consent form

Mutu wa kafukufuku: Vinthu ivo vikukhwaskana na kamwelo ka mankhwala gha kutalikiska moyo (ART) pakati pa bamama awo bakuwokhyesya wana (option B+) pa chipatala cha Mzuzu Health Centre, Malawi.

Sayinani zina linu panyakhe sindikigzani njobe yinu pamalo awo mwapasika pala mwazomelegza kutolapo chigaba.

Ine ……(zina/ sikindigzani njobe) nkhuzomela mwakujipeleka kutola nawo gawo nga wakupereka uthenga mu kafukufuku uyu.

Naberenga/baniberengela ndipo napulikiska uthenga wose wuli mukalata waku khwaskana nakafukufuku uyu kunimanyiksa na kunipempha kuti nichite nawo kafukufuku. Bangunipa mwabi wakufumba mafumbo gha kafukufuku. Napulikiska kuti uthenga uwo nipelekenge uzamusungika mwachisisi, ndipo uzamugwiliskika ntchito iliyose chala yakuniwukila munthazi. Nkhumanya kuti nili na wanangwa kukana kuzgola fumbo lililose kweniso, kuleka na kufuma mu kafukufuku nyengo yiliyose usange nakhumba kwambula kutimbanigza vovwili wa kuchipatala.

…….panyakhe ☐ …….

Pakusayina wakutola gawo Zuba

……. …….

Bakuyendeska kafukufuku Zuba

Usange pali mafumbo panyakhe nkhawa zilizose zakukhwaskana na kafukufuku uyu muli wakumasuka kwiza nadandaulo linu kwa wa: The Chairperson, COMREC Secretariat P/Bag 360, Chichiri, Blantyre 3 or mukhoza kuyimba pa foni nambala iyi: +265 187 4377.

Appendix 9: Letter to the District Health Officer Mzimba North

The University of Malawi

Kamuzu College of Nursing

P.O Box 415

BLANTYRE

4th November, 2018

The District Health Officer

Mzimba North District Health Officer

P.O Box 299

Luwinga

Mzuzu

Dear Madam,

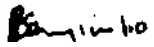
PERMISSION TO CONDUCT A RESEARCH STUDY AT MZUZU HEALTH CENTRE

I am a Master of Science (MSc) student at Kamuzu College of Nursing (Blantyre Campus) and I write to request for permission to conduct a study at Mzuzu Health Centre. The study is titled **'Factors associated with antiretroviral therapy (ART) adherence among breastfeeding mothers under option B+ strategy at Mzuzu Health Center, Malawi'**. This study will be partial fulfilment of the MSc degree in midwifery. The participants will be breastfeeding mothers initiated on ART under option B + strategy with children from 6 weeks to 24 months, and they will be interviewed.

It is expected that the study will explore the factors associated with ART adherence among breastfeeding mothers. Findings will help the health care providers to identify the focus areas for counselling in the PMTCT service context, and this will contribute to the development of retention strategies.

I am looking forward to hearing from you.

Yours faithfully,



Beatrice Kanyimbo.

Appendix 10: Acceptance Letter from District Health Officer Mzimba North

06/11/18
Incharge Mzuzu urban HC
Allow Ms Kanyimbo to proceed with data collection after ethical approval of the protocol.

The University of Malawi
Kamuzu College of Nursing
P.O Box 415
BLANTYRE
4th November, 2018

THE DISTRICT HEALTH OFFICER
MZIMBA NORTH DISTRICT HEALTH OFFICE
06 NOV 2018
P.O. BOX 299

The District Health Officer
Mzimba North District Health Officer
P.O Box 299
Luwinga
MZUZU

Dear Madam,

PERMISSION TO CONDUCT A RESEARCH STUDY AT MZUZU HEALTH CENTRE

I am a Master of Science (MSc) student at Kamuzu College of Nursing (Blantyre Campus) and I write to request for permission to conduct a study at Mzuzu Health Centre. The study is titled **'factors associated with antiretroviral therapy (ART) adherence among breastfeeding mothers under option B+ strategy at Mzuzu Health Center, Malawi'**. This study will be partial fulfilment of the MSc degree in midwifery. The participants will be breastfeeding mothers initiated on ART under option B + strategy with children up to 24 months, and they will be interviewed.

It is expected that the study will explore the factors associated with ART adherence among breastfeeding mothers. Findings will help the health care providers to identify the focus areas for counselling in the PMTCT service context, and this will contribute to the development of retention strategies.

I am looking forward to hearing from you.

Yours faithfully,

Beatrice Kanyimbo.

Appendix 11: Letter to the Hospital Director Mzuzu Central Hospital

The University of Malawi

Kamuzu College of Nursing

P.O Box 415

BLANTYRE

5th October, 2018

Mzuzu Central Hospital (MCH)

Private Bag 209

Luwinga

Mzuzu 2

Dear Sir,

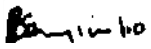
PERMISSION TO PRETEST A RESEARCH TOOL AT MCH, RAINBOW CLINIC

I am a Master of Science (MSc) student at Kamuzu College of Nursing (Blantyre Campus) and I write to request for permission to pretest a research tool at your facility. The study is titled **'factors associated with antiretroviral therapy (ART) adherence among breastfeeding mothers under option B+ strategy at Mzuzu Health Center, Malawi'**. This study will be partial fulfilment of the MSc degree in midwifery. The participants will be breastfeeding mothers initiated on ART under option B+ strategy with children from 6 weeks to 24 months, and they will be interviewed.

It is expected that the study will determine the factors associated with ART adherence among breastfeeding mothers. Findings will help the health care providers to identify the focus areas for counselling in the PMTCT service context, and this will contribute to the development of retention strategies.

I am looking forward to hearing from you.

Yours faithfully,



Beatrice Kanyimbo.

Appendix 12: Acceptance Letter from Mzuzu Central Hospital

Telephone: 01 320 916 / 878 In
Fax: 320223/320973/270
directormch@malawi.net The

reply please quote No.....

Hospital Director,
Mzuzu Central Hospital,
Private Bag 209,
Luwinga,
Mzuzu 2.
02nd May, 2019

Mzuzu Central Hospital

Private Bag 209

Luwinga

Mzuzu, Malawi

Dear Beatrice,

APPROVAL TO CONDUCT RESEARCH STUDY AT MZUZU CENTRAL HOSPITAL

Reference is made to your letter Submitted on 14th March, 2019 in which you requested for permission to conduct a pilot study titled ***"Factors Associated with Antiretroviral Therapy (ART) Adherence Under Option B+ Strategy Among Breastfeeding Mothers At Mzuzu Health Centre, Malawi"*** at our institution (Mzuzu Central Hospital). I am pleased to inform you that your request has been approved.

When you are ready to collect data at our institution, you will be required to present this letter to the in-charge of the department you have selected before you can start your data collection.

Yours sincerely,

Private Bag 209, Luwinga
Mzuzu 2
ADMINISTRATOR
THE CHIEF
Mzuzu Central Hospital

Master R.O. Chisale, Research and Publication Chairperson

For THE HOSPITAL DIRECTOR

Appendix 13: Certificate of Ethics Approval from COMREC

CERTIFICATE OF ETHICS APPROVAL

This is to certify that the College of Medicine Research and Ethics Committee (COMREC) has reviewed and approved a study entitled:

P.03/19/2620 - Factors associated with antiretroviral therapy (ART) adherence under option B+ strategy among breastfeeding mothers at Mzuzu Health Centre, Malawi. Version 2.0 dated 5 April 2019 by Beatrice Kanyimbo

On 29-Apr-19

Approved by College of Medicine

As you proceed with the implementation of your study, we would like you to adhere to international ethical guidelines, national guidelines and all requirements by COMREC some of which are indicated on the next page for your study

29-Apr-19

29-Apr-2019

Dr. YB. Mlombe - Chairperson (COMREC)

Date

(COMREC) Research and Ethics Committee

Appendix 14: Acceptance Evidence to Adapt and Use Research Tools in my Study

Dear Beatrice

Thank you for your email. Sure you can adapt the questionnaire, kindly make sure to acknowledge .

All the best with your studies

Kind regards

Show quoted text

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Mrs Temptation Chigova PhD (c)
PhD Oncology and Palliative Care Nursing (Wits University)
MA NS(UNISA), BSc Ns(UZ), Dip.HIV/AIDS (UNAM), HIV &STI Management (University of Washington)

Dear Beatrice,

Thank you for your request to adapt and use the ART adherence record tool (pages 31 to 43) developed by MSH with funding from USAID. We are pleased to give you permission to adapt and use the tool and ask that you use the following citation as the source for the original.

- Steel G., Nwokike J., Joshi M. 2007. Development of a Multi-method Tool to Measure ART Adherence in Resource-Constrained Settings: The South Africa Experience. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health. Available at https://pdf.usaid.gov/pdf_docs/PNADK153.pdf

Good luck in your study. We would be very interested to see the results of your study so it would be great if you could kindly share the final report/summary with us.

Kind regards
Helena

Helena Walkowiak
Senior Principal Technical Advisor
Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program
Management Sciences for Health
US-New York
Direct: +1-703-840-3808
E-mail: hwalkowiak@msh.org