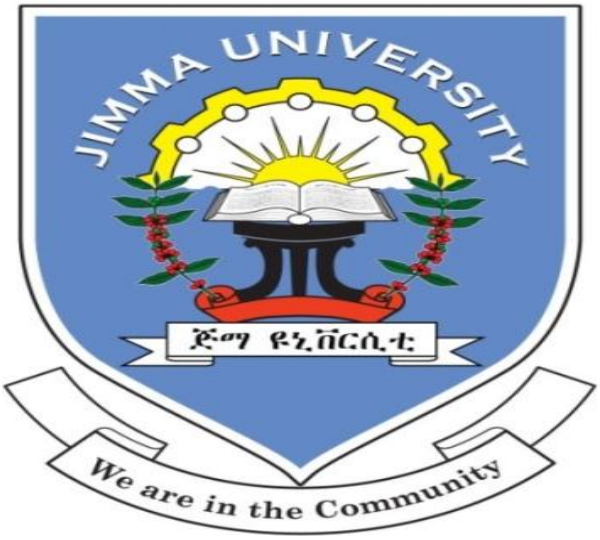
Level of Adherence and Associated Factors to Option B+ PMTCT among HIV Positive Pregnant Women in Hadiya Zone, Southern Ethiopia.



By

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A Research Thesis Submitted To Jimma University, College of Health Science, Department of Population & Family Health, in Partial Fulfillment for The Requirement of Degree of Master of Public Health (MPH) in Reproductive Health

Jimma, Ethiopia

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ABSTRACT

Background (problem statement): Option B+ is a test and treat strategy in which HIV+ pregnant women are initiated on antiretroviral therapy (ART) regardless of their immunologic status & clinical status and are maintained on treatment for life in an attempt to avert mother to child transmission of HIV and improve the survival of mothers, newborns and children. Adherence is the single most important modifiable factor to achieve the above outcome. Non-adherence to PMTCT drugs increases the risk of treatment failure, MTCT, maternal HIV disease progression, and the potential development of drug-resistant virus.

Objectives: The study aimed to identify the level of adherence to the Option B+ PMTCT programme and factors associated with adherence among HIV positive pregnant women in the hadiya zone, southern Ethiopia.

Methods: A facility based cross-sectional study was conducted among 215 HIV-positive pregnant women in 2016. Multiple logistic regressions were used to estimate the net effect sizes of factors associated with adherence to Option B+ PMTCT drugs.

Results: The adherence level of respondents to option B+ PMTCT drugs was 83.7% (95 % CI: 78.3, 88.6). Mothers who were counseled on the side effects of ARV medications had 7.2 times higher odds (aOR 7.2, 95% CI 2.2, 22.8) of adhering to Option B+ PMTCT care and support as compared to those who were not counseled properly. Disclosing their HIV status to their partner was also positively associated with good adherence (aOR 3.09, 95% CI 1.04, 9.1). HIV positive pregnant women with good partner involvement in PMTCT care and support had 72% more likely to be adherent to option B+ PMTCT as compared to low (aOR 0.28; 95% CI: 0.06, 0.12).

Conclusion: The adherence level of mothers towards PMTCT care and support was 83.7%. Proper counseling on the side effects of PMTCT drugs, care and support, HIV status disclosure to partners and Male partner involvement were significant predictors of adherence to PMTCT.

Keywords: Adherence, Option B+ PMTCT, Hadiya zone.

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CONTENTS

ACRONYMS

3TC----------Lamivudine

AZT------ Zidovudine

AIDS-------- Acquired Immune-Deficiency Syndrome

ANC--------- Antenatal care

ART ----------Antiretroviral Therapy

ARV----------Anti-Retroviral

CD4----------Cluster Differentiation T-lymphocyte

CI ----------Confidence Interval

EVF----------Evafirence

FDC---------- Fixed Dose Combination

HC----------Health Center

HIV---------- Human Immunodeficiency Virus

IMB---------- Information-Motivation-Behavioral skills

MOH--------- Ministry of Health

NVP----------Nevirapine

OR ----------Odds Ratio

OI ----------opportunistic infection

PLWH------ -People Living with HIV

PMTCT ------Prevention of Mother-to-Child Transmission of HIV

SPSS ---------Statistical Package for Social Sciences

SSA ----------Sub-Saharan Africa

TDF--------- tenofovir disoproxil fumarate (Tenofovir)

UNAIDS--- Joint United Nations Programme on HIV/AIDS

USA ---------United States of America

VL ----------Viral Load

WHO --------World Health Organization

ZHD----------Zonal Health Department

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CHAPTER ONE: INTRODUCTION

1.1. Background

The acquired immune deficiency syndrome (AIDS) epidemic is one of the most destructive epidemics that the world has ever faced (1). Since the start of the epidemic, around 78 million people have become infected with HIV and 39 million people have died of AIDS-related illnesses globally & among these 20.6 million from Sub-Saharan Africa and 4.5 million in Ethiopia (2). Globally, the number of People living with HIV (PLWH) is estimated as 35 million with the prevalence rate of 0.8% with 2.1 millions new infections. From this 3.2 million are children under the age of 15 years.

SSA, which constitutes only about 10% of the world population, is home to about 70% of HIV/AIDS infected patients & accounts for the greatest share which is 24.7 million with the prevalence rate of 5.5% (3).

In SSA an estimated 60% of people living with HIV were women, mostly in the reproductive age group. Each year approximately 1.4 million women living with HIV become pregnant globally and 98% among these clients are in sub-Saharan Africa, the proportion of women living with HIV ranges from 5% to as high as 30%. With the rising HIV/AIDS prevalence, the number of children under 5 years of age infected with HIV is increasing (3, 4).

The guiding principle & comprehensive strategic approach to the prevention of HIV infection in infants and young children includes the following four components:
The first one is primary prevention of HIV infection. The second point, Prevention of unintended Pregnancies among HIV Infected Women. The third point is preventing HIV transmission from HIV-infected women to their children by providing quality antenatal and delivery care, HIV testing and counseling in ANC, antiretroviral therapy for all pregnant women, ARV prophylaxis to their child and adequate infant feeding counseling. The fourth one is providing comprehensive care for HIV-infected mothers and their infants (5).
According to UNAIDS estimates, 67% of pregnant women living with HIV in low and middle-income countries received effective antiretroviral (ARV) drugs for the PMTCT in 2013, a

substantial increase from 48% in 2010. The annual number of newly HIV-infected children in 2012 was 260 000 in low and middle income counties which show 52% decline from 2001. PMTCT services prevented more than 670 000 children from becoming infected with HIV from 2009 to 2012. Nonetheless, many challenges to implementation remain, chief among which is ensuring that high proportions of women and children in need of antiretroviral therapy (ART) can access it (6).

The World Health Organization (WHO) has started to implement different strategies for the optimization of PMTCT care and support: Option A & Option B. As well as these two options, a third approach is now being used Option B+ which is not completely new, but rather is a more feasible alternative to WHOs proposed option B and With this option, all pregnant women living with HIV are offered life-long ART, regardless of their CD4 count. (8).

The advantage of Option B+ will include simplification for both the mother-infant pair and the provider, which are likely to facilitate higher retention rates and improved clinical benefits, which will decrease the transmission of HIV to infants. Added benefit of Option B+ beyond the clinical benefit will include improved maternal health and reduce the risk of HIV transmission to HIV negative male sexual partners (7, 8).

In 2013, the Ethiopian government adopted Option B+ to substantially increase provision of antiretroviral treatment to pregnant women living with HIV and aims to eliminate new HIV infections in children and keep their mothers alive & the mother and her child are followed up as a pair for up to 18-24 months (5).

The success of HAART, like any medication, is dependent on both the intrinsic properties of the drugs and the individual's ability to take the medication as prescribed which explained by adherence (9). Adherence has been defined as the extent to which a person' s behavior taking medication, following a diet, or making healthy lifestyle changes corresponds with agreed upon recommendations from a health-care provider (10).

There are different methods for assessing adherence. They include direct methods such as biologic markers and body fluid assays, or indirect methods such as self-report/interview, pill counts, pharmacy records, computerized medication caps, and viral load monitoring. While a

combination of these methods may be employed, patients self-report is the most widely used given its ease of implementation and use of already existing resources. Studies have also indicated that self-reports correlate well with both viral load and clinical outcomes (11).

1.2. Statement of the problem

Globally about 3.2 million children under 15 years were living with HIV in 2013. From this 200,000 were new infections in 21 high burdens Sub-Saharan Africa. Without appropriate treatment, out of these infected children approximately half of them will die before their second birthday (6).

In Ethiopia in 2013 an estimated 734,048 people were living with HIV/AIDS, out of which 448,865 (61%) were females & 154,038 were children under the age of 14 years. In the same year, an estimated 34,542 HIV positive pregnant women in need of service for the prevention of mother to child transmission of HIV& an estimated 4.2 million orphans in the country, out of which 792,840 children were orphaned due to AIDS(4).

Vertical transmission from mother to child accounts for more than 90% of pediatric AIDS. Without any interventions, in the range of 20-45% of infants would be infected. However successful implementation of prevention of mother-to-child transmission (PMTCT) with option B+ programs can reduce this risk to around 2% (12).

However, high-income countries have achieved the MTCT rate that is as low as 1–2%. Regardless of differences in treatment strategies, the better outcomes in high-income countries could be explained by the presence of advanced health systems, greater awareness among women, accessible information, and higher socioeconomic status and educational levels compared to limited-resource countries (13).

Non-adherence to PMTCT drugs increases the risk of treatment failure, MTCT, maternal HIV disease progression, and the potential development of drug-resistant virus (14, 15, and 16).
Though several studies in Ethiopia have identified the factors associated with non adherence to antiretroviral therapy among HIV-positive adults, only one from literature search studied antiretroviral adherence issues in HIV-positive pregnant option B+ women (38).

Reports have also shown that the availability of a limited number of regimens and the use of fixed dose combinations in option B+ support adherence. It can also limit unnecessary regimen switching and selective drug taking (17). Moreover, ART preparation at the first visit, the barriers related to the retention and adherence and the public health implications of reduced adherence to Option B+ in resource-limited settings are not well known and need to be fully understood and investigated. So the aim of this study is to identify the level of adherence to the Option B+ PMTCT programme and factors associated with adherence among women on Option B+ in the Hadiya zone, southern Ethiopia.

CHAPTER TWO: - LITERATURE REVIEW

2.1. Prevention of mother to child transmission of HIV/AIDS

Programmes that effectively prevent mother-to-child transmission (PMTCT) of HIV can reduce the rate of transmission under five percent and reduce morbidity and mortality in both mothers and children (18).

In 2010, the World Health Organization (WHO) recommended lifelong ART for women who were eligible for treatment and who had CD4 counts ≤350 cells/μl or in WHO clinical stage 3 or 4. But for women not yet eligible for treatment, WHO recommended two alternative PMTCT strategies for short-term antiretroviral prophylaxis.

Option A started women on ante partum zidovudine (AZT) from14 weeks after pregnancy, as well as on lamivudine (3TC) and nevirapine (NVP) during labour, followed by an AZT/3TC tail for 7 days, with daily infant nevirapine during breastfeeding.

Option B started women on triple-drug prophylaxis 14 weeks after gestation, and continued throughout pregnancy and breastfeeding (19). These two strategies depend on CD4 cell testing to determine women's eligibility for lifelong ART (20).

But in a systematic review on sub-Saharan African PMTCT programmes, CD4 count testing was identified as a major barrier to PMTCT (21).

In response to this barrier, WHO, in 2013, launched a more feasible approach known as Option B+ which is **"**test and treat" strategy in which triple ARVs are started as soon as HIV is detected in a pregnant & breastfeeding woman irrespective of CD4 count, gestational age and WHO clinical stage(3). This approach is the more advantageous in that it requires just one pills taken once daily, no need for CD4 test to initiate ART, makes breast feeding safer, avoids the need for extended infant ARV prophylaxis (Option A), mothers start treatment early, so quality of life and survival are better, maintains continuity of care: ANC to post-weaning so improves infant testing as well as post-partum uptake of FP services, minimize HIV transmission among

discordant partners, ongoing treatment of mother will protect future pregnancies from moment of conception(7).

2.2. Adherence

Adherence is the backbone of antiretroviral therapy. Studies of the antiretroviral therapy (ART) showed that almost perfect adherence; greater than 95% was required to obtain maximal effectiveness (22). Sustaining consistent and nearly perfect adherence is required to optimize the outcomes of ART, such as minimized drug resistance, slowed disease progression, decreased hospitalization and delayed death and general health, longevity, and, quality of life (23).

The success of ART is compromised by failure to maintain optimal levels of adherence over the long term and inadequate adherence is the major cause for sub-therapeutic drug levels and drug resistance that is transmissible to un-infected or infected others. Thus, adherence to therapy has become central and a major concern which requires continuous attention to prevent or delay resistance (24).

According to a retrospective study in Malawi to compare One-Year Outcomes of Women Started on Antiretroviral Therapy during Pregnancy before and after the Implementation of Option B+, more women in the Option B+ cohort had poor adherence or default & also, more challenges of adherence in Option B+(4).

Pregnant women with HIV have been known to have challenges with adherence and retention, irrespective of PMTCT approach. Several studies from Africa have shown that pregnant women have high rates of loss to follow-up (25, 26, 27). Additionally, despite being retained in care, adherence is a challenge, with in the studies from the US and 4 countries in Africa suggesting that only 73.5% of pregnant women achieve optimal adherence (13). This study showed better tolerability of the Option B+ regimen (3TC, TDF, EFV) with no ART switches compared to the pre-Option B+ regimen (d4T, 3TC, NVP), which required switches in 5.9% of women(25,27).

There are several possible challenges to adherence and retention in Option B+ programs. Healthier women may not see the need to continue ART long-term because they feel well and do

not have a clear understanding of the benefits of ART for health after delivery and/or breastfeeding. This misconception was described in a recent publication of perceptions of Option B+ in Malawi, in which women felt the program was being presented primarily for the benefit to the child (for prevention of MTCT) with less focus on concurrent benefits to the mother (28, 29).

Women also reported confusion about Option B+ being presented as an "option" when there were no other therapeutic choices offered for PMTCT, and described feeling pressured to initiate ART immediately, with little or no support around decision-making for their health.

One of the pioneer studies conducted the level of adherence to Option B+ PMTCT at Bewail Hospital, Malawi, found pill count from the electronic medical record system adherence rates of 91% (30).

In a study done in sub Saharan countries, in Nnewi, Nigeria, Prevalence and determinants of non-adherence to antiretroviral therapy among HIV- positive pregnant women, the level of adherence is found to be 78.3%. The common reasons for missing ARV drugs were forgetfulness (63.8%); feeling healthy and hence no need to take ARV drugs (16.3%) and living very far from the hospital (15.0%). Increasing maternal age ($X2 = 13.6$; $P = 0.001$), low educational level ($X2 = 39.36$ $P = 0.002$), extremes of parity ($X2 = 11.3$ $P = 0.03$), being in a sero-concordant relationship ($X2 = 6.2$; $P = 0.05$) and non-disclosure of HIV sero status ($X2 = 12.96$; $P = 0.003$) were significantly associated with non adherence to ART (31).

In another study conducted in Lagos, Nigeria, to identify pattern and determinants of antiretroviral drug adherence among pregnant women, the level of adherence is found to be 80.6% using 3 day recall. The desire to protect the unborn child was the greatest motivation (51.8%) for good adherence. Fear of being identified as HIV positive (63.6%) was the most common reason for non adherence. Marital status, disclosure of HIV status, good knowledge of ART, and having a treatment supporter were found to be significantly associated with good adherence at bivariate analysis. However, after controlling for confounders, only HIV status disclosure and having a treatment partner retained their association with good adherence (32).

In another study conducted in, kissumu, Kenya, triple-antiretroviral prophylaxis to prevent mother-to-child HIV transmission, the researchers got a level of adherence 82% (33).
In another study conducted in western Kenya, to assess Frequency and factors associated with adherence to and completion of combination antiretroviral therapy for prevention of mother to child transmission of HIV, by using electronic medical records, adherence level was found to be 89%(34).

In another cross sectional study conducted in Ashanti Region, Ghana, to assess Knowledge, perception about antiretroviral therapy (ART) and prevention of mother-to-child-transmission (PMTCT) and adherence to ART among HIV positive women, the researchers found that the ART defaulter rate was 27%. More than 90% of the HIV positive women had inadequate knowledge about ART and PMTCT and these women were more likely to default ART (OR = 3.5; 95% CI = 1.89, 6.21). The educational background of HIV positive women did not have significant influence on their knowledge of ART and PMTCT (35).

In another study conducted in a rural health facility in Kyela, Tanzania, to assess adherence to Combination Prophylaxis for Prevention of Mother-to-Child-Transmission of HIV, identified risk factors for declining pre-delivery prophylaxis included maternal age below 24 years, low income level, and enrolment before 24.5 gestational weeks, with odds ratios of 5.8 (P = 0.002), 4.4 (P = 0.015) and 7.8 (P = 0.001), respectively. Women who stated to have disclosed their HIV status were significantly more adherent in the pre-delivery period than women who did not (P = 0.004) (36).

A study done in Ethiopia shows that the number of women initiated on ART increased from 1,257 in 2011 (prior to Option B+) to 10,663 in 2012 (one year after implementation) a 74.8% increase(37).

Tigray region is the first in Ethiopia to have early data on option B+ outcomes. In a cross sectional study conducted in Tigray, Northern Ethiopia, to determine adherence level to and predictors of Option B+ PMTCT program, the researchers found 87.1%% (95 % CI: 82.6, 90.7) of the respondents have ≥95% optimal adherences. In this study factors positively associated

with good adherence were counseling on medication (AOR=4.7, 95% CI: 1.98, 11.35) and disclosing HIV status to her partner (AOR=4.2, 95 % CI: 1.07, 16.33) (38).

In another study, the role of male partner involvement on mother's adherence to PMTCT care and support, Tigray, Northern Ethiopia, the researchers found the adherence rate of mothers towards PMTCT care and support was 84.9%(39).

A prospective cohort study conducted among 282 HIV-positive mothers attending 15 healths facilities in Addis Ababa, Ethiopia, the researchers got adherence level of 82% (40).

Women experiencing side effects of the ARV drugs are less likely to trust the treatment and adhere to it (41). Another study showed that women experiencing milder side effects such as skin rash or skin discolorations, fatigue, headache, and fever were more likely to adhere to Option B+ PMTCT drugs than those experiencing more severe side effects such as metabolic effects (central nervous system (CNS) toxicity, severe hepatic necrosis, and renal toxicity) (42).

Factors most commonly associated with poor adherence are: few antenatal (ANC) visits, lack of male involvement, fear of partner's reaction to disclosure, women's poor knowledge.

Option B+ aims to reduce the HIV prevalence rate amongst these women by placing them on ART for life, no matter their CD4 count. Little is known about the impact of this new approach in Ethiopia. Most importantly, no research has focused on how these changes have affected adherence for the patients. Lack of a firm evidence base, including unstudied effects of long-term ART in otherwise healthy women and infants, and potential for increased drug resistance with poor adherence. Studies have not yet shown whether improved tolerability of the new option B+ regimens is associated with improved adherence and retention. There is a need to better understand the challenges women face, and to develop evidence-based interventions to assist adherence and retention, particularly early in the continuum of care, such that the health benefits of Option B+ can be fully realized.

2.3. Models

Recent reviews suggest that behavioral interventions to promote ART adherence can have significant effects (43).

In the light of the complexity, dynamicity of human behavior and a growing urgency in understanding the challenges to medication adherence confronting the people with (HIV) in clinical care, developing theory-based interventions is essential in promoting an understanding of adherence behavior.

One potentially relevant model, the Information-motivation-behavioral skills (IMB) model, was first developed in 2001 as a general health model and subsequently was tested as a model for ART adherence. Since then it has been repeatedly evaluated and finally developed in 2009 as a three-pronged strategy in the United States of America (USA) for ART adherence. It is comprehensive and addresses the cognitive, motivational, and behavioral aspects of change (44). The model, however, is characterized by a more individualistic approach. The advantage of IMB model is its simplicity and has been shown to be moderately effective in promoting behavior change for ART adherence. The model hypothesizes that adherence-related information and motivation work through adherence-related behavioral skills to affect the maintenance of optimal ART adherence. The researcher has selected the model because it is the only health model tested and being implemented for intervention for ART adherence (45).

Interventions based on this model have been effective in influencing behavioral change across a variety of clinical applications. A meta-analysis of 19 randomized controlled trials of ART adherence interventions found that participants who received an intervention according to IMB skill model were 1.5 times as more likely to report 95% adherence and 1.25 times as more likely to achieve an undetectable viral load as those in comparison conditions (46).

In a study conducted to evaluate the impact of the information, motivation and behavioral skills constructs & its applicability in Ethiopian context, the three constructs accounted for an average of 83.3% of the variance in behavior change (47).

The components of the IMB model which are displayed in the conceptual framework are information, motivation, behavioral skills, and adherence behavior. The model describes several important variables that are behavioral in nature and are also dynamic, and therefore amenable to intervention. Each component is discussed below in detail in light of evidence from previous quantitative and qualitative works on the IMB model of adherence behavior to HIV medication as well as retention in HIV care and adapted for women in Option B+ PMTCT care and support. Accordingly, the following concepts are identified and discussed:

- Adherence-relevant information and heuristics
- Adherence-relevant motivation which refers to a personal and social motivation to follow her option+ ART regimen as prescribed
- Adherence-relevant behavioral skills which comprise an individual's objective abilities and enacting a series of coordinated behaviors involved in the execution of the adherence behavior.
- Adherence level

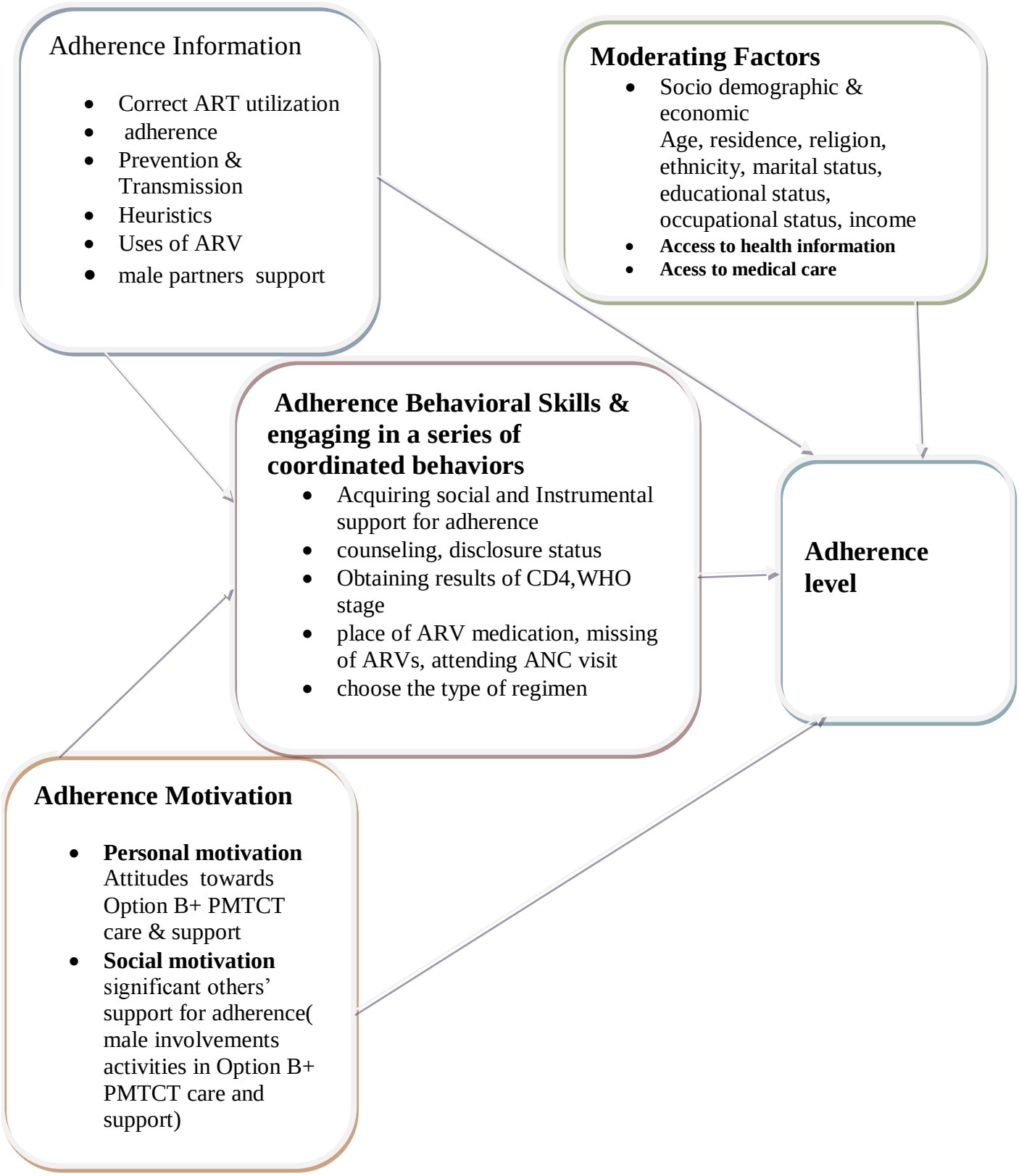


Figure 1 IBM Model of ART adherence adapted for option B+ care & support

2.3.1. Information regarding Option B+ PMTCT care & support

The first determinant of an IMB model, information, reflects objective information (and misinformation) held by a woman regarding Option B+ PMTCT care & support. The information construct also contains cognitive heuristic held by a women such as health beliefs specific to HIV that are often used to guide health behaviors' (e.g. absence of AIDS symptoms means she does not need medical care).

The specific kinds of objective information(and misinformation) relevant to adherence include basic accurate information about the regimen, requirements of adherence, drug interactions and side-effects, information on the disease itself (HIV/AIDS), including the process of adjusting life with HIV and changes in the disease course; and information about the available system(s) of care and support such as information about available treatment(s), their purpose and typical procedures, prevention & transmission and use of HIV treatment (e.g. case management) and patients' rights to receive the services (48).

In a study done in Tigray, northern Ethiopia, about the level & predictors of adherence to the Option B+ PMTCT programme, the researchers found the composite measure of knowledge among HIV positive pregnant women 56.7%, 28.1% and 15.2% had higher, moderate and lower knowledge on Option B+ PMTCT, respectively(38**).**

In another study about the role of male partner involvement on mother's adherence to PMTCT care and support, Tigray, northern Ethiopia, mothers with higher knowledge on PMTCT care and support (AOR=6.20, 95% CI of (3.10, 9.30), were 6.2 times more likely to adhere to PMTCT care and support(39).

2.3.2. Motivation on Option B+ PMTCT care & support

The specific kinds of personal motivation identified in the situated application of the IMB model as critical to adherence to option B+ medication include (49):

- individual's personal motivation:

Personal motivation rests upon an individual's attitudes and beliefs about adherence and non-adherence, in terms of using condom, her feeling of giving birth while ARV, her feeling on

involving her partner in option+ care & support, her attitude on early initiation of ARV, benefits of taking ARV.

In a study about the role of male partner involvement on mother's adherence to PMTCT care and support, Tigray, northern Ethiopia, mothers with positive attitude (AOR=8.2; 95% CI: 4.3, 12.6), were 8.2 times more likely to adhere to PMTCT care and support(39).

- social motivation:

Social motivation reflects her adherence is supported by significant others. Social motivation-related correlates identified in the literature and anticipated to be of relevance to women's experiences of adherence behavior in the current study reflect, male partner involvements in Option B+ PMTCT care and support.

In a study done in northern Ethiopia, about the level & predictors of adherence to the Option B+ PMTCT programme, the composite measure of male involvement in PMTCT services showed that 111 (42.2%), 88 (33.5%) and 64 (24.3%) of respondents had lower, higher & moderate male involvement on PMTCT care and support, respectively(38).

In another study about the role of male partner involvement on mother's adherence to PMTCT care and support, northern Ethiopia, HIV positive pregnant mothers with better male involvement had 8 times more odds to adhere to PMTCT care and support as compared to their counterpart (AOR=8.4; 95% CI: 4.2, 12.9) (39).

2.3.3. Behavioral skills regarding Option B+ PMTCT care & support

Adherence-relevant behavioral skills which comprise an individual's objective abilities and enacting a series of coordinated behaviors involved in the execution of the adherence behavior. Like choosing the type of regimen, acquiring social and Instrumental support for adherence, getting counseling, disclosing her status, obtaining results of CD4,WHO stage, preference of place of ARV medication, not missing of ARVs, attending ANC visit & etc.

2.3.4. **Adherence level**: is the cumulative percent of medication that a patient has taken from the number of drugs that have been prescribed for that patient. (49). The adherent behavior of individuals to ART can be divided into two levels: good *adherence* is practiced by those who took 95% or more of their dosing requirements while *poor adherence* is practiced by those who took less than 95% of the dosages that were prescribed for them during the prescribed period (49,50).

2.3.5. Modifying factors of the IMB model relationship

Some of the moderating factors affecting adherence without the intention of the patient are (51):

- Socio demographic & economic data
  Age, residence, religion, ethnicity, marital status, educational status, occupational status, income
- Access to health information
- Access to medical care

Many literatures have recognized that poor adherence has dire consequences and that though many factors contribute to poor adherence, changing individual adherence behavior is often central to the solution. However, there is no simple solution to the subject of behavior change required for adherence. Health behavior theories may throw light on the processes underlying behavior change to improve ART adherence. Theory based interventions in health care are more effective than those without an explicit theoretical foundation. To understand and overcome the barriers to treatment adherence, considerable further research is needed.

2.4. Significance of the study

In Ethiopia, where half of new HIV infections are the result of mother to child transmission, effective implementation of Option B+ could be an important step toward an HIV free generation (52). However, with Option B+ PMTCT, there is prolonged exposure to ART, which may lead to difficulties in adhering to treatment for HIV-infected pregnant women. As such, there is a scarcity of information on adherence. This study will therefore necessary to fill the knowledge gap and develop appropriate adherence enhancing strategies. Furthermore, adherence is the single most important modifiable factor that compromises treatment outcome & most studies conducted on adherence to ARV treatment have focused on the regular patient population with only a few concentrating on pregnant women and their adherence, but not particularly adherence to PMTCT (Option B+). The aim of this study is to identify the adherence to the Option B+ PMTCT programme and factors associated with adherence among women on ART in the hadiya zone southern Ethiopia. It is expected that the result of the study will be used to address the challenges that patients experience and to encourage them to adhere strictly to ART so that it can be optimally efficacious.

CHAPTER THREE: - OBJECTIVES OF THE STUDY

3.1. General objectives:

- To determine the level of Adherence and Associated Factors to Option B+ PMTCT among HIV Positive Pregnant Women

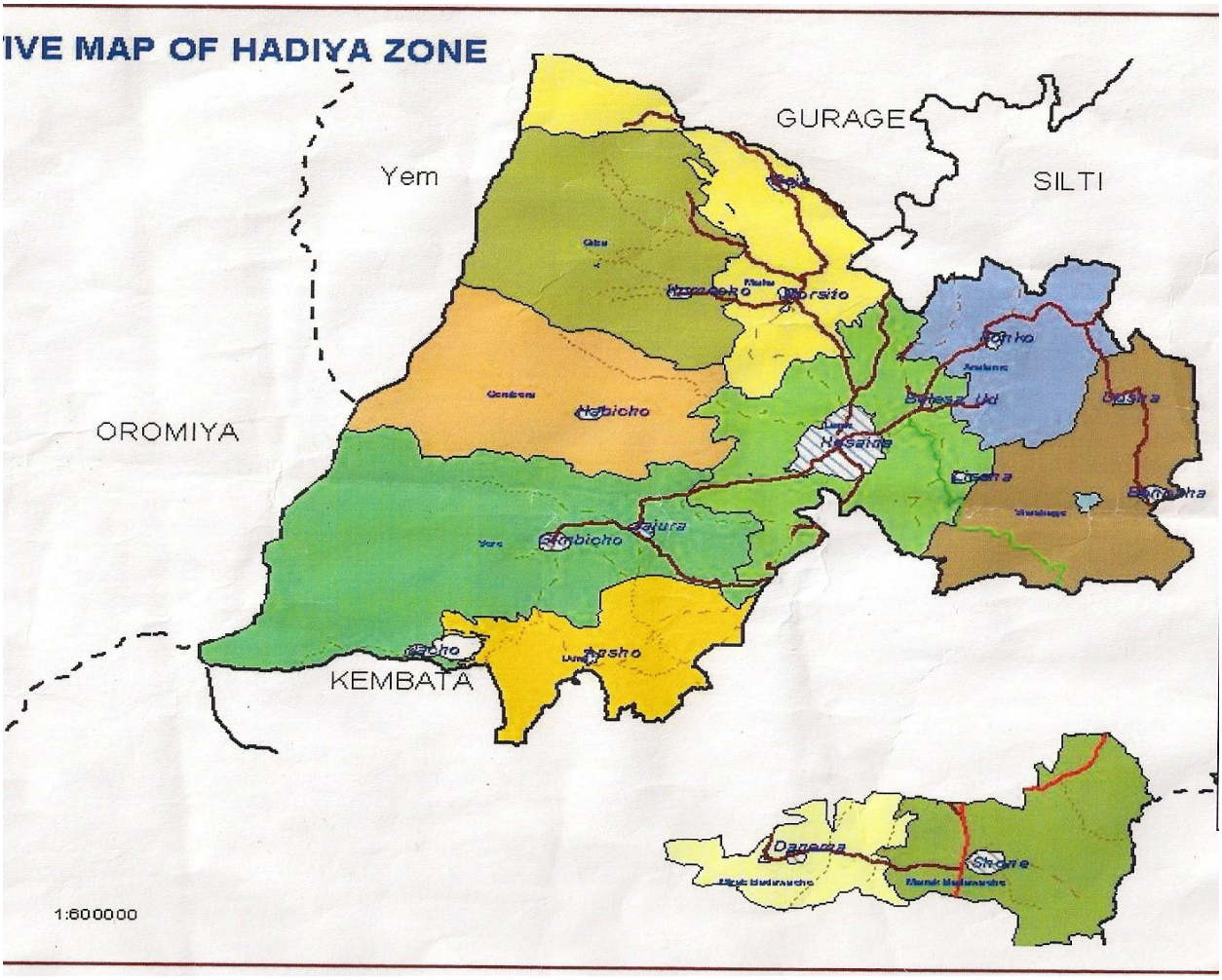
3.2. Specific objectives

- To determine the level of adherence to Option B+ PMTCT drugs
- To identify the factors affecting option B+ adherence behavior.

CHAPTER FOUR: - MATERIALS AND METHODS

4.1. Study Area and setting

The study was conducted in Hadiya Zone, which is established in 1985 EFY with an area of 3542.66sqkm which is 3% of the total area of southern nations nationalities and peoples region (SNNPR). According to the report of zonal health bureau, the total population in 2008 is approximately 1,547,848 (which is 9% of the SNNRP population with the population density of 92 people per square kilometer. The zone is located south west of Ethiopia, 230km far from the Addis Ababa and 194km far from Hawasa, the regional capital. The zone is bordered by Gurage zone in the north, Silte zone in the east, kembeta & Alaba in the south & Yam special woreda & Omo River in the west. In the zone there are 10 woredas, 01 town and 329 kebeles with 303 peasant association & 26 sub cities. The study was conducted at public hospitals & health centers where option B+ PMTCT services were available. The zone is served by 3 hospitals & 62 health center (53). 3 hospitals & 22 health centers are providing integrated maternal, neonatal, and child health (MNCH)/option B+PMTCT services to HIV-positive women, free of charge. The study recruited pregnant HIV-positive women in the zone who were attending the health institutions for PMTCT care and support during the study period.



4.2. Study period

Study was conducted from Mar15-Apr30/2016

4.3. Study design

A facility based cross-sectional study design was used to assess the adherence level and associated factors

4.4. Population

4.4.1. Source Population

All pregnant HIV positive women who were attending the health institutions for PMTCT care and support during the study period.

4.4.2. Study Population

Selected pregnant HIV positive women who fulfill the inclusion criteria & who were attending the health institutions for PMTCT care and support during the study period.

4.5. Sample size determination

First, the sample size was determined by using a single population proportion with the assumption of a 95% confidence level, 5% margin of error, and the expected level of adherence to option B+ Tigray region, northern Ethiopia (87%) (38). to compensate for non-response, a 15% contingency for the calculated sample is considered in advance. Accordingly, the total sample size was

$$n1 = \frac{(Z\ a/2)^2 P\ (1-P)}{d^2} = \frac{(1.96)^2\ 0.87(1-\ 0.87)}{(0.05)^2} = \mathbf{174}$$

Sample size calculation for associated factors

Second, the sample size was determined by using a double population proportion Using Epi Info version 7.1 and based on the study done in Tigray region; the main predictors affecting the adherence were proper counseling on the side effects of PMTCT drugs and HIV status disclosure to their partners.

Sample size calculation for proper counseling

p1 = proportion of adherence among clients who were counseled on ART Side effect (92.2%)

p2 = proportion of adherence among clients who were not properly counseled on ART Side effect (69%)

Zβ = 80%, (power = 0.84), $Z\alpha_{½}$ = 1.96 at 95% CI

Using Epi Info version 7.1, the final sample size calculated is **n2=90**

Sample size calculation for HIV disclosure to their partners

p1 = proportion of adherence among HIV status disclosed clients (90.6 %)

p2 = proportion of adherence among none disclosed clients (75%)

Zβ = 80%, (power = 0.84), $Z\alpha_{½}$ = 1.96 at 95% CI

Using Epi Info version 7.1, the final sample size calculated is **n3=182**

The largest sample size, 182 was taken.

For a response rate of 85%, nf= 182/0.85 =215**, where nf=the final sample size.**

4.6. Sampling procedure

Twenty five health facilities were giving option B+ PMTCT care & support. 10 health facilities out of 25 health facilities were selected using a random sampling method. A specific sample size was allocated to each facility using proportion-to-size allocation. Thus, 67, 26, 17, 34, 30, 7, 15, 5, 6, 8 study participants from Nigist Eleni Mohammod Metesabiya Hospital, Shone Hospital, Gibe Hospital, Hosanna HC, Geja HC, Morsito HC, Kosha HC, Ginbichu HC, Qorga HC, and lissana HC were taken respectively. Within each health facility, women were selected by using consecutive sampling. In total, 215 women were interviewed.

SCHEMATIC PRESENTATION OF THE SAMPLING PROCEDURE

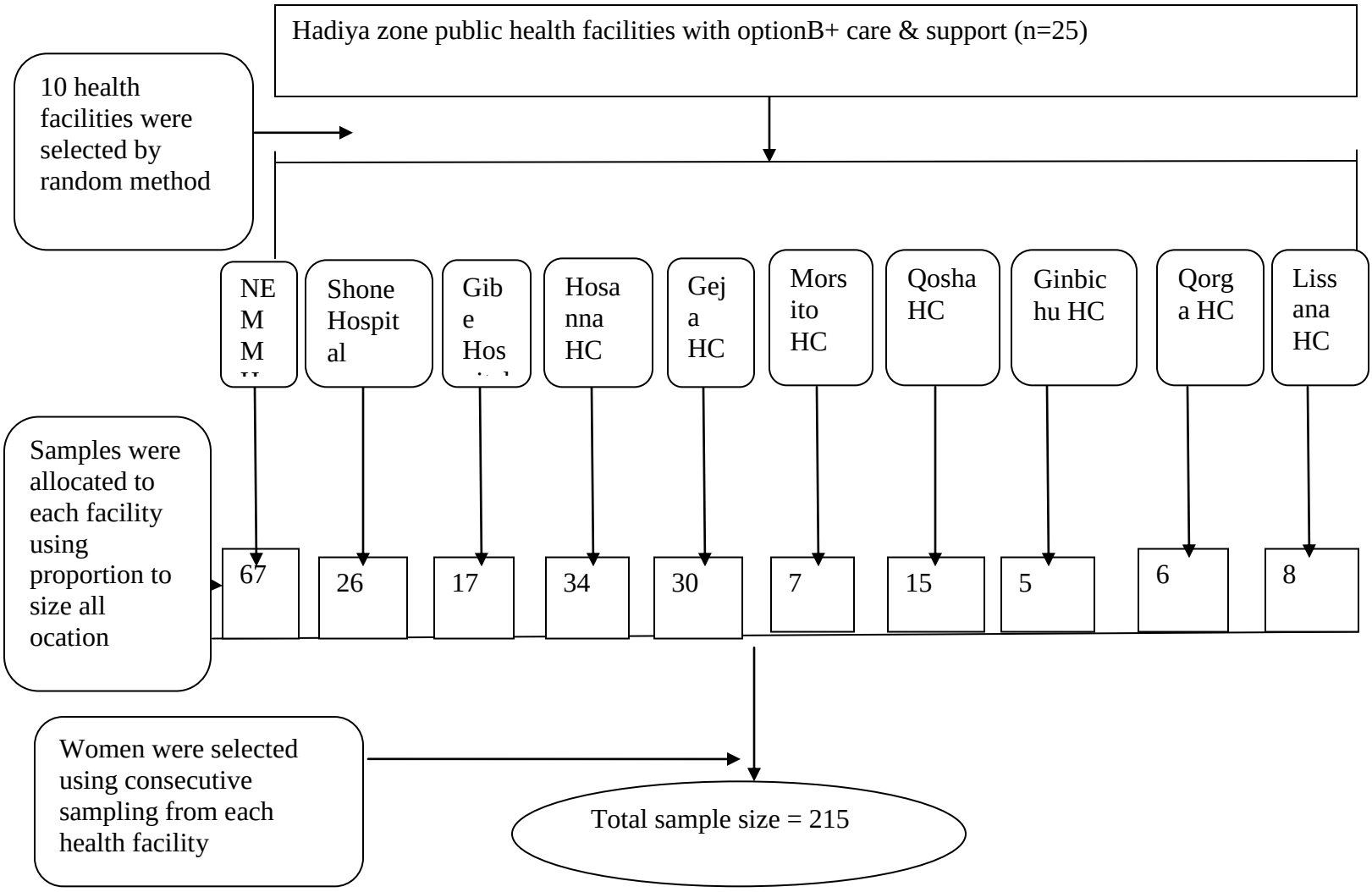


Figure 2 Schematic presentation of the sampling procedure.

4.7. Inclusion & Exclusion criteria

4.7.1. Inclusion criteria

Women who were enrolled in the Option B+ PMTCT programme at the time of the study and who had been on ART for more than 2 months.

4.7.2. Exclusion criteria

Women who started ART before pregnancies were excluded from the study.

4.8. Study variables

4.8.1. Dependent variables

Adherence level

4.8.2. Independent variables:

- Moderating Factors
    - Socio demographic and economic characteristics of women
      Age, Place of residence, Religion, Education status, Occupational status, Household income, Distance
    - Access to health information
    - Access to medical care
- Adherence Information
    - Knowledge of the mother regarding Option B+ PMTCT
- Adherence motivation
    - Attitude of the mother towards Option B+ PMTCT
    - Male partner involvements in Option B+ PMTCT activities
- Adherence Behavioral Skills & engaging in a series of coordinated behaviors

Type of ART drug, partner support, place of ARV medication, use of reminders, missing of ARVs, disclosure status, attending ANC visit, counseling, CD4+ cell count, WHO clinical stage.

4.9. Data collection procedures

Data were collected using a structured interviewer-administered questionnaire. The questions included were based on the Information–Motivation and Behavioral Skills (IMB) model. The questionnaire constituted questions that provide information on socio-demographic and economic characteristics of respondents, clinical characteristics, male partner factors, knowledge and attitude of mothers towards option B+ PMTCT drugs.

A self report from a multi-method tool to measure ART adherence in the resource-constrained settings and a pharmacy adherence policy to support adherence to ART were used (54).

4.10. Measurements

Adherence: the level of adherence was measured using four adherence measurement questions adapted from the experience in South Africa, which were designed to measure adherence in the resource-constrained setting (54). The tool comprises four questions:

1. Do you sometimes find it difficult to remember to take your medication?
2. When you feel better, do you sometimes take a break from your medication?
3. Many patients have troubles in taking their ARV doses as prescribed; did you miss any ARV doses in the last 3 days?
4. Sometimes if you feel worse when you take the medicine, do you stop taking it?

The adherence level of a woman was considered as to have good if she responded 'No' to four of the questions. However, if she responded at least one 'Yes' to the questions, she was considered to have poor adherence level.

Knowledge: the knowledge of the women on Option B+ PMTCT was measured from the total number of correct answers to six knowledge questions, with a minimum score of 0 and maximum of 6. The knowledge of the women on the Option B+ PMTCT programme was considered 'high', 'moderate', and 'low' if they answer >80%, 60– 79%, and <60% of the knowledge questions, respectively (18).

Attitude: the attitude of mothers towards the Option B+ PMTCT programme was defined as 'positive' if the score of the attitude questions is above the median and as 'negative' if the score is below the median.

Male involvement: Regarding male involvement, the composite measure of male partner involvement in the Option B+ PMTCT programme was measured from the total number of correct answers to 10 questions that focus on the male partner's support of his wife, with a minimum score of 0 and maximum of 10. Involvement will be considered 'good' for those who scored >7, 'moderate' for those who scored 4–6, and 'low' for those who scored <3 to the questions on male partner support (18).

4.11. Operational definitions

Adherence behavioral skill: in this study refers to the actions and activities that the women were engaged after having had well informed & motivated to act on the clinical characteristics of the illness as noted in the conceptual model of the study.

OptionB+ women: all Pregnant HIV positive women who were taking lifelong triple ARV (TDF + 3TC +EFV) in the health institutions for PMTCT regardless of *CD4 coun*t, WHO clinical stage or gestational age.

4.12. Data processing and analysis

Data were entered into Epi-Data Statistical software version 3.1, and exported to SPSS version 21 for analysis. Descriptive statistics such as frequencies, proportions, and means were carried out. Binary logistic regression was used to measure the strength of association between independent and dependent variable using odds ratio and 95% of confidence interval. Independent variables which show significant association with dependent variable were candidates for multiple logistic analyses using p-value (less than 0.25) as a cutoff point to see presence of statistical significance. Multiple logistic regression analysis was carried out to identify factors associated with adherence and P value <0.05 was considered as significant. Then outputs were presented using tables and graphs. Finally, the results were compared with available findings indifferent literatures.

4.13. Data quality assurance

The questions were prepared in English and then translated into the local language (Hadiyisa) and then translated back to English to assure the consistency of the questions. The questionnaire was pre-tested on 11 HIV-positive option B+ women in Shurmo HC, Fonko HC, Jawe HC and Achamo HC before the actual data collection to ensure the appropriateness of the content with regard to the questions, language, and organization. The data collectors who were from the same facility but not from PMTCT unit were trained (10 clinical nurses) and two public health officers (supervisors) for one day on the objective, data collection tools, and interview techniques. The supervisors used to check the questionnaires for completeness.

4.14. Ethical consideration

Ethical clearance was obtained from the Ethical Review Committee of Jimma University, College of health Sciences. Letters of permission were obtained from Hadiya Zone health department, woreda health office and from each respective health facilities. Informed consent was obtained from each study participant. All the information obtained from each study participant was coded and confidentiality was kept.

4.15. Dissemination and Utilization of Result

The findings of this study are being presented to Jimma University, College of health Sciences department of population & family health.

The findings will be disseminated to Hadiya zone health department and other stakeholders.

Publication on peer reviewed journal will be considered.

CHAPTER FIVE: RESULTS

5.1. Sociodemographic and economic characteristics of the study participants

A total of 202 HIV positive pregnant mothers were included in the study making the response rate to 94%. i.e. 13 women did not participate in the study for different reasons. The mean age of the respondents was 29.4 years with standard deviation of 4.3. The majority were urban residents (53%) and Orthodox Christians (46%). 55.4% did not have a job – they were limited to indoor activities. Regarding educational status, 58 (28.7%) women were illiterate. With regard to the length of the journey to reach the health facilities for PMTCT services, 58.4% of the women used to walk for less than 1 hour. 93.6% of the respondents earned a monthly income of less than 1000 Ethiopian Birr. Friends, health personnel, Kebele meeting, neighbors and Radio/TV were the source of information for 33.2, 98, 24.3, 21.8 and 34.7 percent of the women respectively.

Table1. Sociodemographic and economic characteristics of women under Option B+ PMTCT care and support in health facilities of Hadiya zone, Southern Ethiopia (n=202)

Variables	Number (*N* = 202)	Percentage
Age, years		
20-24	23	11.4
25-29	95	47
30-34	56	27.7
35-39	28	13.9
Place of residence		
Urban	107	53
Rural	95	47
Religion		
Orthodox	93	46
Muslim	37	18.3
Catholic	7	3.5
Protestant	65	32.2
Ethnicity of the mother		
Hadiya	102	50.5
Kembata	23	11.4
Gurage	27	13.4
Silte	16	7.9
Amhara	23	11.4
Others	11	5.4
Educational status		
No education	58	28.7
primary(1-8)	89	44.1
secondary(9-12) or beyond	55	25.2
Occupational status		
house wife	112	55.4
Business	34	16.8

Salaried	6	3.0
daily laborer	50	24.8
Average time taken in hours to reach to your PMTCT site		
less than 1 hour	118	58.4
greater or equal to 1 hour	84	41.6
house hold earning estimated in birr per month		
<700	132	65.3
≥700	70	34.7

5.2. Clinical characteristics of the study participants

At the start of ART, 123(60.9%) of the respondents were in WHO clinical stage 1. The majority of respondents started New HAART regimen (tenofovir, lamivudine, and efavirenz; TDF–3TC–EFV) immediately after testing for HIV. Concerning the CD4 count, 131 (64.9%) of the respondents had a CD4 count of at least 500 cells/mm^3. Nearly 53.5% of the women had received their ARV medication at PMTCT centers and the remaining women had received treatment at ART clinics even if in areas where there were separate clinics for PMTCT care and support. Regarding adherence counseling, 91.6% of the respondents were counseled about disclosure while they received the drugs. Almost 41.1% of the women had attended antenatal care (ANC) at least two times and 89.6% of ANC attendant had not missed any of the visits.

One hundred fifty five (76.7%) of the respondents had disclosed their HIV status to their partner. Of these, 52.9% of the women had disclosed their sero status after they started PMTCT care and support. The support from health professionals and mother support groups played a major role on the women to disclose their HIV status to their male partner. Consequently, 70.8% of the respondents got support from their partners**.** 35.6% of the women had used strategy to remember taking ARV medication. Of these 35% has used alarm.

Table2. Clinical characteristics by level of adherence among women under Option B+ in public health facilities of Hadiya zone, Southern Ethiopia (n=202)

Adherence level		
	Adherent	**Non adherent**
Variables	**n (%)**	**n (%)**
WHO category at admission		
Stage 1	110(89.4)	13**(**10.6%)
Stage 2,3&4	59(83%)	12(17%)
Type of the regimen		
New HAART regimen (TDF- 3TC- EVF)	160(84.7%)	29(15.3)
Non TDF- 3TC- EVF HAART regimen	9(69.2%)	4(30.8%)
CD4 count at admission (cells/mm3)		
less than 200	7(58.3%)	5(41.7%)
200- 249	6(66.7%)	3(33.3%)
350- 499	38(76.0%)	12(24.0%)
greater or equal to 500	118(90.1%)	13(9.9)
Where the mother is receiving her ARV medication		
At PMTCT center	93(86.1%)	15(13.9%)
At ART clinic	76(80.9%)	18(19.1%)
Counseled on side effects		
Yes	159(88.8%)	20(11.2%)
No	10(43.5%)	13(56.5%)
ANC visits		

One	19(73.1%)	7(26.9%)
Two	71(85.5%)	12(14.5%)
Three	61(83.6%)	12(16.4%)
Four	14(90.0%)	6(10.0%)
Gestational age during the study (weeks)		
less or equal to 12	13(78.9%)	6(21.1%)
13-28	62(84.9%)	11(15.1%)
greater than 28	92(83.6%)	18(16.4%)
HIV disclosure to partner		
Yes	144(92.9%)	11(7.1)
No	25(53.2%)	22(46.8%)
The time the women is disclosing her HIV/AIDS status to her partner		
Before	65(87.8%)	9(12.2%)
After	77(90.6%0	6(9.40
How the women has disclosed her HIV/AIDS status to her		
her own decision	10(55.5%)	8(44.5%)
by health professional support	76(91.6%)	7(8.4%)
MSG (Mother Support Group)	50(89.2%)	6(11.8%)
Receipt of partner support		
Yes	131(94.9%)	7(5.1%)
No	14(75.0%)	6(25.0%)
Any strategy the women is using to remember taking ARV medication		
Yes	67(93.1%)	5(6.9)
No	102(78.5%)	28(21.5%)

5.3. Knowledge, attitude and Male partner involvement

5.3.1. Knowledge

Majority of the respondents, (94.6%), perceived that HIV infected pregnant women can transmit HIV to her unborn baby. In addition, they believe that it is possible to reduce the risk HIV transmission to the baby if she takes PMTCT drugs. More than half of the women (54%) were aware that missing ARV drugs has negative effects on prevention of HIV transmission from mother to child. On the other hand, 92.1% of the respondents believed that good adherence could reduce the risk of opportunistic infections.

In summary**,** the composite measure of knowledge among HIV positive pregnant women showed that 59.9% (121), 21.3% (43) and 18.8% (38) had higher, moderate and lower knowledge on Option B+ PMTCT, respectively**.**

Table3. Knowledge questions and responses regarding Option B+ PMTCT among HIV positive pregnant mothers in Public of Hadiya zone, Southern Ethiopia (n=202)

Characteristics	True n (%)	False n (%)
Condom use can prevent HIV transmission during sex with an HIV infected partner.	125(61.9)	77(38.1)
Sero positive women can transmit HIV to their babies during pregnancy.	191(94.6)	11(5.4)
HIV positive women can reduce the risk of HIV transmission to their babies if they take PMTCT drugs.	193(95.5)	9(4.5)
Missing to take some drugs of PMTCT has no effect on the effectiveness of PMTCT care and support.	93(46)	109(54)
Adhering to ARV drugs can reduce the risk of opportunistic infections	186(92.1)	16(7.9)
Male partners' support during PMTCT care does not have any effect on mothers to adhere to PMTCT drugs	59(29.2)	143(70.8)

5.3.2. Attitude

The composite measure of attitude among HIV positive pregnant women showed that 191(94.6%) and 11(5.4%) of the respondents had positive and negative attitude towards Option B+ PMTCT care and support respectively.

Table 4. attitude questions and responses regarding Option B+ PMTCT among HIV positive pregnant mothers in Public facilities of Hadiya zone, Southern Ethiopia (n=202)

Variable	Agree n (%)	Disagree n (%)
It is tiresome to take PMTCT drugs every day	46(22.8)	156(77.2)
Taking PMTCT drugs benefits not only to the mother but also to the babies.	191(94.6)	11(5.4)
Starting ART treatment earlier can help to improve quality of life and survival of the mother	197(97.5)	5(2.5)
Involving male partner in care and support increases effectiveness of PMTCT services	184(91.1)	18(8.9)
I don't like to give birth taking PMTCT drugs	58(28.7)	144(71.3)
I don't recommend to have sex without condom regardless of the HIV status of partner	173(85.6)	29(14.4)

5.3.3. Male partner involvement

Regarding to male partner involvement in PMTCT care and support, 150(74.5%) of their partners participated in decision making. Half of the women discussed on use of condom with their partner and only 20(9.9%) of the women had visited their option B+ PMTCT site with their partner. As an indicator to the partners support, 18.8%, 48% and 61.4% of them knew the name of the ARV, dosage and frequency of regimen, respectively. Over seventy five percent (75.2%) of the women also received financial support from their partner. In addition, 114(51.3%) used to discuss with their wives on the advantage of ANC and 129(63.9%) knew and remind the appointment date for ANC and 40(19.8%) of the partners had accompanied their wives to ANC.

In summary the composite measure of male involvement in PMTCT services showed that 73 (36.1%) of respondents had lower male involvement on PMTCT care and support; yet, 40 (19.8%) and 89(44.1%) had higher and moderate male involvement, respectively

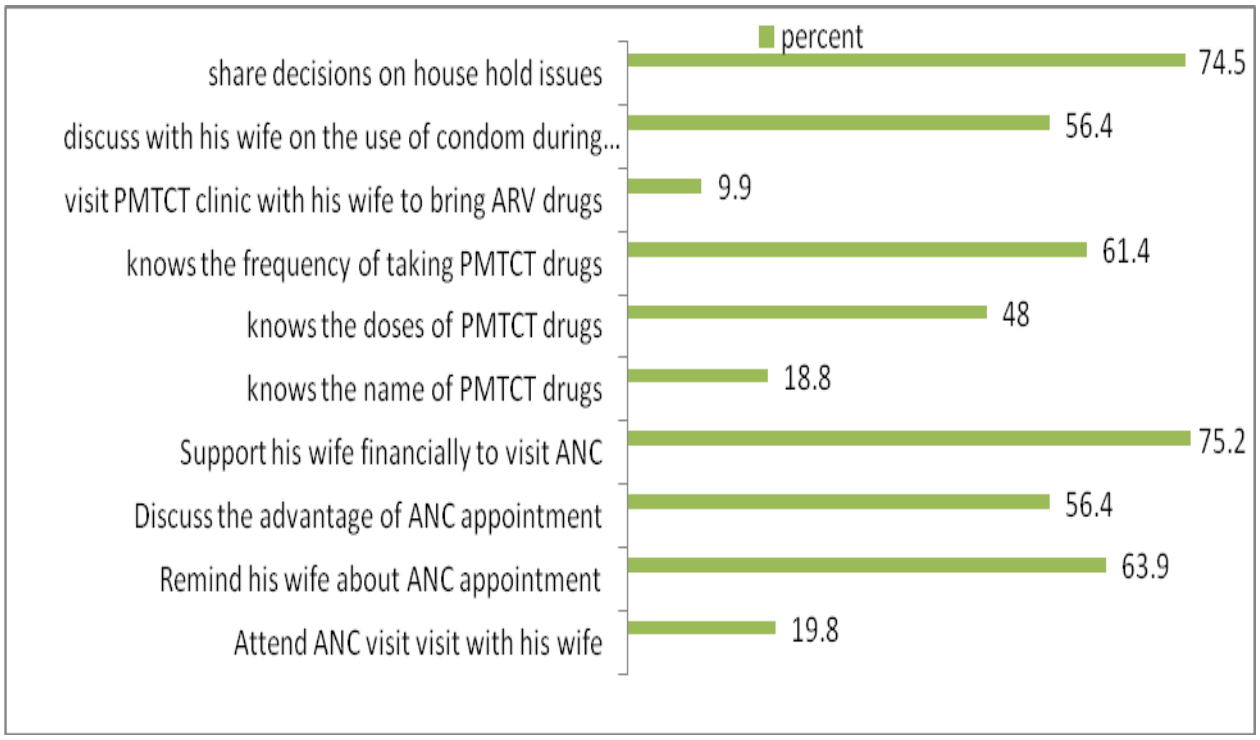


Figure 3: Percentage respondents who had male involvement to adherence of HIV positive pregnant women to option B+ PMTCT care and support in Hadiya zone, 2016.

4.16. Adherence to Option B+ PMTCT drugs

Overall, 83.7% (95 % CI: 78.3, 88.6) of the respondents were adherent to Option B+ PMTCT drugs. The frequently mentioned reasons to non-adherence were inability to remember the time for taking drugs. This study showed that 33 (16.3%) of the respondents were non-adherent to Option B+ PMTCT care and support. Out of these non-adherent respondents, 26(78.8%) of them had missed their ARV medication within the last three days prior to the study. Among the reasons to miss their Option B+ PMTCT ARVs, forgetting to take medications (53.8%) was the dominant obstacle for adherence followed by the fear of side effects (23.1), non disclosure (15.4) and travelled away (7.7).

Table5. **Reasons to non-adherence to Option B+ PMTCT among HIV positive pregnant women in Public facilities of Hadiya zone, Southern Ethiopia, 2016**

Reason for non adherence	Frequency	Percent
Difficult to remember	27	81.8
Feeling better	5	15.1
Missing the medication	26	78.9
Feeling worse	0	0

Table6. Binary and Multiple logistic regression analysis of predictors of adherence to Option B+ PMTCT among HIV positive pregnant women in Public facilities of Hadiya zone, Southern Ethiopia

Adherence				
	Adhered	**Non-Adhered**	**Crude OR**	**Adjusted OR**
Characteristics	**# (%)**	**# (%)**	**(95% CI)**	**(95% CI)**
WHO clinical Stage				
Stage1	110(89.4)	13(10.6)	2.86(1.33, 6.17)	0.17(0.02,1.25)
Stage 2 or 3 or 4	59(74.7)	20(25.3)	1	
Type of regimen				
New regimen	160(84.6)	29(15.4)	2.45(0.7, 8.49)	1.87(0.30,11.51)
Non new regimen	9(69.2)	4(30.8)	1	
CD4 count (cells/mm3)				
>500	118(90.0)	13(10.0)	3.56(1.64, 7.7)	1.19(0.23,6.18)
<500	51(71.8)	20(28.2)	1	
Counseled on side effect				
Yes	159(94.1)	10(5.9)	10.33(4.01,26.63)	7.2 (2.2,22.8)*
No	20(60.6)	13(39.4)	1	

Counseled on HIV Status disclosure				
Yes	161(87.0)	24(13.0)	7.54(2.65,21.44)	0.55(0.07,4.07)
No	8(47.1)	9(52.9)	1	
HIV Status disclosure				
yes	144(92.9)	11(7.1)	11.52(4.97,26.66)	3.09 (1.04, 9.1)*
No	25(53.2)	22(46.8)	1	
Knowledge on Option B+ PMTCT				
High	109(90.1)	12(7.9)	0.44(0.15,1.21)	0.34(0.11,1.03)
Moderate	35(81.4)	8(8.6)	0.21(0.08,0.51)	0.54(0.15,1.96)
Low	25(65.8)	13(34.2)	1	
Male partner involvement				
High	80(89.9)	9(10.1)	2.4(0.37,0.46)	0.28 (0.06,0.12)*
Moderate	29(72.5)	11(27.5)	1.6(0.08,0.16)	0.08(0.01,0.42)
Low	45(61.6)	28(38.2)	1	

4.17. Factors associated with adherence to Option B+ PMTCT drugs

The results of the multivariable logistic regression analysis showed that mothers who were counseled on the side effects of ARV medications had 7.2 times higher odds (aOR 7.2, 95% CI 2.2,22.8) of adhering to Option B+ PMTCT care and support as compared to those who were not counseled properly. Disclosing their HIV status to their partner was also positively associated with good adherence (aOR 3.09, 95% CI 1.04, 9.1). HIV positive pregnant women with good partner involvement in PMTCT care and support had 72% more likely to be adherent to PMTCT (aOR=0.28; 95% CI: 0.06 and 0.12).

CHAPTER 6: DISCUSSION

The overall level of adherence to Option B+ PMTCT care and support was 83.7% (95 % CI: 78.3, 88.6). The main factors affecting adherence for the women included in this study were proper counseling on the side effects of the drugs during PMTCT drug provision, disclosing their HIV status to their partner and HIV positive pregnant women with good partner involvement in PMTCT care and support.

In this study, 83.7% (95 % CI: 78.3, 88.6) of the HIV-positive pregnant women were adherent to Option B+ PMTCT care and support. These results is consistent with the study done in Tigray, Ethiopia where 87.1% (95 % CI: 82.6, 90.7) of the respondents were adherent to option B+ PMTCT (38). This may be due to rapid expansion and scale up of option B+ program at national level. This percentage is slightly lower than that reported from a study conducted in Bwaila Hospital, Malawi (91%) (30). The discrepancy in the results may be attributable to the quality of data used for assessing the level of adherence. In the Malawi study, the researchers used the pill count from the electronic medical record system; in this study the method is self report and may account for the difference in adherence level.

When compared to studies done in other countries of Sub-Saharan Africa, the adherence level in this study is slightly higher than those reported from Nnewi in Nigeria (78.3%), Lagos in Nigeria (80.6%), and Kisumu in Kenya (82%), but lower than that reported from western Kenya (89%) (31,32,33 &34). This may reflect differences in the PMTCT option used, as most of these studies focused on Option A PMTCT; Option A is a different strategy for PMTCT care and support to Option B+. This difference could have had an effect on the adherence level, as the latter may be considered a simplified option. However, the finding in this study shows a lower adherence level as compared to that reported in a study carried out in Addis Ababa, Ethiopia (40). This discrepancy may have resulted from differences in awareness, educational level of the women, and better access to infrastructure and better partner involvement in PMTCT care and support in Addis Ababa than in this study.

In this study 76.7% (95% CI: 70.3, 82.2) of the respondents had disclosed their HIV status to their partner. Statistically, disclosure status was significantly associated with adherence to Option B+ PMTCT care and support. These results is consistent with the study done in Tigray,

Ethiopia where 77.2% of the respondents had disclosed their HIV status to their partner and Statistically, disclosure status was significantly associated with adherence to Option B+ PMTCT care and support (38). But lower than in a study done in Addis Ababa, Ethiopia and Tanzania (36 &40). This difference may be due the better awareness and educational level of the women. Studies done in Nnewi in Nigeria, Lagos in Nigeria, and Ghana show that 88.3%, 86.5%, and 85.5% respectively, of the women had disclosed their HIV status to their partner and statistically, disclosure status was significantly associated with adherence to Option B+ PMTCT care and support (31,32 and 35).These percentages are slightly higher when compared to this study (76.7%). However, they are consistent with those of studies done in Addis Ababa and Tanzania (36 and 40). Disclosure of HIV status to their partner, the partner's involvement in HIV PMTCT, and counseling on ARV drugs had no significant association with adherence in the study done in Addis Ababa (41). Generally, HIV status disclosure is considered important in motivating the partner for VCT, reducing risky sexual behavior, increasing partner support & diminishing the transmission of HIV infection in HIV-negative male sexual partners (discordant couple), which is one of the additional benefits of Option B+ over options A and B (7).

In this study 19.8% of the women had received higher male involvement on PMTCT care and support and statistically, male partner's involvement was significantly associated with adherence to Option B+ PMTCT care and support. This percentage is slightly lower than that reported from a study conducted in Tigray, Ethiopia where 25% of the women had received higher male involvement (38). This difference may be due the better awareness of the women as well as her partner. The partner's involvement in option B+ PMTCT had no significant association with adherence in the study done in Tigray, Ethiopia (38).

Unlike to study in Nigeria (32), male involvement in PMTCT care and support in this study was higher. This could be attributable to the integrated community interventions including PMTCT services in Ethiopia through the aid of Health Extension Program. Male partner involvement was associated with adherence to PMTCT and this was consistent with a study done in Tanzania which indicates that women who disclosed their HIV status were significantly more adherent to prophylaxis in the pre-delivery period than women who did not (36). This association shows that male partners who get involved in PMTCT care and support could have better understanding and awareness towards the treatment. Hence, women who get psychological and financial support

would be more adherent to PMTCT. This finding implies that stakeholders should also focus on male partners to optimize the benefits of Option B+ PMTCT care and support.

Proper counseling on the side effects of ARV drugs was found to be a significant predictor of good adherence to Option B+ PMTCT. This association is consistent with the study done in Tigray, Ethiopia (38). Even though there are no other studies showing this relationship, this association is reasonable since women experiencing side effects of the ARV drugs are less likely to trust the treatment and adhere to it (41). Another study showed that women experiencing milder side effects such as skin rash or skin discolorations, fatigue, headache, and fever were more likely to adhere to Option B+ PMTCT drugs than those experiencing more severe side effects such as metabolic effects (central nervous system (CNS) toxicity, severe hepatic necrosis, and renal toxicity) (42). This is consistent with this study, in which the study participants who were counseled about their medication effect were more likely to adhere to Option B+ PMTCT care and support. This appears plausible since one of the drug regimens of Option B+ (TDF–3TC–EFV) has the potential to induce side effects of CNS toxicity like headache, strange dreams, and confusion; this is particularly due to efavirenz. The missed opportunity to counsel on the potential side effects of this regimen may have a negative impact on the mother's satisfaction with the medication.

This study showed that the majority of respondents (94.6%) perceived that MTCT of HIV/AIDS was possible and that 88.3% of the respondents were aware that it was possible to reduce the risk of infection in the baby if they took PMTCT drugs effectively. This is in agreement with the study conducted in Ghana (35).

A number of participants in the studies carried out in Nnewi, Nigeria (63.8%), Lagos, Nigeria (57.6%), and Addis Ababa health centers (20.8%) showed that the main reason reported by the non-adherent respondents for missing their drugs was forgetfulness (31,32&40). This study also showed a similar finding, forgetting when to take the ARV drugs was the most frequently mentioned reason for non-adherence (51.9%).

CHAPTER 7: LIMITATION OF THE STUDY

The researcher feels that this study has the following limitations that warrant mention:

As the study used cross-sectional design, it did not allow the researcher to establish a causal relationship between significantly associated variables and treatment adherence, as both variables were measured at the same time.

Since the study is also a cross-sectional study, it addresses the adherence during only the three days prior to the time when the study took place. But one should consider is that adherence behavior might vary among different patients at different times and on different days. Adherence is a dynamic process that changes over time with changing beliefs, attitudes, emotions, and daily and larger life events.

"Gold standard" for assessment of adherence does not exist, in this study adherence was measured using self-report; studies suggest that self-reported adherence measurements are known to increase adherence rates (54). This is due to Social desirability (projection of a positive image)

CHAPTER 8: CONCLUSION

The adherence level of mothers towards PMTCT care and support was 83.7%. Although this represents reasonably a good adherence level, it still indicates that a significant number of the women 33(16.7%) were poorly adherent to option B+ PMTCT drugs. This poses a serious threat because when ARV medications are taken intermittently, they develop an increasing inability to combat the HIV virus therefore, negates the efficacy of the ART regimen in the future. This obviously poses an enormous threat to the overall health status of individuals and of the community as a whole because the selection of ARV drugs that are available to patients in developing countries like Ethiopia, are very limited indeed. Health care professionals who administer ARV therefore need to take urgent action in order to improve the level of poor adherence among those who were non adherent to ARV medications.

Proper counseling on the side effects of PMTCT drugs, care and support, HIV status disclosure to partners and Male partner involvement were significant predictors of adherence to PMTCT. The result has positive implication in the prevention of HIV transmission which could be applied

in HIV control interventions in similar settings. The findings revealed the need for on-going informational, educational and communication interventions to address the knowledge, motivation and adherence behavioral skills of patients in order to improve the current levels of ART adherence behavior.

CHAPTER9: RECOMMENDATION

For health facilities:

The health professionals should periodically assess patient's medication adherence at every visit and intervene accordingly.

Encouraging the women to come along with a treatment supporter (partners) for the counseling sessions would help in educating the partners appropriately and improving adherence in the long run.

For FMOH, Regional health bureau and zonal health departments

Currently existing Information, Education and Communication (IEC) interventions on HIV/AIDS should be strengthened at individual and community levels in order to reduce non disclosure and increase partner support.

For researchers:

Since Option B+ continues life-long, there may be change in adherence over the course of treatment, including in the lactating period. So feature research should focus on lactating women.

It is important to state that self-report used to measure adherence is not the gold standard for adherence measurement. It is advisable for the feature researcher to use multiple tools.

The model, however, is characterized by a more individualistic approach: It is clear that poor adherence is also the result of factors outside the individual's control; other research should be conducted including therapy-related factors**,** health care system factors, provider factor and others.

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ANNEXES

English version questionnaire and consent form

Client Exit Interview Questionnaire on Adherence to care for HIV/AIDS Option B+ patients at Hadiya zone public hospitals & health centers.

Date of interview----------

Time at the beginning of the interview----------

Introduction: Hello, Madam. My name is ----------. I am conducting a study among clients who come to the health facility about the level & factors that influence adherence to option B+ PMTCT drugs. The information collected will help the health institution to improve the quality of ART adherence counseling it provides to this health institution and elsewhere.

Confidentiality and informed consent statement: I am going to ask you questions about your adherence to option B+ PMTCT drugs. Your name will not appear on this questionnaire and all the information you provide to me will remain strictly confidential. You are not obliged to answer any questions that you feel uncomfortable with and you can put an end to this interview at any time, if you wish to do so. Your participation in this study does not involve any direct risk or benefit to you but is very important because your answers, as well as those of other participants will help to improve the services offered to you in this health sector and elsewhere.

Would you like to participate in the study? 1. Yes 2. No

Data collector: If the answer is "Yes", please let the participant sign below to certify that the client gave her consent to take part in the survey. Otherwise, thank the client, conclude the conversation and file the questionnaire.

Signature of the participant----------

Part one: Socio-demographic Data

1. Age(in completed years) of the mother----------
2. Place of residence? 1. Urban 2. Rural
3. Religion 1. Orthodox 2. Muslim 3. Catholic 4. Protestant 5. Others
4. Ethnicity 1. Hadiya 2. Kembata 3. Gurage 4. Silte 5. Amhara 6. Others
5. Educational status of the women. 1. No education
   2. Primary (1-8)
   3. Secondary (9-12)
   4. College or beyond
6. Occupational status of the women 1. House wife
   2. Business
   3. Salaried
   4. Daily laborer
   5. Farmer
7. What is the average time taken in hours to reach to your PMTCT site? ----------
8. What is your household earning estimated in Birr per month? (by ethi.birr)----------
9. What is your source of Information about option B+ PMTCT?(multiple answer possible)
   1. Friends
   2. Health personnel
   3. Kebele meeting
   4. Neighbors
   5. Radio/TV
   6. others

Part two: adherence behavioral skills & clinical characteristics

10. What is the WHO clinical stage when you start ART?
    1. Stage1 2. Stage 2 3. Stage 3 4. Stage 4
11. Immediately after testing for HIV/AIDS & known to have HIV/AIDS, in which regimen you are? 1. New HAART regimen (TDF- 3TC- EVF)
    2. Non (TDF- 3TC- EVF) HAART regimen
12. What is the CD4 cell level at admission? ----------

13. Where do you receive your ARV medication?

    1. At PMTCT center 2. At ART clinic

14. Have you got adherence counseling? 1. Yes 2. No

15. If yes to the question number 21, on what issues were you counseled?(tick all possible)

    1. about adherence (dose, schedule)
    2. about side effects
    3. about how ARV works
    4. about disclosure
    5. about risk reduction
    6. Others

16. How many visits did you attend at ANC unit? 1. One 2. Two 3. Three 4. Four & above

17. Have you ever missed any of your ANC visit? 1. Yes 2. No

18. What is your gestational age in completed weeks? ----------

19. Have you disclosed your HIV/AIDS status to your partner? 1. Yes 2. No

20. If yes to the question number 23, when? 1. Before I start PMTCT care & support
    2. After I start PMTCT care & support

21. Why did you disclose your HIV/AIDS status to your partner?

    1. It is my decision
    2. by health professional support
    3. MSG (Mother Support Group)
    4. Others

22. Have you got support from your partner? 1. Yes 2. No

23. Do you use any strategy to remember taking ARV medication? 1. Yes 2. No

24. If yes, which one? 1. Pill box 2. Alarm 3. Reminder note 4. date books

25. Have you every missed your medication with in the previous 3 days 1. Yes 2. No

26. If yes, what is the reason for missing

    1. Forgetfulness 2. Fear of side effect 3. Travelled away 4. Transport cost 6. Very seek/weak 7. Healthy looking 8. Non disclosure 9. Religious believe

Part Three: Adherence Information Assessment Questions

27. Please answer to the following 6 knowledge assessment questions towards Option B+ PMTCT care & support by responding (True or False).
    a. Condom use can prevent HIV transmission during sex With an HIV infected partner.
    b. Sero positive women can transmit HIV to their babies during pregnancy.
    c. HIV positive women can reduce the risk of HIV transmission to their babies if they take PMTCT drugs.
    d. Missing to take some drugs of PMTCT has no effect on the effectiveness of PMTCT care and support.
    e. Adhering to ARV drugs can reduce the risk of opportunistic infections.
    f. Male partners' support during PMTCT care does not have any effect on mothers to adhere to PMTCT drugs

Part Four: Personal & Social Motivation Assessment Questions

28. Please answer to the following 6 attitude assessment questions towards Option B+ PMTCT care & support by responding (Agree, disagree).
    a. It is tiresome to take PMTCT drugs every day.
    b. Taking PMTCT drugs benefits not only to the mother but also to the babies.
    c. Starting ART treatment earlier can help to improve quality of life and survival of the mother.
    d. Involving male partner in care and support increases effectiveness of PMTCT services.
    e. I don't like to give birth taking PMTCT drugs.
    f. I don't recommend to have sex without condom regardless of the HIV status of partner.
29. Please answer to the following 10 male involvements activities in Option B+ PMTCT care and support among HIV positive pregnant women by responding **(Yes or No).**
    a. Does your partner attend ANC visit with you?
    b. Does your partner remind you about your ANC appointment?

c. Does your partner discuss with you about the advantage of your ANC appointment?
d. Does your partner supports you financially to visit ANC?
e. Does your partner know the name of your PMTCT drugs?
f. Does your partner know the doses of your PMTCT drugs?
g. Does your partner know the frequency of taking your PMTCT drugs?
h. Does your partner visit PMTCT clinic with you to bring ARV drugs?
i. Does your partner discuss with you on the use of condom during sex?
j. Do your partner share decisions on house hold issues?

Part five: Adherence level measurement questions

30. Please respond to the four adherence level measurement questions

Treatment was initiated on /---------- / Duration of treatment Months/years----------

Begin by telling the patient that, "Most people with HIV have many pills to take at different times during Begin the day. Many people find it hard to always remember to take their pills. It is important for me to understand how you are really doing with your medicine. Don't worry about telling me if you don't always take all your doses. I need to know what is really happening, not what you think I want to hear."

Clients tend to answer yes to questions posed to them by their health care provider to please them. Based upon this observation, the questions have been designed so that adherent Client gives a no response.

Self-Reporting

Please mark the client's response to the following questions.

Question

A. Do you sometimes find it difficult to remember to take your medication? 1. Yes 2. No

B. When you feel better, do you sometimes take a break from your medication? 1. Yes 2. No

C. Thinking back over the past three days, have you missed any of your doses? 1. Yes 2. No

D. Sometimes if you feel worse when you take the medicine, do you stop taking it? 1. Yes 2.No

Time at the end of the interview----------

Hadiyyis Tamichchaa

Hadiyy zoon fayya'oom mininne HIV/AIDS lamfoor amaansi ciilanne higoobee, issa awwaaxoo ammo'ina gudu xammichcha.

Balla----------

Tammichchi asheeru ammanni----------

I summi----------yamamoommo. Hadiyy zoon fayya'oom mininne HIV/AIDS lamfoor amaansi ciilanne higoobee'issa awwaaxoo ammo'onne qaraare massamoo'isannee, massameena hooro luwwanne tinaato issoommulla. Kiniinse siidoom sawwit fayya'oom min kinnuwinna uwwoo awwaado axissoo'isinna haramookko.

Kabade qaraare hinkid awaaxiitooda'e xammoommo. Ki summi ka xammichchanne kitaabammooyyo. Kiiniinse siidoom sawwitem ayenam la'issoommoyyo. Xammichcha dabarimimmi, dabarimma urimimm, lambe'enne uulissimm ayyi ammanemi xanammookko. Xammichchoom keesenne matem hawojamm afisooyyo.

Xammichcha dabateenna hassaa? 1. Hassaammo 2. Hassummoyyo

Farammehe----------

Luxxi baxxanchcha

1. Umur mee'oo? ----------
2. Heechchi beeyyi 1. Beeroo'o 2. Haxxi uulla
3. Ammannat 1. Ortodoksa 2. Mosliimma 3. Kaatooliika 4. Protestaanta 5. Muleki----------
4. Giirii giichchii 1. Hadiyya 2. Kambaata 3. Guraage'e 4. silte'e 5. Amhara 6. Mulek
5. Mine issimm 1. Aagiisummoyyo 2. Aagiissaammo 3. Annanniniihaammo 4. Lehaakko 5. Fatakkaammo
6. Losan 1. Maham losummoyyo 2. Luxxi gaballa (1-8) 3. La'mmi gabala (9-12) 4. Koleeja te'im hanaann
7. Baxxi 1. Mi'nn amma 2. Nagaade'ee 3. Adii'l baxaancho 4. Balli baxxaanchotte 5. Abuulaanchotte
8. Fayya'oom minna affeena mee'ii sa'aata massoo? ----------
9. Ki aga'nni aagoo'i mee'ii biira? ----------
10. Losano hannii siidootto? 1. Beshiinse 2. Fayya'oommi baxaanii 3. Kabale'iinse 4. Hegeegiinse 5. Radooniinse/televeghiina

La'mmi baxxanchcha

Qaraare masimm duuha'anne gudukki xamichcha

11. Qaraare asheetitok hinka WHO qooxxoo'onnete? 1. Qooxo'i 1 2. Qooxoo'i 3. Qooxo'i 3 4. Qooxo'i 4
12. Xiiqqi mirmara isitaa lasage HIV/AIDS ki orachchonne yoo'isa laqitosam hinka qaraare asheetito? 1. TDF- 3TC- EVF 2. Mulanne
13. CD4 foochchillichcha'i mee'oo? ----------
14. Kabade HIV/AIDS googinne haramammaa waaroo jabbuw hee'aa? 1. Yookko 2. Bee'ee
15. Kabade qaraare hanonette masitootoki? 1. Lamfoor amo'i mirma'l minenee 2. HIV/AIDS qaraa'l minenne
16. Qaraare ogooraamisa masi'm bikinna sogitano siida heelitto? 1. Siidaammo 2. Siidummoyyo

17. Tammichch 17, mati ihulas, mahi bikkinna sogitano siiditto? 1. Qaraare hinkid masakkamisa 2. Qaraa.l hawoji bikkinna 3. AIDS qaraar hinkid baxooda'e 4. Mi.n annina mirma'l wuxeeta la'ishsh bikinna 5. Gaga egellakamisinna 6. Mulek----------
18. Lam foorii amo'i kititila mee'i kore issittaa? 1. Mataa 2. Lamaa 3. Sassaa 4. Sooraagee sooraagi hanaannii
19. Lam foo'l mirmara higisiamman hee'aa? 1. Yookko 2. Bee'e
20. Lamfooroom mee'ii agana? ----------
21. Ki xii'q mirmara ki min anninana la'issaa? 1. La'isaammo 2. La'isummoyyo
22. La'isitti las kinkammane? 1. Lam foor amo'i mirmara isseena illage 2. Lam foor amo'i mirmara isseena illage
23. La'isitt mashkka'i maruchcho? 1. Igaginem 2. Fayya'oom baxaan haramattinne 3. Amo'i haramatinne 4. Mulekki----------
24. Ki min annii haramato siidaa? 1. Siidaammo 2. Siidummoyyo
25. Qaraare masitoo ammanne sawisiisso luwwa awaaxittoo? 1. Awaaxoomo 2. Awaaxoomoyyo
26. Awaaxi'tlas hinkanne? ----------
27. Higukki sas ballanne qaraare masimma xadaaheelitonihe? 1. Xadaammo 2. Xadumuyyo
28. Xadittilas mashkka'I maha? 1. Xadaatette 2. Hawojja baddaa 3. Qeelli googo maraa 4. Tiraanspoorta hoogaa 5. Ihoo sogitanno hoogaa 6. Xisaa 7. Faya'i ihummi bikkinna 8. Min anninna kurummi bee'ii bikkina 9. Ammanati hooroo bikkinna

Sa'xxi Baxxanchcha

29. Kannii woroon yoo lachchi xammichchuwinna hanqa te'im qophphano yitaa dabare
    a. Kondom HIV/AIDS shayyi'x edanchchine higoo bee'issa haramookko.
    b. HIV/AIDS ise woronne yoo lamfoor ama ciilinam higisammo.
    c. HIV/AIDS ise woronne yoo lamfoor ama ciilina higisambee'isa qaraare masim haramookko.
    d. Qaraare mati mati amanne higisakka'a masim matem hawom eebooyyo.
    e. Qaraare danaamisa masim HIV/AIDS googinne haramammaa waroo jabuwiins egerookko.

f. Ki mi’n anni harramati kiina qaraaree danaamisa masim bikkinna maham awaadoo uwooyyo.

Soo’lli Baxxanchcha

30. Kanni woroon yoo sawi’xx gaba’ll xamichchuwwa awoonoommoo awonoommoyyoo yituuyyi dabare.
    a. AIDs qaraare hund ammanem massim hoogisookko.
    b. AIDs qaraare hund ammanem massim aman xale’i ihoon ciillinam harammookko.
    c. Qaraare eri ammanem gaasakka’a masimm lobi umuri hee’oo’isinnaa eri heechcha hee’akkamisinnaa haraamookko.
    d. AIDS qaraare masumuuyyi qarimma hasoommoyyo.
    e. Mi’n anno’i harammati araq awwaado uwookko.
    f. Shaayi’x edanch ammanne, AIDS hee’ukkom bee’ukkom kondomma awaaxi’mm eranne.
31. Kannii woroon yoo mi’n anni haramati xamichchuwina hanqa te’im qophphanno yittaa dabare.
    a. Ki mi’n anni lamfoo’l mirmara kiininem maroo?
    b. Ki mi’n anni lam foo’l mirma’l balla sawaa’issoo?
    c. Ki mi’n anninne lam foor mirma’l bikkinna atooratakkammo?
    d. Ki mi’n anni keese lam foo’l mirmarinna matonna diinatinne haraammoo?
    e. Ki mi’n anni ati masitoo qaraare la’oo?
    f. Ki mi’n anni ati masitoo qaraare hinkaana maasitooda’e la’oo?
    g. Ki mi’n anni ati masitoo qaraare hinkammane masitooda’e la’oo?
    h. Ki mi’n anni fayya’oom mine kiininnem qaraare eebiminna maroo?
    i. Ki mi’n anni kiininne shaayyi’x edanchch ammanne kondomma awaaxim bikkinna atoorasoo?
    j. Ki mi’n anni kiininne mi’n woro’lli sawitenne iitammoo?

Ontti Baxxanchcha

32. Kannii worooni yoo qaraare masimm xammichchuwa dabare

a. Matimati ammanne qaraare masimm ammanne sawimm hoogaa laqqoo?

1. La’oommo 2. La’oomoyyo

b. Orachchi elloo ammane, matimataage qaraare masitoonni uttoo?

1. Uroommo 2. Uroomoyyo

c. Higu sasi ballane, qaraare masiitoon uttiti balli hee’aa?

1. Yookko 2. Bee’ee

d. Matimati ammanne qaraare masittaa xissi baasoohaare qaraare massimma uullissoo?

1. Uulliisoommo 2. Uullisoomoyyo

Declaration

Assurance of Principal Investigator:

I, the undersigned, agree to accept responsibility for the scientific Ethical and technical conduct the research project and for provision of required progress reports as per terms and conditions the health sciences in effect at the time of grant are forwarded the result of this application.

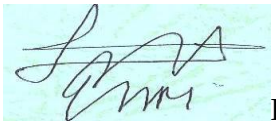
Name of the student_____

Date_____ Signature _____

Approval of the advisors:

This thesis has been submitted with my approval as University advisor.

Name of the first advisor: *Dr.Beyene Wondafrash*

Signature  Date:*June 20/2016*

Name of the second advisor: _____

Signature _____Date _____

Date of submission: _____