Assessment of effectiveness of prevention of mother to child transmission of human immunodeficiency virus in Asella teaching and referral hospital, College of Health Sciences, Aris University: Ethiopia.

By: Mama Abdula (B.Pharm)

A thesis submitted to the Department of Pharmacology and Clinical Pharmacy School of Pharmacy in partial fulfillment of the requirements for the degree of Master of Pharmacy in pharmacy practice (M.Pharm).

Addis Ababa University, Ethiopia

December, 2015

Addis Ababa University

School of Graduate Studies

This is to certify that the thesis prepared by Mama Abdula entitled "Assessment of effectiveness of prevention of mother to child transmission of human immunodeficiency virus in Asella teaching and referral hospital, College of Health Sciences, Aris University: Ethiopia" and submitted in partial fulfillment of the requirements for the Degree of Master of Pharmacy in Pharmacy practice complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

Signed by the Examining Committee:

Name	Signature	Date
Dr. Eskinder Kebede (External examiner)	_____	_____
Dr. Ephrem Engidawork (Internal examiner)	_____	_____
Dr. Workineh Shibeshi (Advisor)	_____	_____
Dr. Tilahun Zeleke (Advisor)	_____	_____

_____

Chair of Department

Abstract

Assessment of effectiveness of prevention of mother to child transmission of human immunodeficiency virus in Asella teaching and referral hospital, College of Health Sciences, Aris University: Ethiopia.

Mama Abdula

Addis Ababa University, 2015

Effective prevention of mother to child transmission (PMTCT) of HIV programme can reduce mother to child transmission (MTCT) of HIV from 20-45% to < 2%. This study was aimed to assess effectiveness of PMTCT programs through determination of the outcome of HIV exposed infants at Asella teaching and referral hospital from February 2012-2015. A retrospective cross sectional study design was conducted. Mother-infant pairs HIV status was obtained from medical records using structured questionnaires and entered into EPI info version 3.5.1 and analyzed by statistical package for social science version 21. Bivariate and Multivariate logistic regression analysis was employed to see the effect of each independent variable on the outcome variable and to control the effect of confounding. The majority 93.1% mothers and 98 (75.4%) infants received antiretroviral (ARV) prophylaxes. About 24.6% infants were not receiving ARV prophylaxes. Only 19.2% infants were tested before six weeks using deoxyribonucleic acid-polymerase chain reaction (DNA/PCR). Infant HIV infection rate was 3.1%, 3.8%, and 7.7% at 6 weeks, 6 months and overall 18 months respectively. Mothers illness during pregnancy (Adjusted odds ratio (AOR) = 20.4), mothers failure to receive antiretroviral therapy during pregnancy/breast feeding (AOR= 17.2), home delivery (AOR= 8.0), infant birth weight (AOR= 2.7) and mixed infant feeding (AOR= 2.0) were the factors that affected HIV free survival in this study. In conclusion this study showed that 92.3% of the infants were having HIV free survival at 18 months. PMTCT intervention uptake with specific reference to ARV usage for PMTCT shows higher uptake in mothers than in infants. However, the uptake of ARVs in infants falls below targets required for eMTCT of HIV, and the targets set in the Ethiopian national strategic plan for eMTCT of HIV <5% by 2015.

Key Word: MTCT, PMTCT, Effectiveness, HIV exposed infants

Acknowledgements

First of all, I am deeply grateful to my advisor, Dr. Workineh Shibeshi for his relevant, timely, and constructive comments and guidance during the entire research process, and Dr. Tilahun Zeleke for his encouragement and advices, Dr. Ephrem Engidawork for his guidance during questionnaire development.

Special thanks to the staff of Asella teaching and referral hospital, College of health sciences, Aris University, ANC and ART clinics.

I would like to thank graduate program of Addis Ababa University for funding this study. And I acknowledge Arsi University for sponsoring me to join masters program at Addis Ababa University.

Last but not least, I would like to thank all my family, my wife, sons and my daughters, and all those I have not mentioned, you are all there in my heart.

Thank you all for your wonderful support. May Allah forever remember you all for the good you have done in my life.

Table of contents

List of abbreviations

3TC	Lamivudine
AIDS	Acquired immune deficiency syndrome
ANC	Antenatal care
AOR	Adjusted odds ratio
ART	Antiretroviral therapy
ARV	Antiretroviral drugs
AZT	Zidovudine
CD_4	Cluster of differentiation 4
CI	Confidence interval
COR	Crude odds ratio
DBS	Dried blood spot test
DNA-PCR	Deoxyribonucleic acid-polymerase chain reaction test
EBF	Exclusive breastfed
EFV	Efavirenz
eMTCT	Elimination of mother to child transmission of HIV
FDRE-MOH	Federal democratic republic of Ethiopia Ministry of Health
FMOH	Federal Ministry of Health
HAART	Highly active antiretroviral therapy
HIV	Human immunodeficiency virus
MNCH	Maternal newborn child health
MoHSW	Ministry of health and social welfare Tanzania
MTCT	Mother to child transmission of HIV
NVP	Nevirapine
PCR	Polymerase chain reaction
PMTCT	Prevention of mother to child transmission of HIV
Sd-NVP	Single dose Nevirapine
TDF	Tenofovir
UNAIDS	United Nations programme on AIDS
UNICEF	United Nations Children's Fund
WHO	World Health Organization

List of Figures

List of Tables

1. Introduction

1.1Background

The 2012 United Nations programme on acquired immune deficiency syndrome (UNAIDS) global report indicates that approximately 69% of the estimated 34 million adults and children living with HIV were from sub Saharan Africa (23.5 million). In sub Saharan Africa, women now account for almost 60% (12.1 million of 20.3 million) of the adults living with human immunodeficiency virus (1). Of these, 3.4 million are children under 15 years of age, 90% of whom live in sub Saharan Africa (1, 2), and most of the new infections were transmitted heterosexually (3). Mother to child transmission of HIV is responsible for about 20% of all HIV transmissions (4). The joint United Nations programmer on HIV has called for the "elimination" of mother to child transmission of HIV by the year 2015 (4). Elimination necessitates lowering the risk of transmission of HIV from mother to child to less than 5% and reducing the infection rate among young children by at least 90% (5).

HIV exposed infants should be tested using a specialized virological test. Yet, in 2013, only 42% of infants born to mothers living with HIV in low- and middle-income countries received this test within two months as recommended by World Health Organization (WHO) (6). Besides, the dominant heterosexual transmission, vertical virus transmission from mother-to-child accounts for more than 90% of pediatric acquired immune deficiency syndrome (AIDS) (7). Without care and treatment, more than half of these children will die before their second birthday (8). Fortunately, the risk of parental transmission of HIV is below 2% with antiretroviral treatments (ART), safe delivery and safe infant feeding (2); in the absence of these critical interventions, the risk of MTCT ranges from 20-45% (1, 2, 3, 8, 9).

Ethiopia is home to approximately 800,000 patients with HIV/AIDS (10, 11). The country prevalence of HIV/AIDS in the general population is estimated to be 1.5% (10, 11, 12) and 2.3% at antenatal care (ANC) (13). Despite remarkable expansion of PMTCT sites, coverage of HIV positive pregnant women receiving antiretroviral drugs for PMTCT was still 55% by 2013 (12). Federal democratic republic of Ethiopia ministry of health (FDRE-MOH) adopted phased approach by prioritizing "hot spot" settings in regions, zones and woredas with the highest unmet

needs for PMTCT programme. The program will then target areas where larger groups of women not yet accessing the services they require.

Regions, zones, and woredas with the highest unmet needs for PMTCT and paediatric HIV treatment and care identified through the national level bottleneck analysis including; Oromia (12,331; 34%), Amhara (8,536; 23%), Southern nations and nationalities peoples region (5575; 15%), Somali (2910, 8%) and Tigray (2,322; 6%) will enable Ethiopian to reach about 86% of the need for PMTCT (14).

By year 2011, it was estimated that ART needs for all ages was around 383,960 of which 43,000 estimated number of HIV positive pregnant women giving birth in the same year (13). There were 7,792 new infections in children under 15 years in 2012 (14) MTCT accounts for over 95% of childhood infections (1, 14). Currently 200,300 children estimated to live with HIV in Ethiopia, only 18,931 (9.5%) received ART in 2013 (13).

The overall goal of this study was assess the effectiveness of PMTCT in Asella teaching and referral hospital by aggregating routinely collected service coverage indicators. This would serve as useful information for policy makers to evaluate gains made from the programme and managers in matters pertaining to improve PMTCT services.

1.2 Statement of the problem

Mother to child transmission of HIV is responsible for about 20% of all HIV transmissions (2), more than 90% of worldwide pediatrics HIV infections, 95% of which are in the Sub-Saharan Africa (SSA) (1). Without any intervention, MTCT of HIV ranges from 14-32% in non-breastfeeding (mostly industrialized) populations to 25- 48% in breastfeeding (mostly resource limited) populations (2). With effective prevention in high-income countries, MTCT rate has been decreased to around 1% through specific PMTC of HIV interventions (3).

In other studies it has been showed that the risk of MTCT can be reduced to less than 2-5% with ART, safe delivery and safe infant feeding practice (8). This low MTCT level has not been attained at national levels in sub Saharan countries due to inaccessibility to highly active antiretroviral therapy (HAART), prelabour interventions and other logistics constrains.

In Ethiopia, since the introduction of PMTCT service in 2001, then the second and the third (currently used) guidelines were formulated in 2007 and 2011 respectively (12), all the guidelines follow the four pronged approach to PMTCT. The number of PMTCT sites has increased significantly from 719 in 2007/8 to 1044 in 2010/2011 (11) to 2,044 in 2012/13 (12) and to 2,150 in 2013/14 (13). However, mother to child transmission of HIV was decreased from 32% to 25% only for the pregnant women with ARV prophylaxis (13). As a result, by June 2013, 64% of all antenatal health facilities were providing PMTCT services and the PMTCT coverage reached at 42.9% which was below the target plan (14).

In view of the newly adopted WHO 2013 guidelines (remarkably increasing eligibility criteria for treatment: CD_4 count cut off at $500mm^3$ for all adults; pregnant women and all children below 15 years of age), it is necessary to scale-up institutional capacity including procurement and distribution of ARVs. Moreover, since March 2013, all pregnant women have been considered eligible to start long-term antiretroviral therapy (ART), through a package known as option B+, which has a great role to ensure prevention of at least 98% of MTCT of HIV (13). Furthermore addressing challenges in treatment adherence and retention is crucial as strengthening referral linkages between ART services and PMTCT services (13).

Oromia is one of the higher HIV prevalence regions in Ethiopia which accounts for 1.7% (13) as initiated to implement free PMTCT program in some districts since 2003. With a more effective treatment, people living with HIV can be expected to live a near normal life expectancy (17). Any commitment to reducing infections in children and keeping them HIV free for their entire lives must start with a strong focus on the health and health related conditions (14).

2. Literature review

2.1 Pediatric HIV/AIDS situations worldwide

The main time of transmission is presumed to be at and around birth when there will be separation of placenta from uterine wall rendering contact between maternal and fetal blood possible, and during birth when the fetus passes through the vaginal canal. The global plan towards the elimination of new HIV infections among children by the year 2015 and keeping their mothers alive was launched in June 2011 (5, 14). The plan sets ambitious targets for reducing new pediatric HIV infections by 90% (5), reducing HIV-associated deaths to women during pregnancy, childbirth and peripartum by 50% (13), and reducing MTCT of HIV to less than 5% at the population level (4, 5). Interventions to reduce pediatric HIV infection have become readily available worldwide, eMTCT throughout pregnancy, delivery and breastfeeding by providing effective medications and providing appropriate HIV treatment, care and support for mother and children have been underscored (6).

In 2009, 53% of HIV-infected pregnant women worldwide received antiretroviral (ARV) drugs to PMTCT (4). While coverage is increasing in sub Saharan Africa, ranging from 8% in some settings to 54% in others (4) throughout Africa, the diagnostic challenge of HIV exposure in infants is being addressed by scaling up virological testing using dried blood spot polymerase chain reaction (DBS/ PCR) (18). Appropriate messaging about PMTCT and pediatric case-finding can successfully mobilize communities and bring mothers into care, although guilt, shame, and hopelessness often prevail (20). How can we better stress the benefits of early treatment for infected children to dispel beliefs that an infected child was a lost cause? If the goal of an "AIDS free generation" is to be accomplished, it is crucial to ensure that newborn children are born free from infection and remain that way for the rest of their lives.

2.2 Mother-to-child transmission of HIV

Mother to child transmission can occur during pregnancy, labour or breastfeeding. Advanced maternal disease, acute maternal infections during pregnancy and lactation and co-morbidity with sexual transmitted diseases increase the risk of transmission (1). The range of transmission was different accordingly. During pregnancy 5-10% of all exposed fetuses were infected. This is

possible through placental tears, chorioamninitis, cigarette smoking and use of illicit drugs; which disrupt the placenta and cause micro-transfusions of maternal blood to the fetus (15). During labour and delivery 10-20% of all children can get infected. This is through direct contact with infectious maternal blood, genital secretions and absorption through fetal or neonatal digestive tract (11, 12). During breastfeeding further 5-15% of infants are infected. This may be through cell-free or HIV-infected cells in milk. The immaturity of the gastrointestinal tract and its damage by introduction of other foods may increase viral permeability (1, 15). The high mortality rate of pediatric HIV in resource limited countries is partly due to lack of early diagnosis and low coverage of pediatric highly active antiretroviral therapy (HAART) treatment. There is an urgent need to integrate low-cost and accessible viral nucleic acid based assays (16).

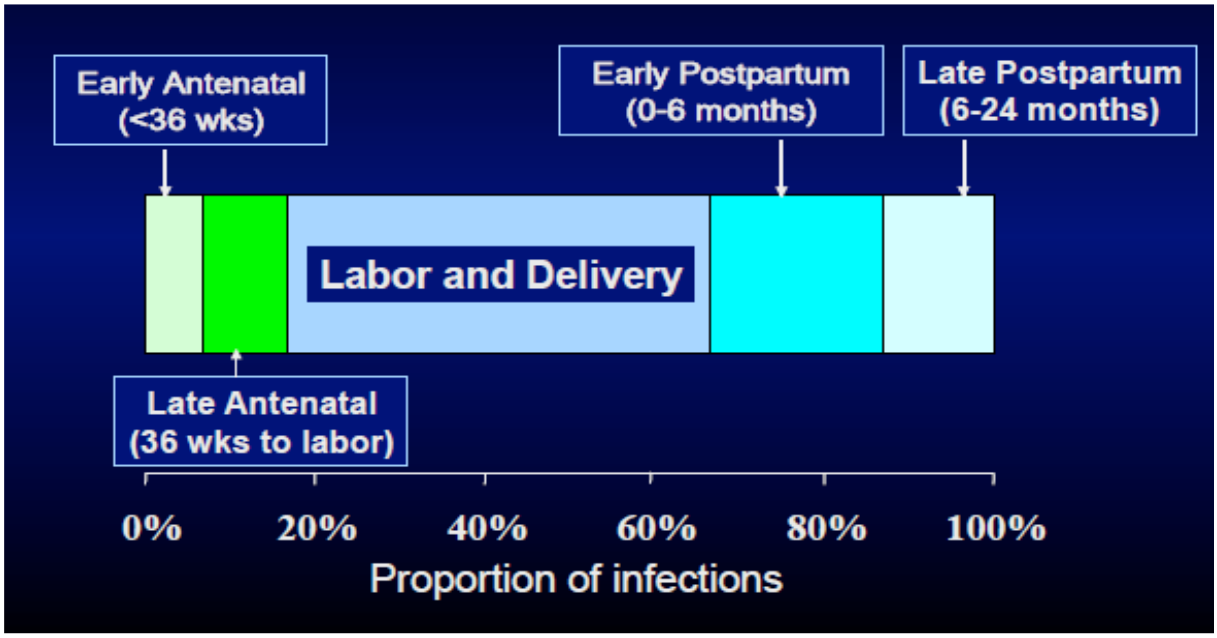


Figure1. Timing of MTCT with breastfeeding and no antiretroviral prophylaxis (22)

2.3 Prevention of mother to child transmission of HIV interventions

The global community has engaged in multi-targeted approaches to prevent and treat HIV which has had a notable impact particularly on countries in southern and eastern Africa over the past decade. More than 90% of children who acquired HIV in 2012 live in sub Saharan Africa. Implementation of the global plan is based on a four-pronged strategy including (1, 2, 12, 15):-

1. The primary prevention of HIV infection among women of reproductive age group.

Avoiding new HIV infection among women that aspire to have children will halt the transmission of HIV to infants. The prevention of HIV should be targeted at "women at risk" and their partners. As vertical transmission is also a route in which new infections can occur HIV prevention efforts should also address the needs of pregnant and lactating women of high prevalence areas (11).

2. Prevention of unintended pregnancies among HIV-infected women.

Lack of adequate reproductive services poses a problem in MTCT of HIV. "Prevention in positives" involves the use of dual contraceptives and other services of reproductive health service package with health education, health promotion and various family planning methods (12). Most HIV infected women of reproductive age that reside in developing countries do not know their HIV status. Availing counseling and testing services can give them a chance to have screening, which could aid in making informed decision about their reproductive lives (12)**.**

3. Provision of specific interventions to reduce vertical transmission of HIV.

The PMTCT program offers a range of services and interventions that reduce the risk of MTCT. These include HIV education, testing and counseling for pregnant and breastfeeding women and their partners, antiretroviral treatment and prophylaxis, safer delivery practices, and counseling on safer infant feeding and care of the HIV exposed infant (3, 13).

4. Provision of treatment, care and support for HIV infected mothers, their infants and family.

Lifelong ART was recommended for all HIV positive pregnant and breastfeeding women regardless of their CD_4 count or WHO clinical stage or gestational age (3). However, all women diagnosed with HIV infection should have clinical and immunological evaluation to monitor their progress as they start ART (3, 12). Continuum of care should be established and HIV positive women, their children and families should be given due emphasis on care and support. Their reproductive health needs should be met and other care of new born should continue (11).

Due to different capability, resource and availability of health service, different region had a different result of PMTCT; the rate of MTCT could be reduced to 5-8% by integrated PMTCT program in developing countries, and it could be reduced to less than 2% in some developed countries (2, 21). A dramatic reduction in MTCT in resource rich countries as come from the use

of HAART not only for women who need treatment, but also for HIV positive women who have higher CD_4 counts (17).

In Europe, the use of antiretroviral therapy has increased from 5% in 1997 to 92% in the period 2001-2003, resulting in a transmission rate of 0.99% in the 2001-2003 periods which was a great achievement (16).

In 2012, British Columbia studies shows that antiretroviral therapy initiated more than 4 weeks prior to delivery reduce MTCT rate to 0.4% (22).This shows that in developed countries the great success was achieved while in developing countries like Ethiopia still number of factors increases MTCT rate.

Table 1: Risk factors for mother to child transmission of HIV (3)

During pregnancy	During labour and delivery	When breastfeeding
-High maternal viral load and low CD_4 count (newly infected individuals or advanced AIDS)		
- Viral, bacterial or parasitic placental infections (e.g., malaria) - Sexually transmitted illnesses.	- Chorioamninitis (from untreated sexually transmitted illnesses or other infections) - Rupture of membranes for more than 4 hours before delivery	- Oral disease in the infant (e.g., thrush or mouth sores) - Breast abscesses, nipple fissures, and mastitis - Duration of breastfeeding - Mixed feeding before 6 months of age

PMTCT is a highly effective intervention and has huge potential to improve both maternal and child health through addressing the risk factors listed in Table 1. Beginning ART before the twelfth week of gestation reduces HIV related mortality in children living with HIV by 75% (6).

Ethiopia has adopted the world health organization (WHO) or United Nations children's fund (UNICEF) which includes four-prong strategy. The most important challenge is the implementation of a comprehensive approach to PMTCT to achieve universal coverage of PMTCT services (12); technical interventions, including antiretroviral medications, essential

obstetric care, health system strengthening, including resource allocation, and gender issues are contained as part of the national comprehensive PMTCT program. Addressing all four prongs has potential to interrupt the cycle that leads to MTCT at several points (13).

2.3.1 HIV counseling and testing

The diagnosis of HIV infection in infants remains a difficulty because the mother passes antibodies to the child which will remain in the fetal circulation for a period of up to eighteen months. HIV diagnosis in infants is usually done by a qualitative HIV deoxyribonucleic acid polymerase chain reaction assay using peripheral blood mononuclear cells or by HIV ribonucleic acid PCR assays which detect plasma viral ribonucleic acid (23). The signs and symptoms of infected children exhibit are different from adults and at times they may show no manifestations at all (23). Because of its high sensitivity and specificity, deoxyribonucleic acid-polymerase chain reaction test has been widely used for diagnosis of HIV amongst exposed infants. The technology allows for polymerase chain reaction to be performed using a small spot from a dried blood spot (DBS) sample, as well as identification of infection from birth (15).

Blood sample is collected from the heel or toe of exposed infants using a pin prick. That sample was collected on a litmus paper and wrapped for transportation. The use of litmus paper is to transfer specimens (dried blood spots) from one remote area to a more advanced lab where diagnosis can be done is a major step forward in early diagnosis of HIV infection in children (15). The advantages of dried blood spot test are that the sample can be easily transported in an envelope, it is relatively inexpensive, does not need high expertise, it does not require refrigeration and small amount of blood taken from the infant is enough (23). Integrated PMTCT services and antenatal care was the key entry point for PMTCT services (for example, through HIV testing). Virologic tests are required to diagnose HIV infection in infants aged less than 18 months and should be performed within the first 14 to 21 days of life and at age 1 to 2 months and age 4 to 6 months (31).

World health organization recommends that pregnant women have their first antenatal care visit in the first trimester of pregnancy and attend a total of at least four visits (32). HIV exposed infants should be tested using a specialized virological test. Yet in 2013, only 42% of infants born to mothers living with HIV in low- and middle-income countries received this test within

two months as recommended by WHO (6). Only 40% of all polymerase chain reaction tests done in that year were conducted at 6 weeks as per the recommendations (29). The infants of mothers who never enter or complete PMTCT are those most at risk for infection. These infants are not the ones who arrive at maternal child clinics for their 6 week dried blood spot test, but are the children of mothers who never received antenatal care, were never tested during pregnancy, seroconverted after testing, delivered at home, were non-adherent to therapy, or were lost to follow-up (20).

A study in Ethiopia that examined the progress and an addressed need in access and utilization of PMTCT service showed that a significant progress had been made in the proportion of pregnant mothers who accepted HIV testing after receiving counseling services (24). According to 2013/14 annual performance report, the number of women who attend antenatal care at least once has increased from 88.0% to 89.1% in the same year and 100% for testing (14). Percentage of infants born to HIV positive women's receiving a virological test for HIV within 2 months of birth was 21% (13).

2.3.2 Antiretroviral treatment and prophylaxis

In 2010 the WHO presented its new guidelines on PMTCT, recommending two PMTCT options: option A and option B. These two options include both treatment and prophylaxis components. In both options CD_4 count is necessary to decide the eligibility of HIV infected pregnant women for lifelong combined ART. For all women who have CD_4 counts $\leq$350 cell/mm^3 initiation of lifelong combined ART is recommended. Importantly, having effective antiretroviral regimens and wide coverage is insufficient; effective delivery programmes are equally important (25). For those women not eligible for lifelong combined ART, option A recommends antenatal prophylaxis with Zidovudine followed by intrapartum and postpartum prophylaxis with single-dose Nevirapine and Zidovudine plus Lamivudine; this might be difficult to implement because of the different drugs administered during antenatal, intrapartum and postpartum care (30).

Option B and B+ are not only more effective at PMTCT and less likely to lead to future drug resistance, but are also easier for health systems to implement and for patients to adhere to (24). The treatment is available as a single-pill fixed-dose combination, made up of a first line regimen of Tenofovir (TDF), Lamivudine (3TC) and Efavirenz (EFV) (13, 17, 25). In option B+ all HIV

positive pregnant women are provided with lifelong combined ART, regardless of the CD_4 cell count (17). Options, B and B+, although simplifying drug prescription, have a short-term drug cost greater than option A. However, when taking into account maternal and infant life expectancy and lifetime healthcare costs, option B is more effective and less expensive than option A. Option B+ offers clinical benefits and economic value comparable to other widely used HIV interventions (13). The three options are summarized in Table 2.

Table2: Treatment option for prevention of HIV from mother to child transmission (3, 25).

<table>
<tr><td colspan="4">Options for preventing mother to child transmission of human immunodeficiency virus.</td></tr>
<tr><td>Option</td><td>Treatment for CD_4 count < 350 cells/mm^3</td><td>Prophylaxis for CD_4 count > 350 cells/ mm^3</td><td>Infant receives</td></tr>
<tr><td>A</td><td>Triple ARVs starting as soon as diagnosed, continued for life.</td><td>Antepartum: AZT starting as early as 14 weeks gestation.
Intrapartum: at onset of labour, single-dose NVP and first dose of AZT/3TC
Postpartum: daily AZT/3TC through 7 days postpartum.</td><td>Daily NVP from birth until 1 week after cessation of all breastfeeding; or, if not breastfeeding or if mother is on treatment through age 4–6 weeks</td></tr>
<tr><td>B</td><td>Triple ARVs starting as soon as diagnosed, continued for life.</td><td>Triple ARVs starting as early as 14 weeks gestation and continued intrapartum and through childbirth if not breastfeeding or until 1 week after cessation of all breastfeeding.</td><td>Daily NVP or AZT from birth through age 4–6 weeks regardless of infant feeding method.</td></tr>
<tr><td rowspan="2">B+</td><td colspan="2">Same for treatment and prophylaxis</td><td rowspan="2">Daily NVP or AZT syrup from birth to age 4–6 weeks regardless of infant feeding method.</td></tr>
<tr><td colspan="2">Triple ARVs starting as soon as diagnosed, continued for life regardless of CD_4.</td></tr>
</table>

The WHO recommended regimens (options A or B) are estimated to be associated with a 2% probability of perpartum transmission and a 0.2% probability of transmission per month of breastfeeding. Perpartum and postnatal transmission probabilities were lowest for women who were taking ART before the pregnancy, namely 0.5% perpartum and 0.16% per month of breastfeeding (27).

- Single-dose NVP (mothers and infants), combined with replacement feeding: 8.8% (28).
- AZT long (from 28 weeks) and single-dose NVP (mothers and infants), combined with short breastfeeding: < 5% (14).
- AZT long (from 28 weeks) and single-dose NVP (mothers and infants), combined with replacement feeding: 2% (22). The WHO has advised each country to make some initial assessments to understand women's attitudes, perception and preference regarding the three treatment options before implementation (28**).** The current global plan can only be achieved by having a positive national trend towards the efforts to accelerate HIV prevention and treatment programmes (30).

Several countries in SSA are currently considering modifying their PMTCT guidelines. Such a decision should be made on the basis of their implementation experience and a previous assessment of how they can better integrate, simplify and optimize the PMTCT programme in the existing HIV/AIDS care and treatment platform(16).

Between 2005 and the end of 2012, expansion of PMTCT programmes and the use of more efficacious ART regimen have helped to prevent 800,000 children globally from becoming newly HIV infected (12).

The Ethiopian federal ministry of health (FMOH) developed an operational plan to phase in option B+ services in all PMTCT facilities by the end of 2013 (26). With foreseen benefits including further simplification and operational simplicity, avoidance of stopping and starting ARV drugs, protection against vertical transmission in future pregnancies and protection against sexual transmission to sero-discordant partners (25). So, assessment of effectiveness of PMTCT of HIV programme among HIV positive women's in Asella teaching and referral hospital is necessary.

2.3.3 Safe delivery practices

About 70% of MTCT in non-breast-feeding infants and about 50% in breast-feeding infants occur during the intra-partum period (24). The risk of intra-partum increases with intra-partum bleeding, premature rupture of membrane, prolonged labor more than 4 hour after rupture of membrane, chorioamninitis and cervico-vaginal infection (32).

Studies have found that there was an increased rate of HIV transmission after a mother's membranes have been ruptured for more than 4 hours before delivery (3). However, the key point was that the longer the membranes are ruptured, the higher the risk of HIV transmission. Certain obstetric procedures such as episiotomy and artificial rupture of amniotic membrane are also associated with increased risk of MTCT (24).

In Ethiopia, skilled birth attendances were 20.4% in 2011/12 (12) and only 64% of MNCH facilities provided PMTCT services in 2011 (14). In Ethiopia the rate of low birth weight was recorded above 30% in women under highly active antiretroviral therapy (HAART) during pregnancy, reaching almost 50% in those on ART prior to pregnancy added to a rate of preterm birth above 20% (19).

Pregnancy itself does not affect the outcome of HIV infection, but HIV may affect pregnancy outcome in numerous ways: HIV-positive pregnant women are at increased risk of premature deliveries, small for date babies and still birth (12). The safety of those treatments during pregnancy is controversial; numerous studies have been conducted assessing the impact of those protocols on birth outcomes namely preterm delivery and low birth weight with conflicting results based on the ART protocol, the timing of the treatment and other associated factors (19).
All women coming for ANC, labor, delivery and post partum follow-up including child health care, if not tested during current pregnancy shall be routinely informed about the benefits of HIV testing for mother and baby in a group or on individual basis and shall be told that their routine laboratory check up includes HIV testing unless they say "NO". The right to say "no" shall be clearly communicated (5, 16).

2.3.4 Safe infant-feeding practices

Transmission of HIV infection through breast milk can occur at any point during lactation (29). A factor that may facilitate breast milk transmission was shown in table (1). Infant gastro-intestinal pathology such as candidacies and necrotizing enterocolitis may disrupt mucosal integrity and aid viral transmission (29, 30).

Globally, about 300,000 babies become infected with HIV through breast milk each year; while at the same time 1.5 million children die each year if the women opt not to breastfeed (33). Twenty-two countries account for more than 90% of the global burden, and Ethiopia is one of these priority countries where one of every 3 children born to women living with HIV still gets infected with HIV (36). There is a need to go back why EBF was recommended in the first place, to focus on mother and the child and survival. In low infant mortality settings, HIV makes a larger contribution to the balance of risk so breastfeeding (in the absence of ARVs) is quite risky (31). With effective ARVs, abstinence from breastfeeding results in worse infant outcomes. In postnatal transmission, the key element is the importance of infant and child mortality (28).

Complete avoidance of breast milk eliminates the postnatal transmissions. Exclusive formula feeding is a preferred infant feeding method where infant formula is affordable, feasible, acceptable, sustainable and safe (AFASS) (32). For instance, in resource poor settings where the risks of infant death due to diarrheal diseases and malnutrition outweighs the risks of HIV transmission, exclusive breastfed (EBF) has been recognized as the best chance of the infant to receive the nutrients and antibodies needed to survive (33).

The risk of HIV transmission from breastfeeding up to 18–24 months is 15–20%, but studies in low-resource environments have concluded that not breastfeeding or stopping breastfeeding early increased mortality and reduced HIV-free survival (34). The mechanism by which EBF is associated with lower MTCT is not fully understood, however they include: the maintenance of integrity of the infant's gastrointestinal barrier, which is regarded as the primary mode of infection (34). Secondly, the immunological factors in the breast milk are said to be responsible for the reduction of viral activity in the human milk (24). Thirdly, EBF maintains the integrity of the mammary epithelial lining and promotes overall breast health (35). Recently a protein known as Tenascin-C (TNC) an innate mucosal host protein found in milk has been identified and is capable of neutralizing HIV through binding to chemokine core receptor site. This finding

potentially explains why the majority of HIV exposed breastfed infants are protected against mucosal HIV transmission (35). For the first 12 months of life, the high levels of nutrients in breast milk protects against mortality from diarrhea, pneumonia and malnutrition (36).

However, around the age of 6 months, breast milk alone can no longer meet all nutritional requirements of the infant, and complementary feeding; the transition from EBF to family foods is necessary. Although complementary foods provide energy and nutrients to help meet the growing child's needs, breastfeeding continues to provide at least half of a child's nutritional requirements between the ages of 6 to 12 months (34). The potential implications of exclusive breastfeeding recommendations are that more HIV-infected mothers will start breastfeeding and more will feed until at least 12 months and more total mothers was partake in exclusive breastfeeding. This was result in improved nutritional intake and HIV free survival among HIV-exposed infants and overall improved infant survival (28).

In Ethiopia, institution based cross sectional study in Gondar town health institutions, on infant feeding practice and associated factors of HIV positive mothers attending PMTCT and ART, 89.5% of the study participants had followed EBF practice, while significant percentage 10.5% of the study participants had practiced mixed feeding (26). For the best possible infant health and development outcomes, all mothers, including those living with HIV must adopt optimal infant feeding practices that maximize protection against early childhood illnesses and lower the risk of HIV infection (34).

Effectiveness of PMTCT is defined as the prophylactic benefit of a PMTCT intervention when implemented in real practice. It can be measured by use of several outcome indicators which include: PMTCT intervention coverage which is intended to act as a surrogate for the number of infant infections prevented, HIV free survival, infant deaths prevented (29).

Study in Zambia suggested that the shift from 2010 option A to the 2013 guidelines would result in a 33% reduction of the risk of HIV transmission among exposed infants. The probability of HIV infected pregnant women to initiate ART would increase by 80%. To achieve the elimination of new child infections, PMTCT programs must achieve high coverage of effective ARV interventions and safer infant feeding practices (21, 36).

3. Objectives

3.1 General objective

- This study was aimed to assess effectiveness of PMTCT programs through determination of the outcome of HIV exposed infants, especially HIV free survival during the first 18 months of life at Asella teaching and referral hospital College of health sciences, Arsi University, ANC and ART clinic from February 2012- 2015.

3.2 Specific objectives:

- To determine the overall rate of transmission of HIV at 6 weeks.
- To determine the overall rate of transmission of HIV at 6 months.
- To evaluate the effectiveness of different regimens in reducing the rate of mother to child transmission at 18 months.
- To describe infant HIV testing practices among infants of HIV positive women.
- To evaluate infant ARV prophylaxis.
- To evaluate infant feeding mode in reducing the rate of mother to child transmission at first 6 months.

4. Methodology

4.1 Study setting

The study was conducted in Asella teaching and referral hospital, College of health sciences, Arsi University: Ethiopia. Asella is the administrative zonal town which is 175 kilo meters from Addis Ababa to south east of Ethiopia. The 2007 national census reported a total population of Asella town to be 67,269 of whom 33,826 were men and 33,443 were women. The catchments population of the hospital is estimated to be 3.8 million. In this hospital ART service started in September 2006. The study was performed at ANC and ART clinic of Asella teaching and referral hospital in a 3 months period; the data was assessed from February 2012- 2015.

4.2 Study design

- A facility based retrospective cross-sectional study design was conducted.

4.3 Source population and study population

- All HIV positive mothers getting service in Asella teaching and referral hospital, College of health sciences, Arsi University, was source population.
- All HIV positive mothers with less than 18 months old child attending ANC and ART clinics in Asella teaching and referral hospital, College of health sciences, Arsi University, from February 2012 to February 2015 were study population.

4.4 Inclusion and exclusion criteria

- An inclusion criterion was all HIV positive mothers with less than 18 months old child attending at ANC and ART service followers with a completed record were included in the study.
- Clients with incomplete medical records, mothers who were transferred into other healthy facility and therefore did not receive PMTCT interventions in Asella hospital were excluded from the study.

4.5 Sample size and sampling technique

Depending on the past registry of the hospital, the total number of HIV positive mothers who have children age at least 18 month during February, 2012-2015 was 267 in numbers from which the study sample was drawn. HIV exposed mothers-infants pair on follow up at the ANC and

ART at Asella teaching and referral hospital, College of health sciences, Arsi University ANC and ART clinic from February, 2012- 2015 who was eligible as they had attained the age of 18 months. The subjects were chosen by using simple random sampling method.

All the available population of HIV positive women enrolled in PMTCT programme at Asella teaching and referral hospital ANC and ART clinic from February 2012-2015 which fulfils the inclusion criteria was included. The enrollments detail was shown below:

267 HIV positive pregnant women at ANC and ART clinic records February (2012- 2015)

88 women were not followed up at Asella teaching and referral hospital

179 Women registered at PMTCT

37 lacked information or transferred out of Asella hospital ANC and ART clinic.

142 Mothers fill inclusion criteria

12 Lost ART patient cards from card room

130 Mothers to infant pairs were included in the final analysis.

Study endpoint

The primary study endpoint was HIV-free survival at 6 weeks to 18 months. Survival was defined as the probability that the child was alive between 6 weeks and 18 months of age, and tested HIV negative at this age.

4.6 Variables

- Dependent variable was HIV free survival of children under 18 months while variables that might determine the risk of HIV infection such as: socio demographic characteristics, mothers (gestational age, ANC, illness during pregnancy, ART or ARV prophylaxis, CD_4 count done), place of delivery, infant feeding practice, age at DNA/ PCR test was done and intake of ARV prophylaxis by infants were independent variables.

4.7 Data collection procedures

Data collectors were four professionals who are holding bachelor degree in nursing, previously worked on ANC and ART clinic. A structured data extraction tool was developed, pre-tested and used to collect the information from the medical record. The structured questionnaire was adapted from the national standard HIV exposed infant follow up chart and PMTCT registration log book which includes, socio-demographic characteristics (mother age, marital status, level of education, infant age, sex of infant, birth weight), the PMTCT interventions offered to the

mother and her infant, DNA/PCR test done, teste results and the first 6 months feeding option of HIV positive mothers for her infant. The data was collected under close supervision of principal investigator and from the patient chart. Training was given for data collector for 3 days prior to the pretest and for 2 days after the pretest. The training includes how to collect data, general objective, relevance of the study, and confidentiality of information. The training was made in the form of discussion by using structured questionnaire. The principal investigator reviewed daily all filled data abstraction formats.

Pre-testing the questionnaire

The structured questionnaires were pre-tested in the selected health institution's ANC and ART clinic. The pre-test was done on 5% of the total sample size. The questionnaire was then assessed for its clarity, length and completeness. Some skip patterns were then corrected.

4.8 Data processing and analysis

The collected data were cleaned, checked for its completeness and internal constency. The soft copies of the data were stored on hard drive and back up copy was stored on separate drive. Later both soft copies and hard copies were stored on flash disks and compact disc (CD). The data was coded, cleaned and double entered in to the preformed access spreadsheets and analyzed using statistical package for social sciences computer package version 21. Descriptive statistics such as mean, median, modal, standard deviation, and interquartile range were used for continuous variables. Categorical data was described in terms of frequencies and percentages. Numerical data from HIV status by the age of 18 months or at last available result before 18 months was used to compute HIV transmission rate among HIV exposed infants and mother to child transmission rates. Survival analysis was performed using Kaplan meier analysis. Infant testing practices were described in terms of frequencies of testing by DNA/ PCR method with special consideration to age at which these tests are done. Bivariate and multivariate logistic regression analysis was employed to see the effect of each independent variable on the outcome variable and to control for the effect of confounding. *P*- Value $\leq$ 0. 05 at 95% confidence interval (CI) were considered statistically significant.

4.9 Data quality control measures

To control the quality of the study; expert adviser of the instrument, training of data collectors, data clearing and editing, strict supervision of data collector and commenting the problem at spot and pretesting on 5% of the total sample size was done. Data clearing and editing were performed to check for variables, frequencies, accuracy, consistency, outliers and missed values.

4.10 Ethical consideration

Letter of ethical clearance was obtained from the ethical review committee of school of pharmacy, Addis Ababa University and letter of permission from authorities of Arsi University College of health sciences, Asella teaching and referral hospital was received. Since the study utilizes routinely collected, aggregated program data at the hospital, obtaining informed consent from individual patients was not possible. But, institutional permission letter was received to review records of HIV positive mothers and their infants. Confidentiality of patient information was ensured as the names or identification number of study participants was not included in the data collection format and keeping the extracted data from charts anonymous (the collected data was not exposed to third person).

4.11 Definition of operational terms

Mother to child transmission

- Transmission of HIV from HIV positive mother to her infant during pregnancy, delivery and during breastfeeding. The term is used because the immediate source of the infection is the mother, and does not imply blame on the mother.

Safe infant feeding:

- Feeding practices that would lead to a healthy, well-grown, able, live, HIV-free child who has no underlying morbidity resulting from incorrect feeding practices.

Prevention of mother to child HIV transmission:

- Are prevention activities that prevent women from being infected by virus, preventing unwanted pregnancy in sero-positive mothers, preventing the virus transmission to the baby during pregnancy, labor and delivery or breastfeeding and provision of care and support.

Vertical transmission:

- Is when the HIV virus passes from an HIV positive mother to her baby. This can happen during pregnancy, during labor and delivery or during breastfeeding.

HIV-exposed infant: Infant born to an HIV-positive woman.

Infant: A person from birth to 12 months of age.

Antiretroviral therapy (ART): Is use of 3 or more ARVs simultaneously to treat HIV infection.

ARV prophylaxis**:** short term use of ARV drugs in the mother and/or infant to reduce MTCT.

5. Results

Socio-demographic characteristics

A total of one-hundred-thirty HIV positive mothers aged between 23 and 39 years were enrolled in the study along with infants delivered during the last pregnancy. The mean age of the participants was 30.6 years standard deviation 4.2. Male HIV exposed infants constitute 52.3% whereas the remaining 47.7% was females. Most (88.5%) mothers were married and 2.3% were single. For sixty-five (50.0%) mothers the highest level of education attained was primary level education. One-hundred (76.2%) infant birth weight was above 2.5 kilo grams and median birth weight was 3.0 kilo grams (Table 3).

Table 3: Socio-demographic characteristics of mother-infant pairs, Asella teaching and referral hospital, Aris University, Oromia region, Ethiopia, June 2015**.**

Socio-Demographic variables		Frequency	Percent (%)
Age of mothers	15-24 years	8	6.2
	25-34 years	103	79.2
	≥35 years	19	14.6
Gender of infants	Male	68	52.3
	Female	62	47.7
Marital status	Single	3	2.3
	Married	115	88.5
	Separated/Divorced/Widowed	12	9.2
Level of Education	Primary school	65	50.0
	Secondary school	17	13.1
	College/University	4	3.1
	Illiterate	44	33.8
Infant birth weight	< 2.5 kilo grams	31	23.8
	> 2.5 kilo grams	99	76.2
Median birth weight in kilo grams (n=130)		3.0 median	2.8-3.2 IQR

PMTCT interventions by mothers

The uptake of PMTCT interventions by mothers is presented in (Table 4). The median gestational age at enrollment into PMTCT programme was 28 weeks (n=130), interquartile range (IQR) 15.5 to 28. Almost all mothers (97.7%) had attended ANC. Seventy-three (56.2%) of mothers attended ANC clinics only one time during the most recent pregnancy. Twenty-nine (22.3%) mothers were ill during recent pregnancy. One-hundred-twenty-one (93.1%) mothers were on ARV prophylaxis, most commonly sixty-nine (53.1%) on HAART and fourteen (11.6%) were on AZT+3TC during pregnancy. About one-hundred-twenty-three (94.6%) were on ART. Seventy-one (54.6%) mothers were on current standard treatment i.e. option B+ (TDF + 3TC + EFV). The majority (97.7%) of mothers know their CD_4 counts before last pregnancy of which forty-seven (36.2%) mothers had CD_4 counts above $500mm^3$ (Table4).

Table 4: Uptake of PMTCT interventions by mothers, Asella teaching and referral hospital, Aris University, Oromia region, Ethiopia, June 2015.

PMTCT Interventions		Frequency or (median)	Percent (%) or (IQR)
Gestational age in weeks		28 median	15.5-28 (IQR)
ANC visit	Yes	127	97.7
	No	3	2.3
Number of ANC visits	only 1	73	56.2
	2-3 times	32	24.6
	4 times	22	16.9
Any illness during pregnancy	Yes	29	22.2
	No	101	77.7
Mothers ARV prophylaxes	Yes	121	93.1
	No	9	6.9
Type of ARVs prophylaxis in mother	AZT+3TC during pregnancy	14	10.7
	Sd-NVP at onset of labor	38	31.4
	HAART	69	53.1
Type of ART in mother	AZT+3TC+EFV	28	21.5
	TDF+3TC+EFV	71	54.6
	AZT+3TC+NVP	12	9.2
	Other*	12	9.2
CD_4 done	Yes	127	97.7
	No	3	2.3
CD_4 counts	<350 mm^3	39	30.0
	350-500 mm^3	41	31.5
	>500 mm^3	47	36.2

*****Other **ABC**, 3TC, LPR/R: AZT+3TC with LPV/R

PMTCT interventions by infant

Table 5 describes the uptake of PMTCT interventions by infant. One-hundred-five (80.8%) infants were tested after six weeks using DBS (DNA/ PCR) and only twenty-five (19.2%) was tested at correct time. Ninety-three (71.5%) and five (3.8%) infants were given Nevirapine syrup and AZT + 3TC for prophylaxis respectively. Surprisingly thirty-two (24.6%) infants were not receiving ARV prophylaxes. The majority (90.8%) of infants were born at public health facility while 9.2% were born at home. One-hundred-fifteen (88.5%) gave birth through spontaneous vaginal delivery. The caesarean section rate in HIV positive deliveries at the hospital was 11.5%. One-handed-eighteen (90.8%) infants were exclusively breastfed compared to twelve (9.2%) which were on mixed feed.

Table5: Uptake of PMTCT interventions by infant, Asella teaching and referral hospital, Aris University, Oromia region, Ethiopia, June 2015.

Interventions		Frequency	Percent (%)
Age at DBS (DNA/ PCR) done	> 6weeks	105	80.8
	< 6weeks	25	19.2
Infant ARV prophylaxis	NVP syrup	93	71.5
	AZT + 3TC	5	3.8
	No prophylaxis	32	24.6
Place of delivery of the infant	Public health facility	118	90.8
	Home	12	9.2
Mode of delivery of infant	Spontaneous vaginal delivery	115	88.5
	Caesarean section	15	11.5
Infant feeding options for the first six months	Exclusive breast fed	118	90.8
	Mixed fed	12	9.2

PMTCT outcomes

Among one-hundred-thirty infants born to HIV positive mothers, ten (7.7%) tested positive for HIV at 18 months birth. The estimated HIV prevalence among HIV exposed infants at 6 weeks was 3.1% (95% CI= 0.8, 12.1%). The prevalence increased to 3.8% at 6 months and between 6

weeks and 18months among infants who were still HIV free at 18 months 4.6% (95% CI = 1.5%-16.5%) with 6 additional infants testing HIV positive. This increase was however not statistically significant, difference = 1.5% (95% CI = -1.2 to 10, p = 0.12. Surprisingly there is no death among infected infant in the study period (Table 6).

Table 6: Infant HIV infection and free survival at 6 weeks, 6 months and 18 Months, Asella teaching and referral hospital, Aris University, Oromia region, Ethiopia, June 2015.

Outcome	6 weeks, No. (%)	6months, No. (%)	18 months, No. (%)
HIV infection	4/130 (3.1)	5/130 (3.8)	10/130 (7.7)
HIV free survival	126 (96.9)	121 (93.1)	120 (92.3)

Infant HIV free survival

The overall infant survival rates at 18 months were high and no death records among infants of HIV positive mothers in the study periods. The cumulative survival at 18 months in HIV exposed infants at Asella teaching and referral hospital, regardless of HIV status was 100% whereas the HIV free survival rate at 18 months was 92.3% compared to HIV free survival rates of 93.1% at 6 months and 96.9% at 6 weeks (Figure 2). This graph compares the cumulative survival among HIV exposed infants to the HIV free survival at mean of covariate. As mean of covariate increases the infants HIV free survival decreases. After 18 months the curve goes to zero indicates no MTCT because the mothers stop breast feeding.

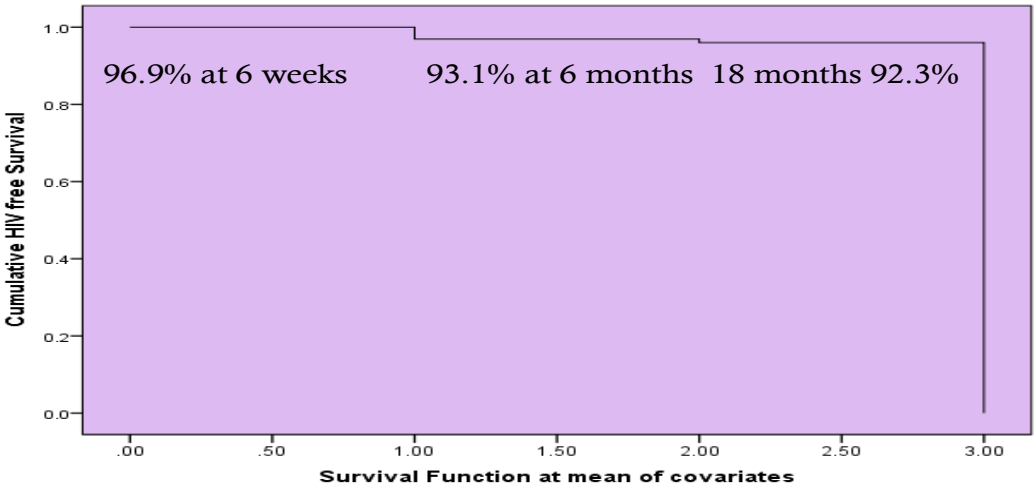


Figure2. Kaplan Meier analysis of HIV free survival at 6weeks, 6months and 18 months among HIV exposed infants, Asella teaching and referral hospital, Aris University, Oromia region, Ethiopia, June 2015.

Factors affecting HIV free survival.

As shown in Table 7, on bivariate logistic regression analysis, level of maternal education, gender of infants, ANC, child ARVs prophylaxis, age at DBS test was done and maternal CD_4 count done before pregnancy had insignificant association; however, mothers age, marital status, infant birth weight, maternal illness during pregnancy, maternal ARV/ART, place of delivery and infant feeding option had statistical significant association with HIV free survival at p-value < 0.05 (Table 7).

As indicated in Table 7, in order to identify independent factors of HIV free survival among infants born to HIV positive mothers, multivariate analysis was performed. Accordingly, Infant birth weight, mother's illness during pregnancy, mothers ARVs or ART, place of delivery and breastfeeding were fitted to the model. This finding showed significant association for: infant birth weight [AOR: 2.7, 95%CI= 0.6, 12.0], mothers illness during pregnancy [AOR: 20.4, 95%CI= 3.3, 125.7], mothers who failed to ARV prophylaxis [AOR: 17.2, 95%CI= 2.9, 100.4], home delivery [AOR: 8.0, 95%CI= 0.9, 68.5] and mixed infant feeding [AOR: 2.0, 95%CI= 0.2, 21.4]. Infant birth weight < 2.5 kilo grams were 2.7 times less likely to have HIV free survival than the counter parts; male gender were 0.8 times less likely to be HIV free survival than female gender. This indicates an association between sex and HIV free survival of infant at 18 months of life and MTCT of HIV. The justification might be boys receiving complementary foods at an earlier age, which thus put them at higher risk of becoming infected as stipulated on WHO 2007. Moreover, infants whose mothers had illness during pregnancy were 20.4 times less likely to be HIV free survival compared to infants whose mothers had no illness. Furthermore, infants who mothers failed to receive ARV prophylaxis were 17.2 times less likely to be HIV free survival compared to infant who mothers get ARV/ART prophylaxis or treatment. Among 121(93.1%) mothers who received ARV/ART 5 (4.1%) infants was having HIV infected compared to 4 (44.4%) infants who mothers did not received ARV/ART. Being mothers on ARV/ART during pregnancy/ breast feeding there infant were 40.3% reduction in infant HIV infections. An infant delivered at home was 8 times less likely to have HIV free survival compared to a mother who gave birth at health facility. Infant who practice mixed feeding were 2.0 times less likely to have HIV free survival compared to infant who practice exclusive breastfeeding when controlling for the other variables. Infants born from a mother with an age group > 35years were less likely to

be HIV free survival (AOR = 2.3 (0.37, 15.2) than the other age categories; however, it was not statistically significant. Infants born from non-educated mothers tend to be less likely HIV free survival than those having educated mothers (AOR = 1.4 (0.2, 15.7).

Moreover, child who failed to receive ARVs prophylaxis were 2.2 times less likely to be HIV free survival compared to infant who received ARV for prophylaxis. Infant whose DBS/PCR test was done after 6 weeks were 2 times less likely to be HIV free survival compared to infant who's DBS/ PCR tested done before 6 weeks. An infant born to a mother who had not CD_4 count was 3.8 times less likely to be HIV free survival compared infant born to a mother whose CD_4 count done, controlling for the other variables. An infant born to a mother whose CD_4 count is <350mm^{3}and 350-500mm^{3}was 3.7and 3.1times respectively less likely to be HIV free survival compared infant born to a mother whose CD_4 count >500mm^3(Table7).

Table7. Bivariate and multivariable logistic regression analysis on HIV free survival and associated factors in PMTCT among infants born to HIV positive mothers, Asella teaching and referral hospital, Aris University, Oromia region, Ethiopia, June 2015.

Variables		HIV free survival		95% CI)	
		Negative	Positive	Crud odds ratio	AOR
Mothers age (years)	15-24	8	0	1	1
	24-35	97	6	5.2[1.3, 16.3]	2.1[0.4, 24.6]
	> 35	15	4	4.3[1.1, 17.1] *	2.3[0.37, 15.2]
Infant birth weight	< 2.5 kilo gram	25	6	5.7[1.5, 21.8] *	2.7[0.63, 12.1] *
	> 2.5kilo gram	95	4	1	1
Level of Education	Primary school	61	4	1	1
	Secondary school	16	1	0.5[0.1, 2.0]	0.6[0.1, 2.5]
	College/University	4	0	1.2[0.1, 9.9]	000
	Illiterate	39	5	1.1[0.1, 10.0]	1.4[0.2, 15.7]
Marital status	Single	1	2	1	1
	Married	110	5	44[3.4,270]**	23.1[3.1, 156.1]
	Others***	9	3	7.3[0.4, 92.3]	8.4[0.4, 108.0]
Gender of infants	Male	62	6	0.7[0.2, 2.7]	0.8[0.2, 4.4]
	Female	58	4	1	1

ANC	Yes	118	9	1	1
	No	2	1	6.5[0.5, 79.4]	1.2[0.3, 57.8]
ANC visit	Only 1	66	7	1	1
	2-3 times	30	2	1.6[0.3, 8.0]	0.9[0.2, 5.7]
	4 times	22	0	000	000
Maternal illness	Yes	21	8	18.9[3.7,95.2]**	20.4[3.1, 25.7]*
	No	99	2	1	1
Maternal ARVs	Yes	116	5	1	1
	No	5	4	29.0[5.9,142.3]*	17.2[2.9,100.4]*
Type of ARVs prophylaxis in mother	AZT+3TC during pregnancy	14	2	6.8[1.3, 36.3]	4.6[0.7, 29.6]
	Sd-NVP at onset of labor	38	4	4.8[0.7,35.2]	5.1[0.6, 50.0]
	HAART	69	0	1	1
Place of delivery	Health facility	113	5	1	1
	Home	7	5	16[3.8, 69.2] **	8.0[0.9, 68.5*
Infant feeding option	EBF	111	7	1	1
	Mixed fed	09	3	5.3[1.3, 24.0] *	2.0[0.2, 21.4]*
Infant ARV prophylaxis	Yes	92	6	1	1
	No	2	4	2.2[0.6, 8.3]	1.4[0.25, 7.4]
Age at DBS done	< 6weeks	21	4	1	1
	> 6weeks	99	6	3.1[0.8, 12.1]	4.3[0.8, 21.9]
CD_4 done	Yes	118	9	1	1
	No	2	1	6.6[0.5, 79.4]	3.8[0.1, 780.0]
CD_4 counts	< 350 mm^3	34	5	2.0[0.4,10.3]	3.7[0.3, 43.0]
	350-500 mm^3	38	3	11.7[1.1,124.8]	3.1[0.4, 25.8]
	> 500 mm^3	46	1	1	1

*Statistically significant at 95% CI, *P*- value less than 0.05, 1- reference group.
** Strongly statistically significant at 95% CI, *P*- value less than 0.001
*** Others (widow/separate/divorce)

However, age of mothers, and marital status that had significant association in the bivariate analysis but lost their significance when controlled for confounding factors in the final model.

6. Discussion

The major aim of this study was to assess the effectiveness of PMTCT programs through determination of the outcome of HIV exposed infants, especially HIV free survival during the first 18 month of life in Asella teaching and referral hospital, College of Health Sciences, Arsi University. This study had used a different indicator which includes: the number of infant infections prevented, HIV free survival, infant deaths prevented, number of infant received ARV prophylaxes and other PMTCT program indicators. Among these indicators infant HIV free survival at the first 18 months of life were considered to be main indicator of the PMTCT program. The overall MTCT rate for the programme was 7.7% which is almost close to the national estimate of 7.0% in 2014 (13, 14).

The present MTCT rate was greater than in the developed countries (about 1%), due to the combination of widespread access to antiretroviral therapy (ART), elective caesarean sections, safe formula feed and access to quality medical services that conspicuously lack in developing countries. The joint United Nations programmers on HIV/AIDS have now called for eMTCT of HIV by 2015 (4). Elimination necessitates lowering the risk of transmission of HIV from mother to child to less than 5% and reducing the infection rate among young children by at least 90% (1, 2, 5, 8).

Regarding interventions to reduce transmission of HIV from pregnant and lactating mothers, 93.1% of mothers and 75.4% of infants were on ARV prophylaxes in the PMTCT programme at Asella teaching and referral hospital respectively. The PMTCT intervention uptake like ARV usage for PMTCT shows higher in mothers than infants. The justification might be; virtual eMTCT of HIV (reduce population-level MTCT rate to < 5% by 2015) there should be at least 90% of women and 90% of infants who test positive for HIV on ARVs (13). An infant delivered from mothers received AZT + 3TC during pregnancy for prophylaxis were 85.7% less likely HIV infected while an infant delivered from mothers whose received Sd-NVP at the onset of labour for prophylaxis were 89.5% lesslikly HIV infected than an infant delivered from mothers on HAART had 100% HIV free survival. The finding was consistent with other studies (10).
Therefore, it is necessary to find out if there are barriers to ARV usage among these infants and to eliminate these barriers to ensure all mother infants pair who test positive for HIV not only

receive but are adherent to ARVs for prophylaxis. This is consistent with other study, in which the pregnant women who were identified to be sero-positive and received ARV prophylaxis were 89.6%, 6.9% did not receive the service and one of the women refused (24). The majority of women on prophylactic ARVs were on HAART (53.1%) as is stipulated in (13): Tenofovir and Efavirenz based regimens are recommended in recognition of their more favorable safety profiles compared with AZT and NVP (17).

The median gestational age at enrollment into PMTCT programme was 28 weeks. Beginning antiretroviral therapy before the twelfth week of life reduces HIV related mortality in children living with HIV by 75% (6).

Moreover, duration of ART treatment also matter the probability of infection, the mother who received ART more than 4 weeks prior to delivery was less likely to be MTCT rate at 6 week or 5.5% compared to mothers receiving ART for a shorter time or less than four weeks which was 9.3% (28). MTCT in women on ART, this shows longer time on ART lower chance they have to transmit HIV to their infants. This approaches to the number of women whose CD_4 counts were above 500 mm^3 (36.2%) which is the current guideline for initiation of triple ARVs. If the mothers are not getting ARV or ART then transmission rates were vary by CD_4 count (28).

Those infants born from mothers who did not receive either ARV or ART prophylaxis were having a greater risk of HIV infection. In this finding 6.9% of mothers did not receive either ART/ARV prophylaxis; this was consistence with other studies (8, 18, 29). The justification was taking ART or ARV could reduce maternal viral load and transmission of the virus to the newborns; those having no history of treatment were more likely to infect their babies than their counterparts. This finding is consistent with other studies (8, 15, 18). Without any treatment, 20-45% of babies born to HIV positive mothers will start life infected (1, 9) and almost half of these will die before they are two years old (1, 6, 8, 18).

Therefore, there should a need for repeated ART adherence counseling, health education on ART and related side effects, and more community involvement in all ART and PMTCT activities. In-depth interviews revealed that women main motivation for ART adherence was to protect the infant from HIV infection (15). Asella teaching and referral hospital can certainly take up this new directive to eliminate mother to child transmission of HIV.

As regards to PMTCT interventions in infants prophylactic ARV usage among HIV exposed infant was lower than maternal ARV usage at 75.4% and majority of these infants (71.5%) were on Nevirapine syrup for 6 weeks for infant who DNA/PCR test was negative. This may be explained by the fact that Nevirapine syrup is given at the time of delivery whereas maternal ARV is given at the ANC visit (97.7%) or/and at ART clinic follow up periods. Those infants who did not receive ARV prophylaxis right after birth were at risk of acquiring HIV infection. In this study 75.4% of infants had received ARV for a prophylaxis which was a challenge to Ethiopian 2015, goal to increase proportion of HIV exposed infants who receive ARV prophylaxis to 90% (13).

Surprisingly there is no death among exposed and infected infant in the study period; this might be achieved due to ARV improves maternal health, which in turn improves child's survival, followed by different chances like, current high coverage of ANC (97.7%) even though it has no statistical significance with the outcome variables, ANC clinically important for improved maternal health, promoted skilled health facility delivery (90.2%), exclusive breast feeding for the first 6 months (90.8%) and through clinical pharmacist ensuring appropriate counseling services and additionally there was mother to mother counseling in this study hospital. Overall, the summation of these activities resulted in absence of infant death before 18 months of life at the study hospital.

In addition, for enhanced survival infants whose mothers should be encouraged to exclusively breastfed her infants for the first 6 months of life and to continue to do so for up to 1 year which was consistence with other studies (29) and when HIV infected mothers decide to stop breastfeeding, they should do so gradually within one month. This will result in improved nutritional intake and HIV free survival among HIV exposed infants and overall improved infant survival (28). This study provides further evidence based data that maternal using two or three ARV/ART drugs extends infant life. The survival benefit of ART programs in the study area should be promoted in the community.

An infant who's DBS (DNA/PCR) test done before 6 weeks of age were 19.2%. Yet in 2013, only 42% of infants born to mothers living with HIV in low and middle income countries received this test within two months as recommended by WHO (6). And also, in Ethiopian, Percentage of HIV exposed infants receiving a virological test for HIV within 2 months of birth

was 21% (13). So, DBS/ PCR test done after 6 weeks was more likely to result in HIV positive status than infants tested at the right time. The justification may be due to early infant diagnosis identifies infants infected with HIV and starts them on ART to improve their survival (3), while the infant diagnosed after 6 weeks were more likely exposed to HIV infection as a 0.2% probability of transmission per month of breastfeeding (27).

Place of delivery can also matters infant HIV free survivals; as this study shows infants born at home were 8 times less likely to be in HIV free survival compared to those born at the health facility. The risk of intra-partum transmission increases with intrapartum bleeding, premature rupture of membrane, prolonged labor more than 4 hour after membrane rupture, chorioamninitis and cervico-vaginal infection (32). This is because of the fact that women attending skilled delivery service would be given ART or ARV prophylaxis for PMTCT of HIV during labor and delivery (36). Even, HIV exposed newborns would have the opportunity to receive ARV prophylaxis immediately, thereby minimizing the risk of acquiring HIV infection during labor and delivery as the highest proportion of newborns are infected during this time. This finding is consistent with other studies (24, 32). However, in this study 9.2% women did not attend skilled delivery care, leaving the devastating effects of HIV to their children. This finding is consistent with other studies (36, 29).

Infant feeding practices showed a higher prevalence of EBF in this population of HIV exposed infant at Asella teaching and referral hospital at 90.8% was higher than the country prevalence which is 32% (13), Consistent with other studies (26). Yet breastfeeding has remained the most common culturally accepted method of feeding the baby; in west Oromia region as replacement feeding is mostly associated with stigma and discrimination (33). There were high rates of mixed feeding -9.2% and these infants were 2 times less likely to have HIV free survival compared to infants who practice exclusively breastfeed.

The mechanism by which EBF is associated with lower MTCT is not fully understood, however they include: the maintenance of integrity of the infant's gastrointestinal barrier, which is regarded as the primary mode of infection (34). Secondly, the immunological factors in the breast milk are said to be responsible for the reduction of viral activity in the human milk (24). Thirdly, EBF maintains the integrity of the mammary epithelial lining and promotes overall breast health (35). Recently a protein known as Tenascin-C, an innate mucosal host protein found in milk has been identified and is capable of neutralizing HIV-1 through binding to

chemokine core receptor site. This finding potentially explains why the majority of HIV exposed breastfed infants are protected against mucosal HIV transmission (35).

The 6 week and 6 month MTCT rates was 3.1% and 3.8% respectively seen at Asella teaching and referral hospital are close to those seen in the Kisumu breastfeeding study among this same group of mother-infant pairs which were 4.2% and 7.0% respectively (36) and 4.1% at six weeks and 5.0% at six months (15). For HIV exposed children EBF was recommended for the first six months with introduction of healthy, balanced, and appropriate complementary food at six months and continuation of breastfeeding without exceeding the maximum recommended duration of 18 months. If the mother decided to wean after EBF for six month: weaning should be done gradually over a period of one month as showed in other studies (28) in conjunction with advice and nutritional support as showed in other studies (19) abrupt weaning has its accompanying problems such as poor hygiene, diarrhea and malnutrition as showed in other studies (1).

This study found that 97.7% of mothers had CD_4 counts taken before last pregnancy. This correlates with other studies (9, 13). This may mean that HIV testing services have been rolled out for every pregnant mother attending ANC is offered an opportunity to test for HIV. Infants whose mothers had CD_4 counts before pregnancy were more likely to survive within the first 18 months of life than mothers who did not. Possible explanations for this is at these women have had the opportunity to be enrolled in care and where necessary have had ARVs initiated to suppress viral load (29).

Infant birth weight also matter the chance of MTCT of HIV. In Asella teaching and referral hospital finding infants birth weight < 2.5 kilo grams was 23.1%. This finding is consistence with (36) and which were 2.7 times less likely to be HIV free survive compared to infants who were birth weight > 2.5 kilo grams. Other explanations for this 19.4% of infant were infected when infant birth weight was < 2.5 kilo grams while 4% so as counterpart. Cohort study network's surveillance monitoring for ART toxicities showed that use of protease inhibitors early in pregnancy may be associated with increased risk of prematurity (2); However, ART alone does not appear to help children achieve full growth recovery or sustain their growth over the

long term (19). The extended maternal prophylaxis with ART results in low HIV transmission during breastfeeding and high HIV free infant survival at 18 months (15, 28).

The overall infant HIV free survival rate at 18 months was 92.3% is higher than other studies (10) found in northwest Ethiopia 89.9% and Rwandan 91.9% (21) and lower than other studies (16, 22). Women with preconception knowledge of own CD_4 count had slightly higher infant HIV free survival compared to women with no preconception knowledge of CD_4 tests before pregnancy. The overall infant HIV free survival rate at 18 months was higher than the country and United Nations high level meeting on AIDS 2011, leaders committed to achieve the goal of MTCT of HIV to less than 5% (1, 2, 14, 27, 28, 33) and eliminating new HIV infections among children by 2015 as stipulated in other studies (14, 19, 36).

7. Study limitations

This study was however, limited by the fact that it was conducted in only one referral hospital using secondary data; also difficult to obtain some essential information such as household monthly income, maternal viral load and time when infants prophylaxis were initiated from the charts. The relatively small sample size might also affect the power of the test.

Therefore, generalization of the findings may not be possible. Although this study might suffer from its lower precision, it would be valuable evidence to evaluate program effectiveness and provide a foundation for future intervention.

8. Conclusion

In conclusion, about one-hundred-twenty (92.3%) of the infants were not infected at their final infection status. While the infant HIV infection rate of 7.7% is above that required for virtual eMTCT of HIV. The PMTCT intervention uptake with specific reference to ARV usage for PMTCT shows higher uptake in mothers than in infants. However, the uptake of ARVs in infants falls below targets required for eMTCT of HIV, and the targets set in the Ethiopian national strategic plan for eMTCT of HIV <5% by 2015. Even though we were not achieved the countries strategic plan the struggle we ever had for PMTCT program we practiced were effective, up on routine follow up and adhered to the program. The MTCT rate increase substantially after 6 weeks indicating the urgent need for interventions to reduce breast milk transmission.

Furthermore, failure to provide mothers and infant ARV prophylaxis and maternal illness during pregnancy, home delivery, infant birth weight and mixed infant feeding practice in the first 6 months of life was the factors that affecting infant HIV free survival.

9. Recommendations

- We need to address the sub-optimal ARV coverage among HIV positive women and their infants by identifying barriers to ARV/ART usage in these groups and eliminating these barriers.
- All women should be encouraged on testing for HIV during pregnancy.
- CD_4 count should be mandatory and routinely done to all HIV positive mothers and DNA/ PCR test for HIV infected infants and improve laboratory diagnostic capacity for early infant diagnosis.
- We should encourage safe breastfeeding practices at Asella teaching and referral hospital by ensuring all HIV positive lactating women are on ARV/ART and counseling them on the importance of EBF of their infants for the first 6 months of life while mixed feeding should be discouraged in our counseling. Mothers should also be counseled on proper weaning practices and encouraged to breastfeed their infants until they are in the first birth day to enhance infant survival.
- A research at the national level involving more health facilities needs to be done to assess effectiveness of PMTCT programme.

References:

1. Barnabas R, Rukundo A, Mutibwa D, Sebikali J, Tumusiime D, Turyamureeba R, et al. Knowledge and practices of women regarding PMTCT in Mwizi sub county a micro-research report March, 2012.
2. Olubukola A, Kuti M, Taiwo B, Berzins B, Demetrious N, Ellen G. Ogunbosi O.*et al.* Missed opportunities for PMTCT of HIV in Ibadan, southwest Nigeria. World Journal of AIDS 2014 (4) 356-364.
3. MoHSW. Tanzania national guidelines for comprehensive care services for PMTCT of HIV and keeping mothers alive September, 2013.
4. UNAIDS. Global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive. Geneva: joint United Nations programme on HIV/AIDS 2011.
5. Elena G, Miller L, Spensley A. Country adaptation of the 2010 WHO recommendations for the PMTCT of HIV bull world health organ 2012; 90:921–931.
6. UNAIDS. The gap report children and pregnant women living with HIV July 2014.
7. Nigatu T, Woldegebriel Y. Analysis of PMTCT service utilization in Ethiopia reproductive health 2011; 8(6).
8. Ishikawa N, Shimbo T, Miyano S, Sikazwe I, Mwango A, Massimo N. et al. Health outcomes and cost impact of the new WHO 2013 guidelines on prevention of MTCT of HIV in Zambia 2014; 9(3).
9. Hussein I, Ali A. Pregnant women's satisfaction and comprehension level of information given during HIV counseling and testing for PMTCT in public health facilities in Addis Ababa, Ethiopia journal health Dev. 2011; 25(2).
10. Bezabhe W, Woldesellassie M, Gregory M, Bereznicki L, Chalmers L, Peter G. Adherence to ART in adult patients who are HIV-positive in northwest Ethiopia: a study protocol. Bio med journal open 2013; 3(59).
11. FDRE. Country progress report on HIV/AIDS response March 31, 2012.
12. FMOH. Guidelines for PMTCT of HIV in Ethiopia federal HIV/AIDS prevention and control office August 2011.
13. FDRE. Country progress report on the HIV response March 2014.

14. FDRE. MOH. The national strategic plan for eMTCT of HIV 2013-2015 September, 2013.
15. Matilda M. PMTCT of HIV by ART and the impact on maternal health in Dares Salaam, Tanzania 2014.
16. Derebe G, Biadgilign S, Trivelli M, Hundessa G, Robi Z, Mikael G. et al. Determinant and outcome of early diagnosis of HIV infection among HIV-exposed infants in southwest Ethiopia. Biomedical center Research Notes 2014 7:309.
17. Doherty M. The WHO guidelines for antiretroviral therapy: evidence-based recommendations to face new epidemic realities 2013.
18. Onankpa B, Yusuf T. PCR pattern of HIV-exposed infants in a tertiary hospital: Pan African medical journal 2014; 18(345).
19. Nlend A. The therapeutic committee of centre hospitalized 'ESSOS Djoungolo: birth outcomes in HIV-1-infected women receiving HAART prior to conception versus during pregnancy in Yaounde, Cameroon 2014; 6: 135-138.
20. Sugandhi N. Pediatric AIDS in the elimination agenda. Public library of science August 2013; 10(8).
21. Ruton E, Mugwaneza P, Shema N, Lyambabaje A, Bizimana D, Tsague L, et al. et al. HIV-free survival among nine to 24 month old children born to HIV positive mothers in the Rwandan national PMTCT programme: a community-based household survey. Journal of the international AIDS society 2012; 15(4).
22. Tulloch K. Prevention of mother to child transmission of HIV/ AIDS: Children's and women health center of British Columbia 2012; 26(6):757-63.
23. Daniel A. Effectiveness of PMTCT programs in sub Saharan Africa, a meta-analysis, 2012.
24. Wanzahun G, Atta A. Prevalence of HIV/AIDS and its associated factors PMTCT service users in Jinka town health institutions, south Omo Zone, south Ethiopia. Science journal of public health 2013; 1(3):125-130.
25. Gourlay A, Birdthistle I, Mburu G, Iorpenda K, Wringe A. Barriers and facilitating factors to the uptake of ARV for PMTCT of HIV in sub Saharan Africa: a systematic review the international journal of AIDS society 2013;16:18588 Available at http://www.jiasociety.org/index.php/jias/article/view/18588

26. Muluye D, Wolde Y, Gizachew M, Tiruneh M. Infant feeding practice and associated factors of HIV positive mothers attending PMTCT and ART clinics in Gondar town health institutions, northwest Ethiopia. Biomedical Center public health 2012; 12:240.
27. Rollins N, Mahy M, Becquet R, Kuhn L, Creek T, Mofenson L. Estimates of peripartum and postnatal MTCT probabilities of HIV for use in spectrum and other population based models 2012; 88:44–51.
28. WHO. Report from the consultative meeting on updating estimates of MTCT rates of HIV 1-2, Washington DC January 2011.
29. Emily W**.** Effectiveness of PMTCT at Naivasha district hospital, Kenya: Outcomes of HIV exposed infants 2014.
30. Doherty N, Biadgilign S, Trivelli M, Hundessa G, Robi D, Makonnen M, et al. The WHO guidelines for ART: evidence based recommendations to face new epidemic realities November 2013.
31. Nicole H, Grace M. immunology of pediatric HIV infection children's hospital Los Angeles July 01, 2014
32. Mirkuzie H, Hinderaker G, Molla M, Marie K, Moland O. Current status of medication adherence and infant follow up in the PMTCT of HIV programme in Addis Ababa: a cohort study journal of the international AIDS Society 2011; 14 (50).
33. Abebe B. EBF knowledge of HIV positive mothers and associated factors in selected health institution of west Oromiya, Ethiopia: universal journal of food and nutrition science 2014; 2 (3): 37-44, available at http://www.hrpub.org
34. Sint T, Lovich R, Hammond W, Kim M, Melillo S, Luf L, et al. Challenges in infant and young child nutrition in the context of HIV/ AIDS November 2013; 27(02).
35. Genevieve G. Frederick H, Joshua D, Carrie H, Erika L, Lisa W, et al. Tenascin-C is an innate broad-spectrum, HIV neutralizing protein in breast milk PNAS October, 2013.
36. Berhan Z. Prevalence of HIV and associated factors among infants born to HIV positive women in Amhara region, Ethiopia. International journal of clinical medicine 2014; 5:464-474. Available at http://dx.doi.org/10.4236/ijcm

Appendix I: Data collection form

Data abstraction format

Will be used in abstracting mothers and HIV exposed infants data from client's record

Part I: Mothers

Section A: Socio-demographics

Questions

1. Mothers age: ----------years
    a. 15-24
    b. 25-34
    c. ≥ 35
2. Level of education
    a. Primary school
    b. Secondary school
    c. College/University
    d. Illiterate
3. Marital status
    a. Single
    b. Married
    c. Separated/ divorced/ Widowed

Section B: Pregnancy intention

4. Did you have CD_4 counts loads taken before your last pregnancy?
    a. Yes
    b. No
5. If # 4 yes, what was the CD_4 count in---------- mm^3?
    a. < 350
    b. 350-500
    c. > 500
6. Antenatal care clinic attend?
    a. Yes
    b. No
7. If # 6 yes, how many visits?

a. Only 1

b. 2-3 times

c. 4 times

8. Were you on ARVs prior to pregnancy with this infant?
    a. Yes
    b. No
9. If # 8 yes, please specify which ones?
        a. AZT + 3TC during pregnancy
        b. Sd-NVP at the onset of labor
        c. HAART
        d. None taken
10. Were ART drugs initiated?
    a. During pregnancy
    b. During labor/ delivery
    c. After delivery for a short period of time
    d. During breastfeeding
11. What was the maturity of your pregnancy at the time of diagnosis?
    a. < 12weeks
    b. 12-24 weeks
    c. 24-36 weeks
    d. > 36 weeks
12. Any illness during pregnancy?
    a. Yes
    b. No
13. Where did you deliver?
    a. Public health facility
    b. Home
14. How did you deliver your child?
        a. Normal delivery
        b. Caesarean section
15. What feeding option was chosen for infants first 6 months of life?

a. Exclusive breast feeding
b. Mixed feeding

Part ii. Information to be extracted from infant health records

16. What is current age of infant----------?
17. What is gender of infant?
    a. Male
    b. Female
18. What was the infant birth weight?
    a. < 2.5 kg
    b. > 2.5 kg
19. Did child receive ART prophylaxis?
    a. Yes
    b. No
20. What drugs were given?
    a. NVP syrup
    b. AZT syrup
    c. AZT+ 3TC
21. Is child still taking drugs?
    a. Yes
    b. No
22. Has your child tested for HIV?
    a. Yes
    b. No
23. If # 23 yes, what is the HIV test result?
    a. Negative
    b. Positive
24. If # 24 positive, has CD_4 been done?
    a. Yes
    b. No
25. If CD_4 test done, please state the result -----
26. Is child is on ART for treatment?

a. Yes

b. No

27. If on treatment, please state drugs given

    a. AZT, 3TC, NVP

    b. AZT, 3TC, LPV/R

    c. ABC, 3TC, NVP

    d. Other specify……

28. What was the DBS result?

    a. Positive

    b. Negative

29. At what age was DBS (DNA/ PCR) done?

    a. < 6 weeks

    b. > 6weeks

30. Status of the child after 18 months?

    a. Positive

    b. Negative

Appendix II: Addis Ababa University research and ethics committee clearance letter.

Addis Ababa University

School of Pharmacy
Ethical Review Board

Date: March 02, 2015

Ref. No: ERB/SOP/43/02/2015

To: Mama Abdulla
School of Pharmacy

Subject: Ethical Clearance

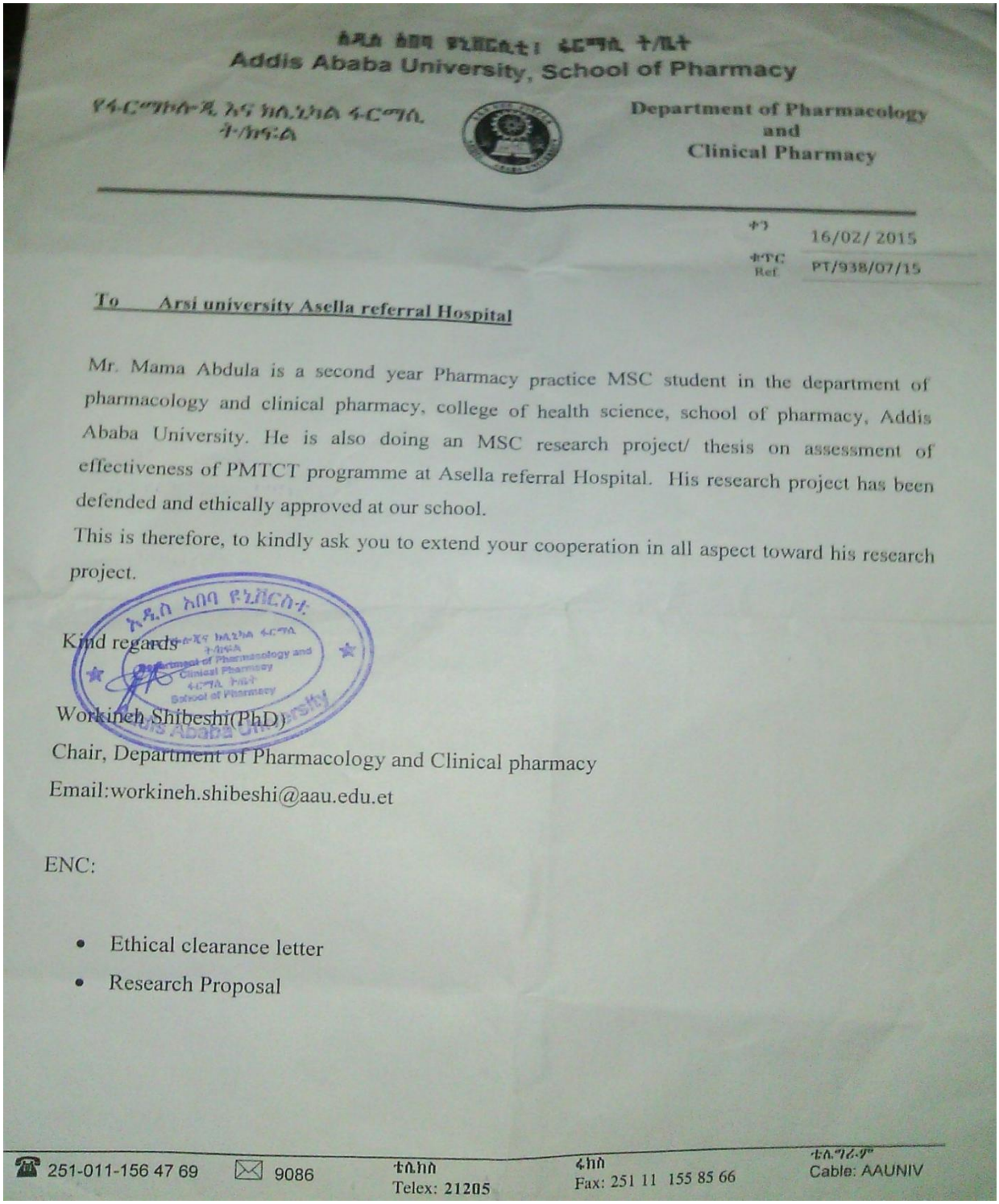
It is to be recalled that you submitted a study proposal entitled, "Assessment of effectiveness of prevention of mother to child transmission of HIV among HIV positive women's in Arsi University Asella health and referral hospital: Retrospective cross-sectional study", for ethical approval by the School's Ethical Review Board (ERB). The Board thoroughly reviewed the proposal based on its operational guidelines and found it to fulfill all ethical requirements stipulated in the guidelines. This is, therefore, to inform you that the proposal is ethically approved for implementation.

With best regards,

Esubalew Adugna (BPharm, MSc)
Secretary, ERB

School of Pharmacy
Addis Ababa University

Appendix III: Addis Ababa University School of pharmacy, Department of pharmacology and clinical pharmacy approval letter.



አዲስ አበባ ዩኒቨርሲቲ፣ ፋርማሲ ት/ቤት
Addis Ababa University, School of Pharmacy

የፋርማኮሎጂ እና ክሊኒካል ፋርማሲ ት/ክፍል

Department of Pharmacology and Clinical Pharmacy

ቀን 16/02/ 2015

ቁጥር Ref PT/938/07/15

To Arsi university Asella referral Hospital

Mr. Mama Abdula is a second year Pharmacy practice MSC student in the department of pharmacology and clinical pharmacy, college of health science, school of pharmacy, Addis Ababa University. He is also doing an MSC research project/ thesis on assessment of effectiveness of PMTCT programme at Asella referral Hospital. His research project has been defended and ethically approved at our school.

This is therefore, to kindly ask you to extend your cooperation in all aspect toward his research project.

Kind regards

Workineh Shibeshi(PhD)

Chair, Department of Pharmacology and Clinical pharmacy

Email:workineh.shibeshi@aau.edu.et

ENC:

- Ethical clearance letter
- Research Proposal

☎ 251-011-156 47 69 ✉ 9086 ቴሌክስ Telex: 21205 ፋክስ Fax: 251 11 155 85 66 ቴሌግራም Cable: AAUNIV

Appendix IV: Permission to conduct the study letter from the Aris University Authority.

አርሲ ዩኒቨርሲቲ

ጤና ሳይንስ ኮሌጅ

ስልክ 251-223-311-231
ፋክስ +251-223-313-533
✉ 04,396 ,አሰላ ኢትዮጵያ
E- mail dejenlem2012@gmail

ARSI UNIVERSITY

COLLEGE OF HEALTH SCIENCES

Phone : 251-233-311-231
Fax:+251-223-313-533
✉ 04 or 396 Asella , Ethiopia
E- mail dejenlem2012@gmail

ቀን/Date 23/02/15

ቁጥር/Ref AU/HLSIC/SM/142/233

Chief Clinical Director

Dejene Lemma (MD. Pediatriacian)

Enquiry: Mr. Mama Abdula Seid

Greeting,

Re: Permission to conduct the study entitled: Assessment of effectiveness of prevention of mother to child transmission of HIV among HIV positive women's in Aris University Collage of health sciences, Asella teaching and referral hospital, Ethiopia.

1. Letter from Addis Abebe University and research proposal was referred.
2. Permission to conduct the above mentioned study is herby garneted.
3. Kindly be informed that; in the course of your study there should be no action that disrupts the services.
4. After compilation of the study a copy should be submitted to the hospital to serve as resource.

Your cooperation was highly appreciated.

Aris University Collage of health sciences
Asella teaching and referral hospital
Chief clinical director

Dir Dejene Lemma
Pediatrics
Chief Clinical Dir

Arsi University College of Health Sciences