FACTORS AFFECTING ADHERENCE TO TREATMENT IN HIV EXPOSED INFANTS IN MUMIAS REGION, WESTERN KENYA

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JOMO KENYATTA UNIVERSITY OF AGRICULTURE AND TECHNOLOGY

2016

Factors affecting adherence to treatment in HIV exposed infants in Mumias region, Western Kenya

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A thesis submitted in partial fulfillment for the Degree of Master of Science in Epidemiology in the Jomo Kenyatta University of Agriculture and Technology

2016

DECLARATION

This thesis is my original work and has not been presented in any other University.

Signature…..... Date….....

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This thesis has been submitted for examination with our approval as University supervisors.

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DEDICATION

I dedicate this work to God the Almighty, my family especially my Dad, Mum and my Husband for their continuous support throughout my study period.

ACKNOWLEDGEMENT

Special thanks go to the Institute of Tropical Medicine and Infectious Diseases and Jomo Kenyatta University of Agriculture and Technology for allowing me to pursue my graduate degree in their institutions. My sincere gratitude goes to my supervisors Prof. Matilu Mwau and Dr. Joseph Ng'ang'a for their guidance during my research.

My special thanks also go to my family members especially my Parents and Husband for the encouragement and financial assistance.

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ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral
CDC	Centre for Disease Control
CHW	Community Health Worker
DNA	Deoxyribonucleic Acid
EID	Early Infant Diagnosis
ELISA	Enzyme-Linked Immunosorbent Assay
HIV	Human Immunodeficiency Virus
KEMRI	Kenya Medical Research Institute
MCT	Mother to Child Transmission
NASCOP	National Aids and STI Control Program
PCR	Polymerase Chain Reaction
PMTCT	Prevention of Mother to Child Transmission
STIs	Sexually Transmitted infections
UNICEF	United Nations Children and Education Fund
NVP	Nevirapine
EFV	Efavirenz
3TC	Lamivudine
ZDV	Zidovudine
HIV	Human Immunodeficiency Virus

ABSTRACT

Kenya runs a robust Prevention of Mother to child Transmission (PMTCT) of Human Immunodeficiency virus (HIV) Program. Early Infant Diagnosis (EID) supports PMTCT. Human Immunodeficiency virus exposed infants are either put on prophylaxis or antiretroviral therapy (ART) treatment depending on their HIV status. However, the extent of adherence to treatment in HIV exposed infants in low resource setting is unknown. Factors, which affect adherence to treatment in Mumias region, are unknown. To address this knowledge gap, this study aimed at determining the factors that affect adherence to treatment in HIV exposed infants in selected Early Infant Diagnosis (EID) sites in Mumias region, Western Kenya. This was a cross-sectional analytical study. The number of missed appointments defined adherence. The respondents were caregivers with HIV exposed infants. Variables collected using questionnaires included age and sex of the caregiver, level of education, income level, occupation, religion, marital status, number of children, children infected, HIV status of the infant, cost associated with access to the health facility. A univariable regression model was used to describe relationship between various variables and adherence to treatment. The study enrolled 384 participants who presented their HIV exposed infants in health facilities for treatment and care. The Roche Amplicor_ HIV DNA PCR kit was used to test for HIV status of the exposed infants. The health facilities include St. Mary's Mission Hospital, Mumias Model Health Centre, Mumias Sugar Clinic, Matungu Sub-County Hospital, Bukaya Health Centre, Malaa Health Centre, and Makunga Health Centre. The study recruited per health facility, as follows 116, 35, 60, 89, 32, 21 and 31 respectively. Nearly all (97.9%) the participants were female and 85.4% of them were married. Their age ranged from 15 to 66 years. The mean age was 32.8 years with a median age of 33 years. More than half (66.7%) of the respondents were Christians, 31.8% of them were Muslim and 0.5% were traditionalists. Majority (71.9%) of the participants reported social stigma from friends, family and community. On the other hand, 12.5% of the respondents lacked formal education while 53.9% of them attended primary school, 25.5% of them completed secondary education. Only 8.1% of the respondents had attained tertiary education. Majority (60.7%) of the

participants had one child while the rest (35.4%) had more than one child under their care. This was separate from the HIV exposed infant recruited in the study. According to the study responses, more than half (56.3%) of the respondents were employed. In terms of EID education, nearly all (95.7%) the respondents had undergone training on the importance of EID to HIV exposed infants. According to the study responses, 95% of the respondents who earn less than 500 shillings a month had to have at least 51 shillings for them to access treatment in terms of transport. In terms of transport, respondents who earn more than 3000 shillings a month had to incur at least 40 shillings as transport cost. Laboratory results indicated that 5.2% (20 out of 384) of the HIV exposed infants were HIV positive. Nearly half (49.8%) of the HIV exposed infants adhered to treatment. The odds ratio of non-adherence in a respondent who had any ill child was 5.3 (95%CI, 1.6-18.3, P<0.05). Similarly the odds ratio of adherence among respondents with four children under their care was 2.7 (95%CI, 1.0-6.8, P<0.05). Respondents who used less than Ksh.50 as transport cost were more likely to adhere to treatment (OR 1.7, 95% CI 1.1-2.6). Respondents who were given monetary assistance from family members or spouse were less likely to adhere to treatment (OR 0.5, 95%CI, 0.20-0.99, p<0.05). Several factors like transport cost to the health facility, presence of any other ill child, number of children and monetary assistance affect adherence to treatment in HIV-exposed infants. Therefore, efforts must concentrate on addressing the needs that reduce vulnerability of life groups such as infants and women in terms of HIV.

CHAPTER ONE

INTRODUCTION

1.1 Background of the Study

Early diagnosis of human immunodeficiency virus (HIV) in exposed infants and prompt initiation of treatment are critical steps in Prevention of Mother to Child Transmission (PMTCT) of the disease. Mother to Child Transmission (MTCT) of HIV can occur in utero, during delivery or through breastfeeding (NASCOP, 2012). The importance of initiating antiretroviral therapy in HIV positive infants is to increase their chances of survival (Killam *et al.,* 2010). Outcomes of treatment in HIV-exposed infants has shown antiretroviral therapy reduces infant death and HIV infection (Persaud *et al.,* 2011).

Besides initiating treatment, early infant diagnosis (EID) involves management and care of uninfected infants to minimize post-natal transmission of HIV (Persaud *et al.,* 2011). National AIDS and STI Control Programme (NASCOP) has provided an algorithm on management of HIV-exposed infants. The interventions include HIV testing in exposed infants, relay of results to mother and health provider, provision of prophylaxis for all HIV-exposed infants, initiation of antiretroviral therapy (ART) for HIV positive infants, guidance on the feeding methods and retesting of infants at 9 and 18 months to capture post-natal transmissions (NASCOP, 2014).

Although NASCOP has provided clear guidelines on treatment of HIV-exposed infants, Kenya still accounts for 4% of all new pediatric HIV infections in the world (Sirengo *et al.,* 2014). Every year, Kenya records 13000 new HIV infections resulting from mother to child transmission (MTCT) (Sirengo *et al.,* 2014). There are challenges that affect treatment and care of infants in low-resource settings especially in rural areas (Busza *et al.,* 2012). The turnaround time for results is between 1-3 months long. The long turnaround time leads to loss of follow up of HIV-exposed infants who consent and enroll into the EID program (Hassan *et al.,* 2012). Level of adherence of the infants under the EID program has been reported to be less than

50% (Nyandiko *et al*., 2010). There is communication breakdown between the testing laboratory and health provider on lost or delayed samples (Creek and Smith, 2008). Although NASCOP carries out frequent outreach programs, HIV positive mothers face individual barriers that interfere with HIV treatment and care. It has been reported that mothers lack awareness of the existence of the EID program, fear stigmatization and lack resources of transportation to the health facility (Manzi *et al*., 2005).

No study has reported on the individual barriers of caregivers under EID in Mumias region. Mumias is located in Kakamega County. Mumias is divided into two sub counties Mumias East and Mumias West. According to the 2009 census, the population of Mumias is 116,358. The main tribe in Mumias is Luhya. Mumias Sugar Company is the major employer in the region. Furthermore, the company has employees from other regions of Kenya. Mumias is linked by Busia County on the West and Bungoma County on the North. Mumias is a good study area because the prevalence of HIV in Kakamega County is 5.9% (NASCOP, 2014). In addition, the HIV prevalence among women in Kakamega County is 7.3% (NASCOP, 2014). Mumias town is in close proximity with Counties such as Busia, Kisumu and Siaya, which have HIV prevalence of 6.8%, 19.3% and 23.7% respectively (NASCOP, 2014). The main EID sites in Mumias include St. Mary's Mission Hospital, Matungu Sub-county hospital, Mumias Sugar Clinic, Mumias Model Health Centre, Makunga Health Centre, Bukaya Health Centre and Malaa Health Centre.

HIV-exposed infants present a variety of social, economic and demographic factors, affect adherence to treatment. The aim of this study is to address the gap in the knowledge on the factors that affect treatment of HIV-exposed infants in selected EID sites in Mumias region, Western Kenya.

1.2 Statement of the problem

The outcomes of treatment in HIV-exposed infants has shown antiretroviral therapy reduces infant death and HIV infection. However, this is only possible if the treatment of the HIV-exposed infants is initiated early especially for HIV positive

infants. Early infant diagnosis prevents mother to child transmission of HIV. Early infant diagnosis in low-resource setting has multiple gaps; consequently HIV-exposed infants die before reaching two years of age (Newell *et al*., 2004). Mumias is a low-resource setting region in Western, Kenya. There is little knowledge about HIV-exposed infants who are under EID program in this region. Social, economic and demographic factors that affect treatment of HIV-exposed in rural areas have been poorly documented in this region. In addition, the aforementioned factors remain unknown in Kenya especially in Mumias region.

1.3 Justification

It has been reported that less than one-third of Kenya's HIV-infected infants receive antiretroviral therapy (WHO, 2012). Although NASCOP has provided clear guidelines on treatment of HIV-exposed infants, Kenya still accounts for 4% of all new pediatric HIV infections in the world (Sirengo *et al.,* 2014). In addition, the level of adherence to treatment in infants under the EID program in Kenya has been reported to be less than 50% (Nyandiko *et al*., 2010). There are challenges that affect treatment of infants in rural areas (Busza *et al.,* 2012). Inadequate knowledge on the social, economic and demographic description of HIV-exposed infants contributes to poor enrollment into treatment. Little is known about other factors that affect management of HIV-exposed infants in Mumias. This is crucial in reducing infant mortality caused by HIV. This study will provide much needed information on factors that affect treatment of HIV-exposed infants in Mumias.

1.4 Research Questions

1) What are the social, economic and demographic factors of HIV-exposed infants who get into treatment?
2) What is the level of adherence between HIV positive infants and HIV negative infants under EID program in Mumias?
3) Which factors affect adherence to treatment in HIV-exposed infants?

1.5 Objectives

1.5.1 General Objective

The main objective was to determine the factors that affect adherence to treatment in HIV exposed infants in selected EID sites in Mumias region, western Kenya.

1.5.2 Specific Objectives

1) To describe the social, economic and demographic characteristics of the caregivers who bring their HIV-exposed infants into treatment.

2) To determine the level of adherence between HIV infected infants and uninfected infants.

3) To determine factors that affect adherence to treatment in HIV-exposed infants.

CHAPTER TWO

LITERATURE REVIEW

2.1 Human Immunodeficiency Virus

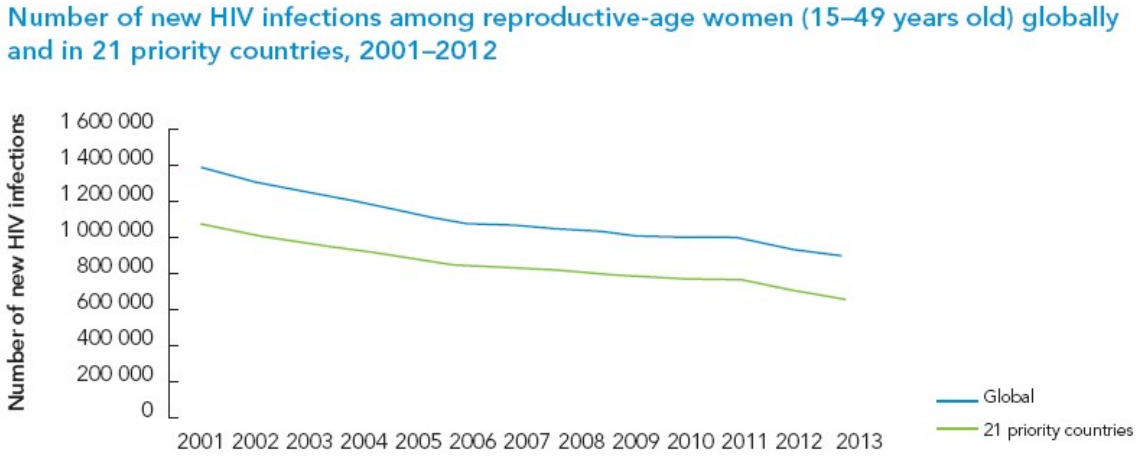
The Human Immunodeficiency Virus (HIV) is a blood-borne virus (Beck *et al*., 2001). Human immunodeficiency virus is commonly transmitted through sex with an infected person, sharing of needles with a HIV positive person and through mother to child during pregnancy. Human immunodeficiency virus transmission in infants occurs either antepartum, intrapartum or during postpartum (Ng'eno *et al*., 2014).

2.2 HIV Burden in Women

Women account for nearly half of the 36.9 Million people living with HIV in the world (WHO 2014).The affected women are from developing countries. In Sub-Saharan Africa HIV, disproportionately affect women (Quinn & Overbaugh, 2005). In 2013, in Sub-Saharan Africa an estimated 380,000 (out of 2 Million) new HIV infections occurred among young women aged 15 to 24 years (Quinn & Overbaugh, 2005). About 16 Million women from Sub-Saharan Africa are infected with HIV (WHO, 2012). In 2014, 109500 out 1.5 Million pregnant women living with HIV in the world were on antiretroviral therapy (WHO, 2014).

The prevalence of HIV in Kenya is 6% (NASCOP, 2014). The prevalence rate of HIV-1 in Kenyan women is 7.6% while in men the prevalence is 5.6% (NASCOP, 2014). In Kenya women who are aged between 15 and 24 years, have a HIV incidence rate of 21% (NASCOP, 2012). Results from a national study in Kenya, show that women had a significant higher HIV prevalence than men (6.9% versus 4.4%) (Waruiru *et al*., 2014). The prevalence of HIV in women increases with age, peaking in the 35-39 years (Sirengo *et al.,* 2014). It has been reported that the proportion of women infected with HIV is high. For instance, in Kassanchis health centre in Ethiopia, 54.1% of the VCT clients are women (Koye & Mekuria, 2013).

Kenya is among the 21 priority a country with a high burden of HIV among women of childbearing age (Figure 2.1).



Source: UNAIDS estimates, 2013.

2.1: The HIV infection among reproductive-age women globally between 2001 to 2013.

According to a national survey in Kenya, women who lack formal education had a high HIV prevalence (1.3%, 95% CI: 0.1 to 2.6) than women with higher education levels (x^2=9.8, P=0.02, DF=3) (Sirengo *et al*., 2014). However, studies have shown that there is no statistical significance between level of education and HIV infection (p =0.653 and p = 0.469 for secondary and tertiary education respectively (Ng'ang'a *et al*., 2009).

2.2.1 Management of HIV in Women

Management of HIV in women involves a combination of nutritional factors and Antiretrovial therapy. Access to treatment begins with access to HIV counseling and testing (Waruiru *et al*., 2014). Treatment of HIV is important because it prevents and reduces HIV-related morbidity and mortality, preserve immune function, suppress viral replication, prevent emergence of drug-resistant, prevent transmissions and improve quality of life (Tonwe-Gold *et al*., 2009). In HIV positive mothers, the ultimate goal of treatment is to prevent HIV transmission to the child during pregnancy, birth and postpartum (PETRA, 2002).

Treatment involves a combination of different antiretroviral drugs. This drugs include Nucleoside reverse transcriptase inhibitors, Efavirenz, (EFV) and nevirapine (NVP); the non-nucleoside reverse transcriptase inhibitors include Lamivudine (3TC), abacavir (ABC),zidovudine (AZT), didanosine and tenofovir (NASCOP, 2011). Others include lopinavir (LPVr) and ritonavir. In Kenya, the ARV combinations are AZT/3TC/NVP, AZT/3TC/LPVr and AZT/3TC/ABC. Monitoring of CD4 count and viral load levels of the HIV positive women is also important during treatment of HIV. Polymerase chain reaction is used to determine the viral load (NASCOP, 2011).

2.3 HIV burden in Children

Majority of children acquire HIV from their HIV-infected mothers (Azcoaga-Lorenzo *et al*., 2011). This occurs during pregnancy, childbirth or while breastfeeding (Ng'eno *et al*., 2014). In 2013, an estimated 2.6 Million children out of 36.9 Million infected people were living with HIV in the world and 91% of the HIV infected children in the world are from sub-Saharan Africa (WHO, 2014). In 2014, 220,000 (out of 2 million) children below 15 years of age were infected with HIV (WHO, 2014). In Kenya 12940 out of 88,620 new HIV infections occurred among children below, 14 years of age (NASCOP, 2014). Kenya accounts for all 7% child death caused by HIV in the world (NASCOP, 2014). An estimated 15% of deaths of children below 5 years are due to HIV (Liu *et al*., 2012). HIV accounts for 1.5% of all deaths in infants below 12 months and 4.9% of deaths in children between 1 to 4 years of age (Azcoaga-Lorenzo *et al*., 2011). Kenya is among the 21 Global Plan Countries with the highest number (85%) of children living with HIV (Figure 2.2).

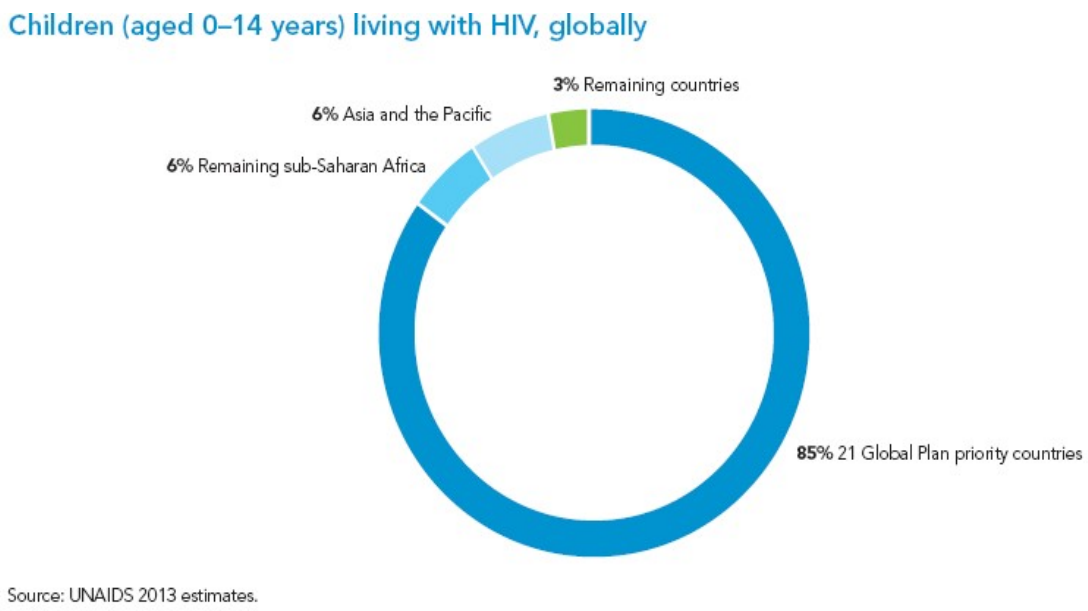


Figure2.2: HIV burden in children under 14 years worldwide.

Beginning ART in HIV-exposed children before they reach 12 weeks, reduces HIV-related mortality by 75% (Ekouevi *et al*., 2011). Failure to implement prevention of mother to child transmission has resulted into hundreds of thousands of preventable HIV infections among newborns (Bajunirwe and Muzoora, 2005). To achieve mother to child infections to <5% at 18 months researchers and policy makers need to evaluate emerging challenges that affect treatment of HIV (Ubesie, 2012).

2.3.1 Management of HIV in infants

Management of HIV infected and uninfected infants involve initiation of prophylactic and therapeutic medications, medical follow up, and management of intercurrent illnesses. It has been reported that 90% of pediatric HIV infections occur through MTCT (Shargie *et al*., 2014). Prevention of mother to child transmission is a key step in management of HIV infections in infants. Early Infant diagnosis of vertically acquired HIV infection has important implications for decisions concerning initiation of prophylactic and therapeutic medications (Azcoaga-Lorenzo *et al*., 2011). Early detection of HIV in infants is done using Polymerase Chain Reaction (PCR). In Kenya, the Ministry of Health has put in place guidelines used in the treatment of HIV exposed infants (Figure 2.3).

Treatment of HIV positive infant contains at least three drugs from two classes of Antiretroviral drugs (ARV) (WHO, 2010). The pediatric ARVs given to HIV positive infants in Kenya include Nevirapine (NVP) and Efavirenz (EFV), which are non-nucleoside reverse transcriptase inhibitors (NASCOP, 2014). Nucleoside reverse transcriptase inhibitors include lamivudine (3TC), Zidovudine (AZT), didanosine, abacavir and tenofir (NASCOP, 2014). The choice of ART regimen to HIV positive infants depends on whether they were exposed to ARVs before in utero, during childbirth or during breastfeeding (PETRA, 2002). Infant Prophylaxis includes NVP Only, NVP+AZT+3TC, NVP for 6 weeks, NVP during breastfeeding period (Persaud *et al*., 2011). The feeding regimens for the HIV exposed infants include exclusive breastfeeding, exclusive replacement feeding and mixed feeding (Shapiro and Lockman, 2010). Adherence to ART regimens and feeding regimens in HIV-exposed infants determines the effectiveness of treatment (Nassali *et al*., 2009). Adherence to treatment in HIV exposed infants depends on the mother.

2.4 Factors affecting Treatment of HIV in Women and Infants

A woman's health can be described in six dimensions: emotional, mental, social, cultural, spiritual and physical wellbeing (Figure 2.4) (Phillips, 1995).It is important to maintain and balance between the six different aspects of one's health. It has been reported that gender, disability, housing, early life experiences, income and income distribution, education, race, employment and working conditions, social exclusion, food insecurity, social safety net, health services and unemployment and job security as major socio-economic features affecting women (Raphael, 2009).

According to Health Canada, biology and genetics endowment, physical environments (neighborhood safety) and personal health practices and coping skills also affect health-seeking behavior of HIV positive women (Health Canada, 1994). The realities of HIV positive women can be described in terms of age, immigration, geographic location, childcare, culture, language, stigma, and discrimination (Greene *et al*., 2013). Other elements relevant to the physical dimension of HIV positive women's health, include HIV disease, antiretroviral therapy, comorbid conditions (Hepatitis C), and conditions specific to women (gynecologic diseases). From the

figure it is evident the components overlap and are not mutually exclusive. However, in practice, they may operate either alone or in combination with other elements simultaneously depending on the context (Carter *et al*., 2013).

The economic status of the family determines their priority to accessing basic needs like food and shelter (Muchedzi *et al*., 2010). The quality of services offered to the HIV positive mother and infant motivated them from accessing treatment (Chinkonde *et al*., 2009). The socioeconomic status of HIV positive mothers plays a significant role in accessing treatment among HIV exposed infants. For instance, it has been reported that HIV positive women from wealthier households are more likely to receive treatment than those from poor households (Koye & Mekuria, 2013). Furthermore, HIV positive women who are poor achieve low levels in adherence, live in rural areas (Quinn & Overbaugh, 2005). Studies have also examined education and poverty levels as having important implications in treatment of HIV in women (Issiaka *et al*., 2001).

Limited education attainment is associated with HIV-related risk behavior (Fylkesnes *et al*., 2001). Most HIV positive women are economically dependent on their partners (Krishnan *et al*., 2008). Although women with no formal education have low HIV prevalence levels, those infected lack resources to seek treatment (Bwirire *et al.*, 2008).

Access to basic education and income-generating programs promote independency among HIV positive women (Fawzi *et al*., 2010). Lack of financial security among HIV positive women contributed to high risk of HIV transmission (Magadi, 2011). A study done in Rift Valley showed that socioeconomic factors like acres of land owned, number of animals owned and cultivated farmlands determined the adherence to treatment of HIV positive women (Ng'ang'a *et al*., 2009). Efforts must concentrate on addressing the socioeconomic needs of HIV positive mothers.

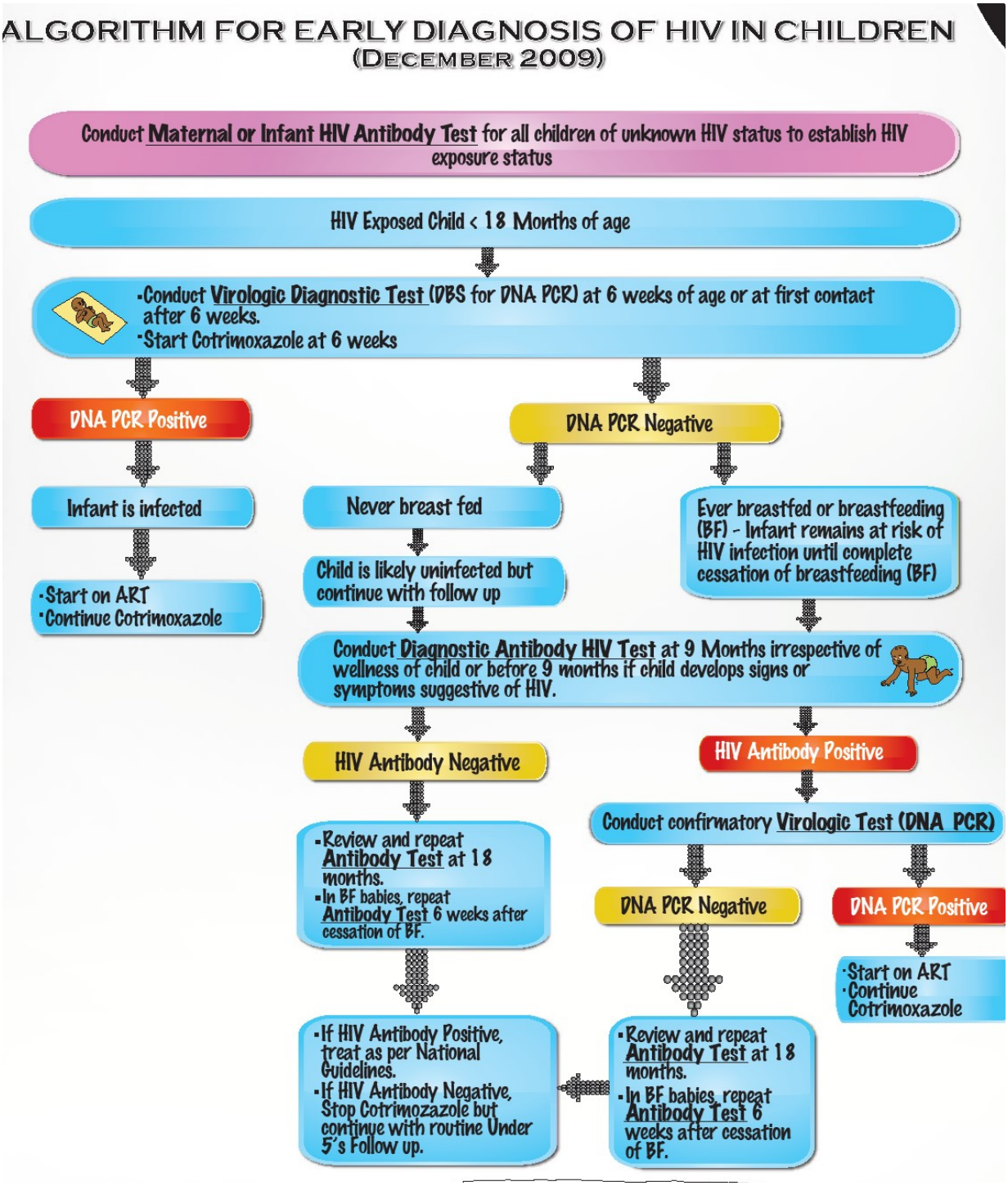


Figure 2.3: Standard treatment employed to HIV exposed infants in Kenya.

(Source: NASCOP, 2014)

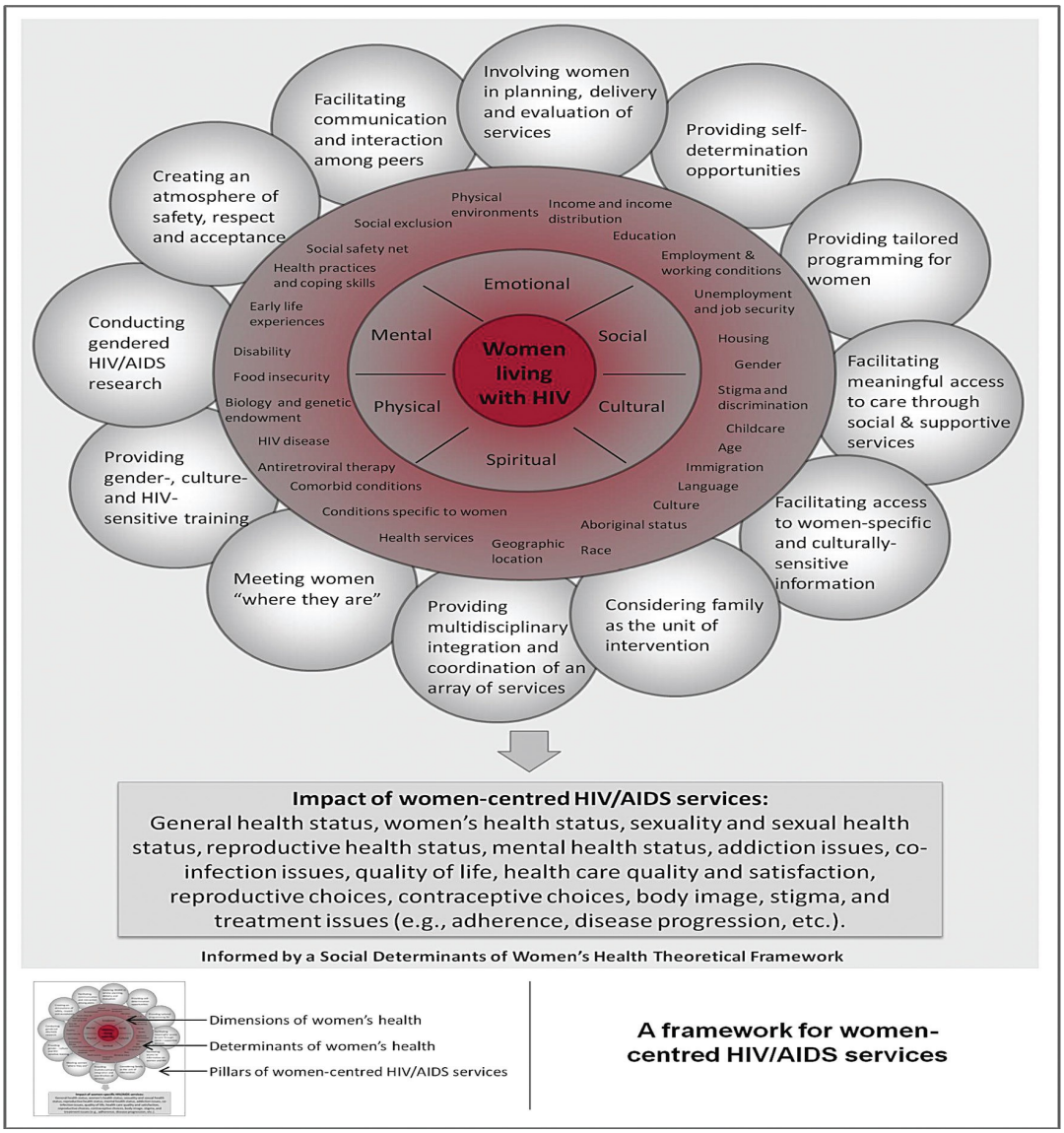


Figure 2.4: A summary of the factors that affect the lives of HIV positive women.

(Source: Barnett, 2000)

HIV positive women face stigmatization from partner, friends and family members (Bajunirwe and Muzoora, 2005). HIV stigma can be a barrier to seeking treatment (Shushtari *et al*., 2014). Based on studies disclosure of HIV is important in

Studies in other settings have found stigma from partners and family to influence a woman's ability to access treatment (Turan *et al*., 2008). The male partner's reaction is always in terms of domestic violence and rejection (Turan *et al*., 2011). Fears of negative male partner reactions (fear of domestic violence and rejection by one's partner) and lack of knowledge about male partner HIV testing influences women's decision regarding HIV testing and treatment (Chinkonde *et al*., 2009). Gender norms and relations, as well as power dynamics within male-female relationships in Africa settings affect treatment of HIV positive mothers and infants (Bandali, 2011). Without social support, it is difficult for HIV positive women to adhere to treatment and breastfeeding regimens that are necessary in reducing mother to child transmission of the disease (Walcott *et al*., 2013).

CHAPTER THREE
MATERIALS AND METHODS

3.1 Study Site

Mumias is in the Western part of Kenya and is located in Kakamega County (Figure 3.1). The names of the seven health facilities where the study was carried out were St. Mary's Mission Hospital, Mumias Model Health Centre, Mumias Sugar Clinic, Matungu Sub-County Hospital, Bukaya Health Centre, Malaa Health Centre and Makunga Health Centre. These health facilities were suitable for study because they offer PMTCT services and are selected EID sites. The selected health facilities also have a major role in provision of ARVs to HIV positive children/individuals. In addition, the health centers have recorded approximately 700 of HIV positive mothers in the region hence act as a good catchment area for study.

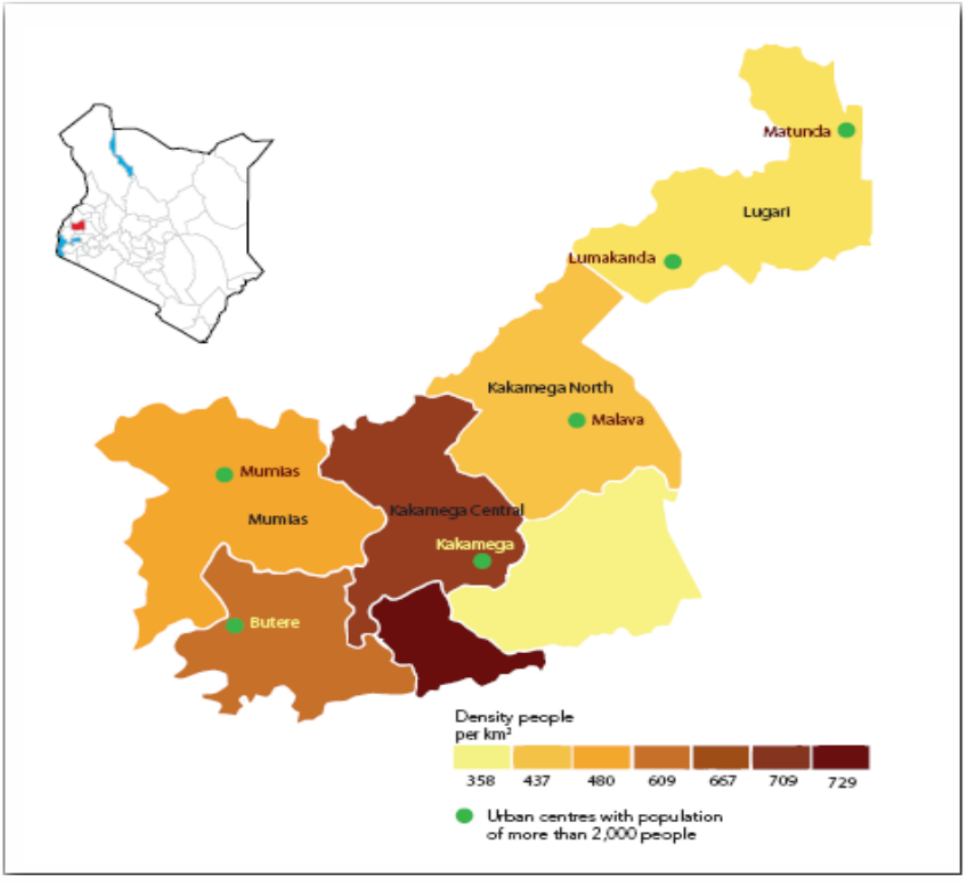


Figure 3.1: Location of the Mumias on the Kenyan map and in Kakamega County.

3.2 Study Population

The study population comprised of HIV exposed infants who were under Early Infant Diagnosis program in the selected health facilities.

3.2.1 Inclusion Criteria

The study included HIV exposed infants who were below 18 months old.

3.2.2 Exclusion Criteria

The study excluded HIV exposed children below 18 months whose caregivers declined to participate or refused to give their consent.

3.3 Study Design

This study design was a cross-sectional analytical study where study participants were recruited under a protocol entitled "Factors affecting treatment in HIV exposed infants in Mumias region, Western Kenya." Questionnaires were used to collect data. The participants were recruited as they sought treatment is selected health facilities in Mumias East and Mumias West Sub-Counties.

3.4 Sampling Procedure

The study utilized purposive sampling. Before responding to the questionnaires, the interviewer explained the importance of the study to the mothers of the HIV exposed infants.

3.5 Sample Size

The percentage of the HIV exposed infants who undergo EID is 45% (Kenya AIDs response progress report, 2014). Therefore, estimation of the sample size for this study was done using Cochran formula (Cochran, 1977) as shown below

$$n = Z^2 P(1-P)/e^2$$

=1.96 X 1.96 X 0.45X0.55/0.05X0.05

$$= 380.32$$

$$\sim 381$$

where n was the sample size, Z^2 was the abscissa of the normal curve that cuts off an area at the tails (1– equals the desired confidence level, which was 95%), e was the sampling error (5%). p was the estimated proportion of an attribute that is present in the population. The value for Z was found in statistical tables, which contain the area under the normal curve (1.96); Note that the sample size was from a community with similar characteristics. The minimum sample size was 381; however, 384 caregivers of HIV exposed infants were enrolled into the study.

3.6 Data Collection

The caregivers of the HIV exposed infants had to sign an informed consent (Appendix 1). The contents of the questionnaire included level of education, level of income and occupation, age, marital status, number of children, social support (Appendix 2). The questionnaires were prepared in English. Before the commencement of the study, the questionnaire was pretested on at least 8% of the population attending EID treatment in Lung'anyiro dispensary. The importance of the pretesting was to check on the ability of participants to comprehend the questions, the duration the interview will take, language comprehension and structuring of the questions. After pretesting, the questionnaire underwent slight modification to fit the study population. The data was collected everyday for a period of seven months.

The level of adherence in HIV-exposed infants was measured in terms of missed appointments (Appendix 2). Each participant responded on the number of missed appointments since enrollment.

3.7 Collection of Dried Blood Spot

The filters papers were labeled clearly using the HIV-exposed infants codes. The toe finger was sterilized with surgical spirit and allowed to dry. Using a sterile lancet, the toe finger was pricked and the fine drops of blood collected onto the filter paper. At

least three circles were filled and the filter paper placed onto the drying rack. Each filter paper was placed separately to avoid cross-contamination. Each filter paper was packed into a glycine envelope, with the labeled area appearing clearly. The glycine envelope was then placed into a zip-lock bag with a desiccant and a humidity indicator paper.

3.8 Detection of HIV in Infants

Using dried blood spots, polymerase chain reaction (PCR) technique was used to diagnose HIV in the exposed infants. The master mix reagent contained primers, probes specific for both HIV-1 target ribonucleic Acid (RNA), proviral Deoxyribonucleic Acid (DNA), and HIV-1 internal control RNA. The detection of amplified DNA is performed using target-specific and IC-specific dual-labeled oligonucleotide probes that permit independent identification of HIV-1 target amplicon and HIV-1 IC amplicon (Beck *et al.,* 2001).

The Roche Amplicor_ HIV DNA PCR kit was used for the PCR procedures. Briefly, a clean handheld punch (1/4 inch) was used to punch a disk (6mm 60 2) from the dried blood spot (DBS) into a 2 ml screw cap tube, and 1ml of Roche Specimen Wash Buffer added. DNA extraction, PCR amplification and analysis were done as per the manufacturer's recommendations. Samples were considered unequivocally positive if they had an optical 65 density (OD) of _0.8 and negative if they had an OD <0.2 (Zijenah *et al*., 1999).

3.9 Data Management and Analysis

The obtained data on factors affecting treatment of HIV exposed infants in Mumias region, western Kenya was stored in a Microsoft excel sheet, and computational analysis performed with SPSS version 20.

For specific objective one, to describe the social, economic and demographic characteristics of the caregivers who bring their HIV-exposed infants into treatment. Descriptive statistics were used to describe the social, economic, and demographic characteristics of the caregivers.

For specific objective two, to determine the level of adherence. Frequencies and percentages were used to calculate the level of adherence to treatment in HIV infected infants and uninfected infants.

For specific, objective three, to determine factors that affect adherence to treatment in HIV-exposed infants. Logistic regression was used to determine factors that were significant.

3.10 Ethical Considerations

Scientific and ethical approval for the study was obtained from the Ethical Review Committee and Scientific Steering Committee of the Kenya Medical Research Institute; KEMRI SSC # 2656 (Appendices 3 and 4).

CHAPTER FOUR

RESULTS

4.1 Study Participants

Three hundred and eighty four participants were enrolled into the study. The respondents were caregivers of HIV exposed infants. The participants were recruited from seven health facilities namely St. Mary's Mission Hospital, Mumias Model Health Centre, Mumias Sugar Clinic, Matungu Sub-County Hospital, Bukaya Health Centre, Malaa Health Centre and Makunga Health Centre (Figure 4.1). Majority, 369 (96.1%), of the caregivers to the HIV exposed infants were mothers while eight (2.1%) of them were fathers and the rest 7 (1.8%) were grandmothers.

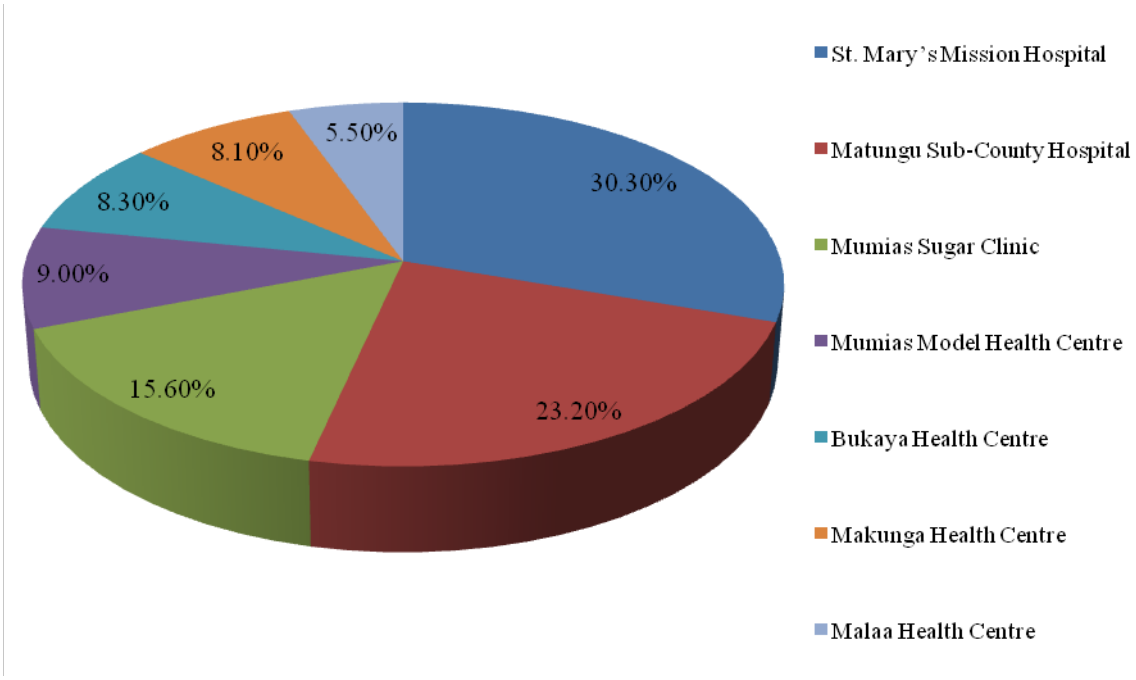


Figure 4.1: Number of respondents of HIV exposed infants.

4.2 The Social, economic and demographic Characteristics of Study Participants.

The main community in the study area is Wanga. A total of 376 (97.9%) participants' were female while 8 (2.1%) were male. Furthermore, 56(14.6%) of the participants' were single while 328 (85.4%) were married.

The participants' age ranged from 15 to 66 years (Figure 4.2). The mean age was 32.8 years, median 33 years while mode 32 years. More than half (50.5%) of the caregivers were aged between 25-34 years old.

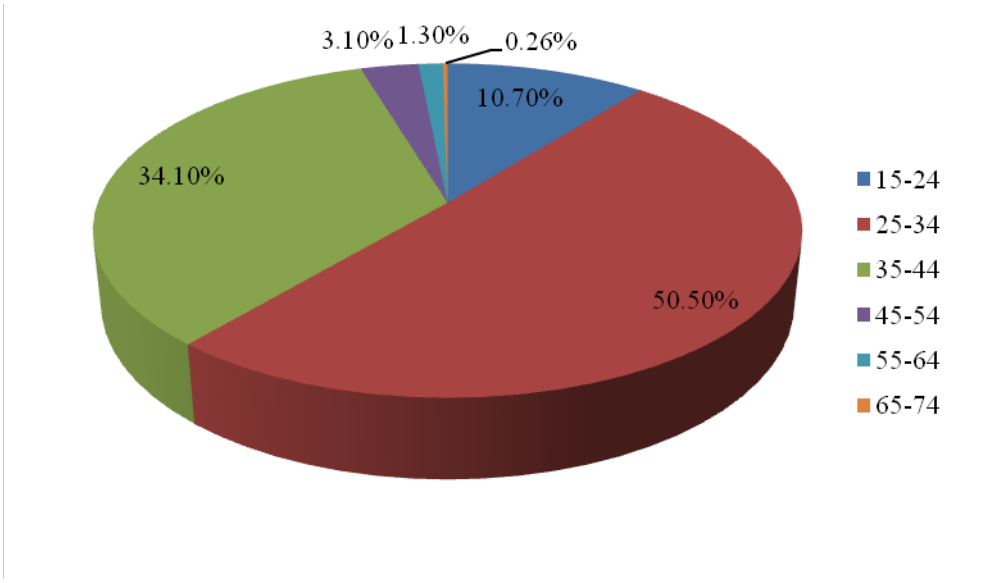


Figure 4.2: Age distribution of the respondents of HIV exposed infants in Mumias region, western Kenya.

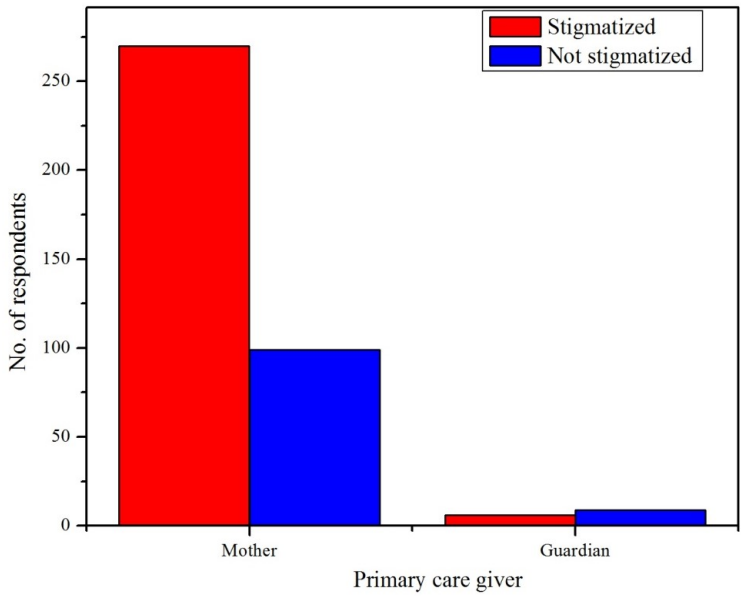


Figure 4.3: The number of respondents in study who reported social stigma.

The study shows 270 (73.2%) out of the 369 mothers are stigmatized (Figure 4.3). The guardians to the HIV exposed infants were fathers and grandmothers and 6 (40%) of them reported social stigma .

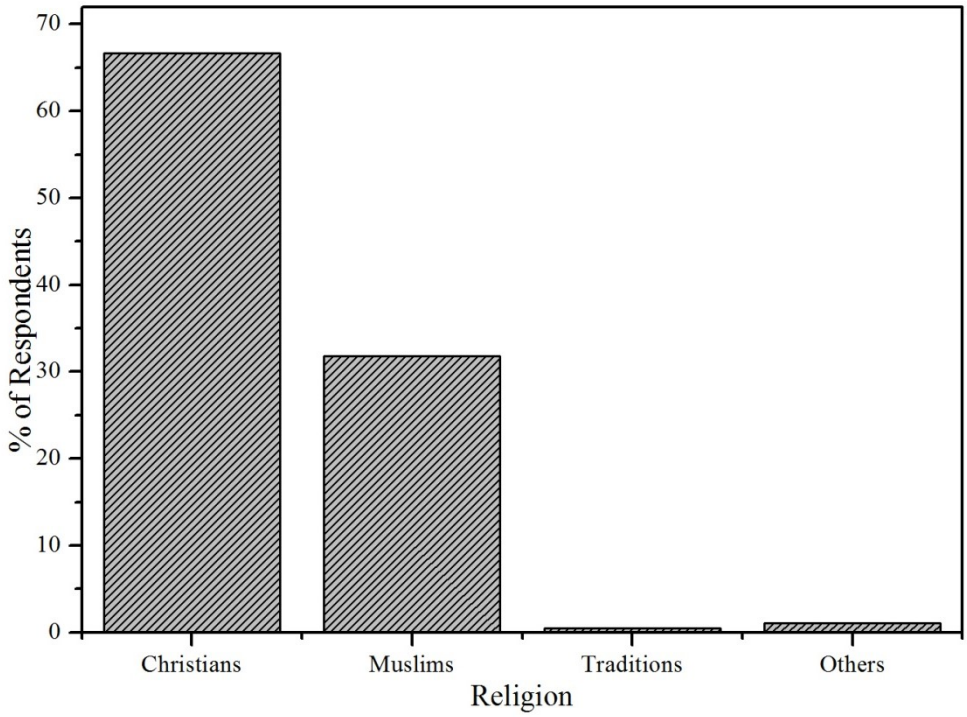


Figure 4.4: Religions practised by respondents who enrolled in the study.

More than half (66.7%) of the respondents were Christians, 31.8% of them were Muslim and 0.5% were traditionalists (Figure 4.4).

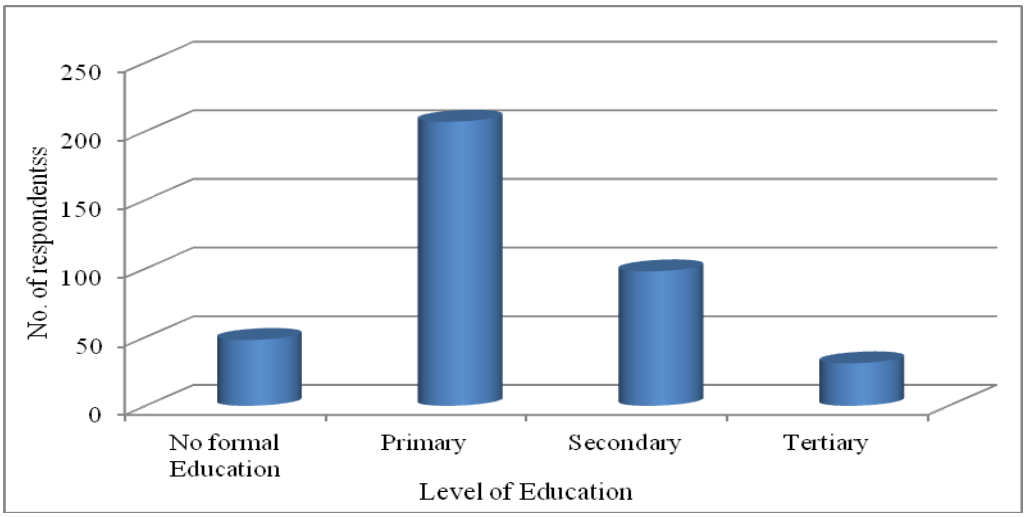


Figure 4.5: The level of education among the respondents who brought their HIV exposed infants for treatment.

Forty-eight (12.5%) of the respondents lacked formal education while 207 (53.9%) of them at least attended primary school, 98 (25.5%) of them completed secondary

education (Figure 4.5). Only 31(8.1%) of the respondents attained tertiary education. Tertiary education was in terms of university or college attendance.

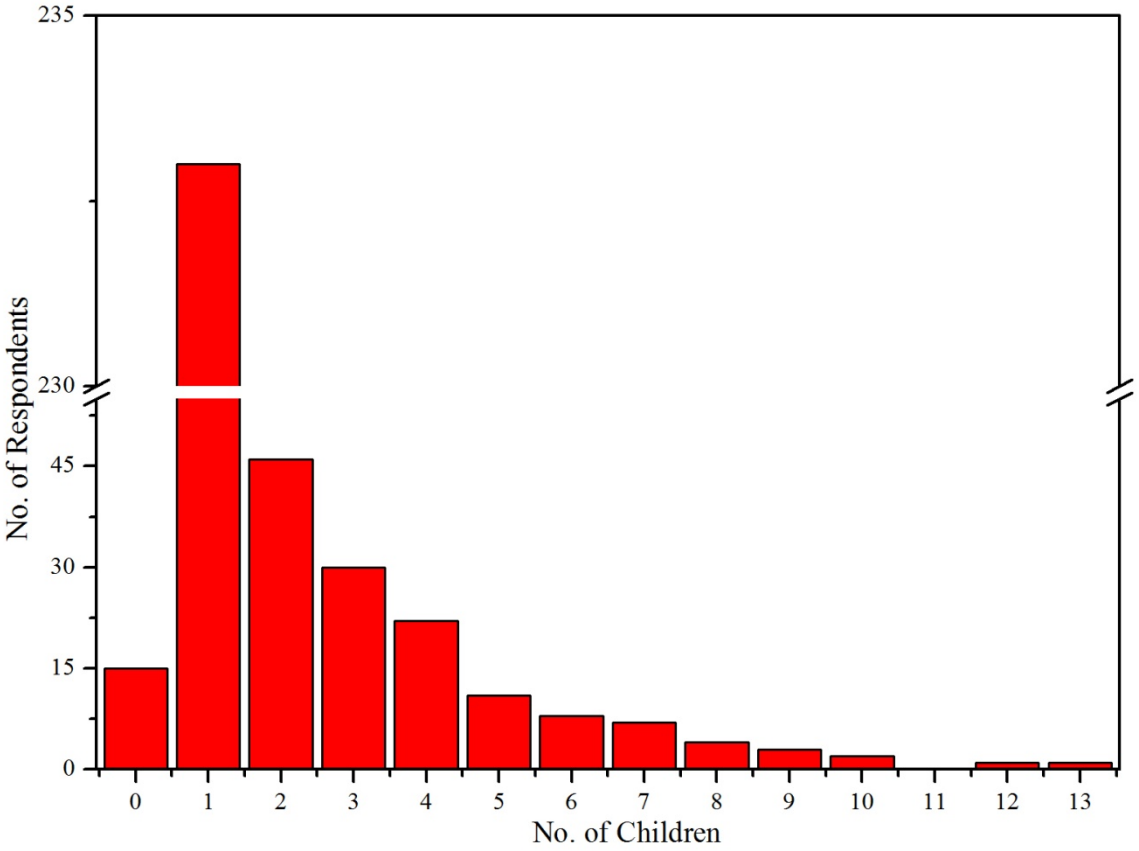


Figure 4.6: The number of children under the care of each respondent in the study.

Majority (60.7%) of the participants had only one child while 35.4% respodents had more than one child under their care. This was separate from the HIV-exposed infant who was recruited into the study. Only two (0.5%) participants had 12 and 13 children respectively (Figure 4.6).

More than half (56.3%) of the respondents were employed (Table 4.1). In terms of EID education, nearly all the respondents had undergone training on the importance of EID to HIV exposed infants (Table 4.1). Only 20 (5.2%) out of 384 infants were HIV positive. However, very few (5.7%) of the HIV exposed infants were sick at the time of study. Most (95.8%) of the respondents had other children under their care. very few respondents (6%) were visited by CHW.

Table 4.1: Characteristics displayed by respodents who enrolled in the study.

Characteristic	Total	%
Occupation		
Employed	216	56.3
Unemployed	168	43.8
EID education		
Yes	361	94
No	23	6
Sick child		
Yes	22	5.7
No	362	94.3
HIV results		
Positive	20	2.6
Negative	364	97.4
CHW visit		
Yes	23	6
No	361	94
Children		
Yes	368	95.8
No	16	4.2
Social support		
Yes	251	65.5
No	133	34.5

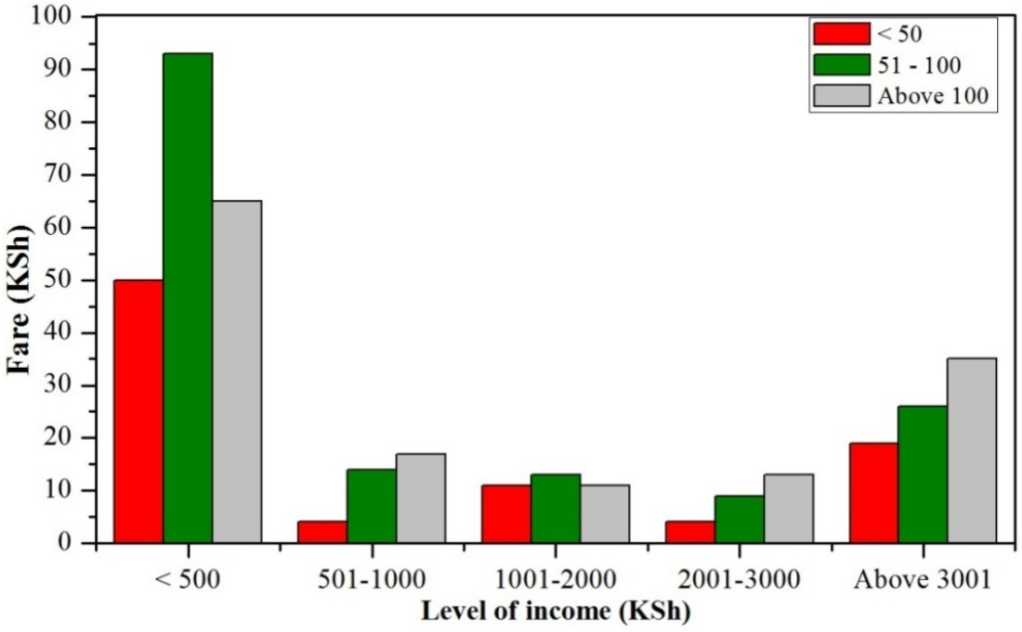


Figure 4.7: Level of income versus transport cost used by respondents.

Most (95%) of the respondents who earn less than 500 shillings a month had to have at least 51 shillings for them to access treatment (Figure 4.7). On the other hand, respondents who earn more than 3000 shillings a month must incurred at least 40 shillings as transport cost.

4.5 Level of adherence to treatment among HIV exposed infants in selected EID site in Mumias region.

The study measured level adherence in terms of missed appointments. The HIV status of the infants was determined using dried blood spot (DBS) technology and the automated PCR Roche CAP/CTM. At the time of study 20 (5.2%) infants were positive while 364 (94.8%) were negative (Table 4.2). Regardless of their HIV status, all HIV exposed are put on cotrimoxazole prophylaxis. From the study, it shows 14 (70%) of the HIV positive infants were non-adherent while 179 (49.2%) of the HIV negative infants adhered to treatment. A total of 191 (49.7%) of the HIV exposed infants adhered to treatment while 193 (50.2%) did not adhere to treatment.

Table 4.2: Level of adherence in HIV positive and HIV negative infants.

HIV status of Infants	Adherence			
	Adherence	Non-adherence	**Total**	**%**
positive	6	14	**20**	**5.2**
Negative	185	179	**364**	**94.8**
Total	**191**	**193**	**384**	**100**

4.6 Factors affecting adherence to treatment in HIV exposed infants in the study site.

From the study, the following factors were insignificant in affecting adherence to treatment and care; the primary caregiver, age of the caregiver, marital status, level of education, occupation, income, HIV status of the infant and assistance from the community.

Using odds ratio, significance was set at $P<0.05$. Monetary assistance, transport cost, EID education, presence of other children, number of children and presence of another sick child, were significant in adherence to treatment among HIV exposed children.

Table 4.3:The influence of transport cost on adherence to treatment.

Transport cost	Adherence	Non-adherence	odds	95% CI	
Less than 50	55	33	1.7	*1.1	2.6
51-100	68	87	0.8	0.6	1.1
Above 100	69	69	1.0	0.7	1.4
Other	1	2	0.5	0.1	5.5

Respondents who used less than Ksh.50 as transport cost were more likely to adhere to treatment. The odds of adherence was 1.7 (95% CI 1.1-2.6) (Table 4.3).

Table 4.4: The Effect of Financial assistance on adherence to to treatment.

Financial assistance	Adherence	Non-adherence	odds	95% CI	
100	14	7	2.0	0.8	5.0
101-500	51	58	0.8	0.6	1.3
501-1000	4	9	0.4	0.1	1.4
0	115	97	1.2	0.9	1.6
Above 1000	1	2	0.5	*0.2	1.0

A total of 212 (55.2%) respondents did not receive financial assistance while seeking healthcare. However, the odds of non-adherence among respondents who received financial assistance of above 1000 was 0.45 (95% CI 0.2-0.9) (Table 4.4).

Table 4.5: Knowledge on EID among respondents and its effect on adherence to treatment

Education EID	Adherence	Non-adherence	odds	95% CI	
Yes	186	175	0.9	0.8	1.2
No	5	18	1.1	*1.1	8.3

Most (94%) of the respondents reported having knowledge on EID (Table 4.1). The odds of adherence among respondents who lacked knowledge on EID was 1.1 (95% CI 1.1-8.3) (Table 4.5).

Table 4.6:The Influence of the number of children on adherence to treatment

Children	Adherence	Non-adherence	odds	95% CI	
0	10	5	2.0	0.7	5.9
1	102	131	0.8	0.6	1.0
2	24	22	1.1	0.6	1.9
3	19	11	1.7	0.8	3.6
4	16	6	2.7	*1.0	6.8
5	8	3	2.7	0.7	10.1
6	1	7	0.1	0.1	1.2
7	6	1	6.0	0.7	49.8
8	2	2	1.0	0.1	7.1
9	1	2	0.5	0.1	5.5
10	1	1	1.0	0.1	16.0

Nearly all 96.1% the respondents had other children under their care, 60.7% participants had one child under their care. When the respondent had four children the odds of adherence was 2.7 (95% CI 1.0-6.8) (Table 4.6). The other numbers of children were insignificant on adherence to treatment (Table 4.6).

When there was another sick child at home the odds of missing a clinical appointment was 5.3 (95% CI 1.6, 18.3) (Table 4.7).

Table 4.7: The effect of other HIV infected children on adherence to treatment in HIV exposed infants.

Children	Adherence	Non-Adherence	odds	95% CI
Not Applicable	160	175	0.91429	0.7378 -1.13289 6
Positive	14	13	1.07692	0.5062 -2.29106 1
Sickly	16	3	5.33333	*1.55404 -18.30352

CHAPTER FIVE
DISCUSSION

5.0 Introduction

Ninety percent of HIV infections in children are due to Mother to Child Transmission (WHO, 2012). Mother to Child Transmission of HIV can occur during pregnancy, delivery or through breastfeeding (NASCOP, 2012). A combination of early infant diagnosis and immediate initiation of treatment is crucial in Prevention of Mother to Child Transmission of HIV. The caregiver determines management of HIV in infants. Management of HIV in women overlaps with their social, demographic and economic characteristics.

5.1 Social, economic and demographic factors that affect adherence to treatment in HIV exposed infants.

Three hundred and seventy six out of three hundred and eighty four of the respondents were women. Commitment to treatment in HIV exposed infants' lies on health seeking behavior of the mother or caregiver. The majority of the caregivers in this study were females (97.9%) while males were 2.1%. A study done in Kenya, Lesotho and Tanzania proved that women are disproportionately infected with HIV (Sia *et al*., 2014). Similarly, many studies have confirmed that more women seek medical assistance when compared to men (Galdas *et al*., 2005). Furthermore, in the African culture, it is the responsibility of the mother to bring up a child. Adherence to treatment in HIV exposed infants depends on the caregiver. The level of adherence in relation to gender was insignificant. However, men have a poor health seeking behavior when compared to women. It has been reported that income level, level of education and cultural practices are some of the social determinants that dictate a woman's ability to adhere to treatment (Bandali, 2011).

In this study, more than half (50.5%) of the respondents were aged between 25-34 years of age. This peak age differs from a study done in North Rift Valley of Kenya that reported the highest proportion of HIV infected women was in the age group 21–25 years (Ng'ang'a *et al*., 2009). However, contradiction may be due to location of

the study sites whereby this study was carried out in Mumias region, Western Kenya whereas the other was in North Rift Valley of Kenya. More over the studies were carried out in different times 2014.

Majority of the respondents (85.4%) were married. This clearly shows that there is a relationship between HIV status and marital status. Similarly, a study done in Ethiopia reported that a majority, 85.9%, of the HIV positive women who seek HIV care and support service were married (Berhan *et al*., 2014). This finding is in agreement with previous reports where susceptibility and vulnerability to HIV/AIDS was attributed to marital and family status (Dada-Adegboha, 2004). While many studies have researched on marital status and HIV infection, there is no documentation on marital status versus commitment to treatment. However, marital status was insignificant in relation to adherence to treatment ($P>0.05$).

In this study, respondents reported stigmatization as a social challenge they face because of their HIV status. HIV positive people face stigmatization from family members, community and friends. Most of the mothers (73.2%) reported social stigma (Figure 4.3). This contributes to poor adherence to treatment and care. All HIV exposed infants are usually put on cotrimoxazole prophylaxis (WHO, 2014). Missing even one appointment is detrimental to the treatment outcome. Social stigmatization leads to high loss to follow-up in PMTCT programs (Manzi *et al*., 2005). Other studies have reported that HIV positive women fear stigmatization from health workers, male partners, family and community members. Consequently, mothers avoid treatment while others drop out of PMTCT programs (Bwirire *et al*., 2008). Studies have shown that stigma affects quality of life, healthcare access and healthcare outcomes (Holzemer *et al*., 2009). Mothers also face stigma and discrimination from friends, family, co-workers, health workers, and community (Brickley *et al*., 2009). Fear of rejection and domestic violence from a negative male partner influences a woman's decision regarding HIV treatment (Brickley *et al*., 2009). In Iran, it was reported that 2.8% of the people living with HIV/AIDS had not disclosed their HIV status to any family members, and 42.9% had not disclosed to any friends and 26.9% of participants had not disclosed their HIV status to any

network members (Shushtari *et al*., 2014). People living with HIV/AIDS fear stigma and discrimination from their social network. Consequently, stigma prevents enrollment inar ce and adherence to the prescribed antiretroviral regimen among HIV positive women (Killam *et al.,* 2010).

In this study, 65.5% respondents received social support from the extended family and the surrounding the community. However, receiving social support occurs only if the HIV positive person discloses his or her status. According to other studies people living with HIV/AIDS fear disclosing their HIV status to family, friends and community (Ssali *et al*., 2010). Disclosure of HIV status is important for improving psychological well-being, commitment to treatment and reducing risk of transmission (Shushtari *et al*., 2014). Other studies have shown that social support of people living with HIV/AIDS is important in adherence to treatment (Clingerman, 2004). Support from community encourages participants to seek treatment and care. Community health workers (CHW) visited only 23 (0.1%) participants from Matungu Sub-County hospital. HIV positive women fear discrimination from health workers (Turan *et al*., 2011). However, social and psychological support from CHW encourages HIV positive women to be committed to treatment.

Early infant diagnosis education was significant in adhering to treatment (Table 4.5). Other studies have reported access to basic education as a major factor that promotes health-seeking behavior in women (Fawzi *et al*., 2010). A study done in Ethiopia reported that more than half (66.8%) of the enrolled HIV, positive pregnant women were unable to read and write (Berhan *et al*., 2014). Women with no formal education lack resources to seek treatment (Bwirire *et al*., 2008). Mothers of HIV exposed infants undergo EID education before enrollment into treatment and care. This education is crucial in commitment to treatment and care. EID education enlightens the caregivers on the management of HIV in exposed infants. In this study, 95.7% of the mothers had knowledge on EID while 94% of all the respondents had EID knowledge. In addition, respondents who had EID knowledge were more likely to adherence to treatment (OR 1.09). This contradicts a study done in Malawi, which reported that mothers lack awareness of the existence of the EID program

(Manzi *et al*., 2005). However, the difference in the reporting may be because the studies were carried out in two different countries, Kenya and Malawi. Furthermore, with the increased fight against MTCT more HIV positive women have undergone EID education.

Religion is a social determinant that affect adherence to treatment and care. The main religion practiced by the respondents was Christianity (66.7%) while Muslims were 31.8%. In this study, religion was insignificant in relation to adherence to treatment. However, other studies have shown that religious attitudes towards HIV positive people determine their commitment to treatment. Muslims view HIV/AIDS as the consequence of sinful behavior thus, HIV infected people are immoral, promiscuous and unfaithful (Hasnain, 2005). Therefore, caregivers of HIV exposed infants may face discrimination in relation to Islamic religion. Consequently, fear of stigma and discrimination leads to poor adherence to treatment (Hasnain, 2005). On the contrary, Christianity provides spiritual support to HIV/AIDs patients thus improving lives (Guillory *et al*., 1997). Many religious organizations are supporting the fight against HIV especially among vulnerable groups like women and children.

Women face socio-economic challenges that negatively interfere with commitment to treatment. Poverty levels among HIV positive women determines treatment outcome among HIV positive women (Fawzi *et al*., 2010). Most of respondents who earn less than 500 Kenyan shillings used at least 50 Kenyan shillings to access treatment and care. Respondents who used less than Ksh.50 as transport cost were less likely to adhere to treatment**.** This may be because they focus on other basic needs like food. Furthermore, the respondents use other means of transports like cycling and walking. Studies have shown that HIV positive women from wealthier households are more likely to receive treatment than those from poor households (Hassan *et al*., 2010). In this study, caregivers who received monetary assistance of above 1000 Kenyan shillings adhered to treatment of the infant (Table 4.1). This study did not measure the wealth status of the participants in relation to adherence to treatment. The economic status of the family determines their priority to access basic needs (Muchedzi *et al*., 2010). In 2010, UNICEF stated high poverty levels as a factor that negatively contributes to healthcare access (WHO, 2012).

Employment and income overlap when accessing healthcare. In this study, 43.8% of the Respondents were unemployed. This means most of these caregivers lack a steady income. Financial dependency among women determines their commitment to treatment and care. It has been reported that provision of better jobs and guaranteed economic empowerment among HIV positive women motivates them to seek healthcare (Busza *et al*., 2012. It has been reported that majority (57.8%) of the HIV positive mothers in Ethiopia were housewives and thus lacked steady income (Berhan *et al*., 2014).

The number of children under the care of the respondent determined their adherence to treatment and care. Furthermore, if another child was sick the odds of missing an appointment were significant. Most of the time the caregiver concentrates on the sick child thus forgetting or neglecting the HIV exposed infant. Household capacity is important health seeking behavior (Jefferis *et al*., 2008). However, no studies have shown the effect of having more than one HIV positive child in relation to adherence to treatment and care.

5.2 Level of adherence in HIV exposed infants in selected EID sites in Mumias region.

In this study, adherence was measured in terms of missed appointments. At least 49.8% (191) of the HIV exposed infants' adhered treatment (Table 4.2). In addition, only 30% of the HIV positive infants adhered to treatment. Similarly, other studies have reported that the level of adherence among HIV exposed infants to be 50% (Nyandiko *et al*., 2010). Missing even one appointment is detrimental to the treatment outcome of the HIV exposed infants.

5.3 Limitations of the study

This study had a number of limitations. The DBS samples collected for testing were from a one-time encounter with the HIV exposed infants. Confirmation of the HIV status of an infant is done at 18 months (Beck *et al*., 2001).

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

1. This study demonstrated that social, economic and demographic characteristics of the caregivers determined their commitment to treatment. Majority of the caregivers were mothers who reported social stigma and discrimination from the community, family and friends. Furthermore, only 20% of the mothers had formal education.

2. The level of adherence between HIV infected infants and uninfected infants differed. Majority of the HIV exposed infants missed their clinical appointment. On the other hand, 49.2% of HIV negative infants and 70% of the HIV positive infants were non-adherent to treatment. The level of adherence of HIV exposed infant was 49.8%.

3. Factors which affect adherence to treatment in HIV-exposed infants included monetary assistance, EID education, availability of any sickly children, the number of children under the care of the respondent and transport used to reach the health facility.

6.2 Recommendations

1. The findings of this study suggest that efforts must concentrate on addressing the HIV needs of the poorest and other vulnerable groups like infants and women. Women face different social and economic challenges that interfere with the treatment of HIV exposed infants.

2. The level of adherence of HIV exposed infant was 49.8%. Greater awareness about EID would encourage caregivers of HIV- exposed infants to enroll their children into treatment. This would result in better treatment outcomes and increase survival of the HIV positive infants.

3. Various social, economic and demographic factors affect adherence to treatment in HIV-exposed infants. They include monetary assistance, transport cost, EID awareness, number of children and health status of the children. Efforts must concentrate on addressing the aforementioned in order to improve management of HIV in exposed infants.

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APPENDICES

Appendix 1: Informed consent

KEMRI-ITROMID Nairobi

PROPOSAL TITLE: FACTORS AFFECTING ADHERENCE TO TREATMENT IN HIV EXPOSED INFANTS IN MUMIAS REGION, WESTERN KENYA

Introduction

I Sophia K. Musenjeri I am conducting a study to assess the **factors affecting adherence to treatment in HIV exposed infants in Mumias region, western Kenya.** The information will be used to improve the health care in children who are born with HIV. Before you make a decision on whether to participate in the study or not, there are various bad or good things you need to know in case you want to participate in the research. Therefore, this form tells you more about the study and you are free to interrupt at any point and ask a question.

Being in the study is your choice

This consent form highlights or give you gives you more information about the study. The risks and benefits will be explained to you. After understanding the study and in case you agree to take part in the study, you will be required to sign this form.

Risks and Benefits of the study

Besides psychological disturbance to the affected parents, the study the child will be pricked lightly on the heel to draw blood for HIV testing. However, we shall only require you to respond to the questionnaire.

This research has undergone review by Kenyan Medical Research Institute (KEMRI) Ethical Review Committee thereby approving it. In case of any further clarifications or questions, you are free to contact the secretary of the KEMRI ERC by calling 020-272-2541, or 020-272-6781.

New findings

The results of this research will be disseminated to the relevant health ministries in Kenya especially the ministry of public health and sanitation and the ministry of medical services..

Problems and questions

In case you want further clarification or have questions, please contact Sophia K. Musenjeri, the principal investigator on mobile no. 0720300861.

Your statement of consent and signature

- If you have understood the information in the consent form by either it being read to you or through explanation and you voluntarily, agree to participate in this study. Please sign as a proof of my acceptance.

…….

Participant's signature and date

…… …….

Researcher conducting Consent discussion (print)

Researcher signature and date

Appendix 2: Questionnaire

This questionnaire is to be administered to the Parent/Caregiver Socio-demographic Data whose child is under the EID program

Parent/ guardian of the child

Primary care giver;

1. Mother
2. Guardian (specify the person)……

Personal details

Clinic/ health facility name ……..

Date of hospital visit/Place of interview ……..

Study Number …….…….....

1. **Socio-Demographic characteristics**
   a. Sex: Male ( ) Female ( )
   b. Please tick where applicable (√)

Primary care giver	Mother Father guardian
Age: write the date as DD/MMYY	
Marital status	1. Single
	2. Married
Level of education	1. No formal education
	2. Primary
	4. Secondary

	6. Tertiary education
Occupation	1. Employed
	2. Unemployed
Religion	1.Christian
	2.Muslim
	4.Traditional 5. Other

1. **Survey on economic status of the mother/caregiver**

a. How much do you earn? Please estimate in figures

.....

.....

.....

.....**b. How much fare did you use to reach the health centre?**

>50 ( ) between 50-100 ( ) <100 ( ) other ( )

c. Do you get any assistance in form of money in order to take care of the child?

Yes ( ) No ( )

If yes how much.....

4. **Survey on EID**

Do you have any knowledge or education on EID?

Yes ( ) No ( )

What were the results of the HIV test?

Negative ( ) positive ( )

a. Is your child on any drugs?

Yes ( ) No ( )

Do you pay for the drugs?

Yes ( ) No ( )

If yes, please specify the amount.....

b. Are the drugs always in constant supply?

Yes ( ) No ( )

If not please give the reasons why.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

c. Have the community health workers ever visited you at home?

Yes ( ) No ( )

If yes, how often?.....

d. How do they assist you in taking care of the child?

.....

.....

.....

.....

.....

L. Do you have other children?

YES ( ) NO ( )

If yes, please specify the number.....

m. Are the other children affected/infected?

YES ( ) NO ( )

If yes, please specify in which way

.....

.....

.....

.....

n. Do you have any other forms of support? Please specify by whom

Extended family members ( ) Community ( ) other ( )

o. Are there any other problems/challenges you incur as a parent under this program?

YES ( ) NO ( )

If yes, please name them

.....

.....

.....

.....

p. How does the society treat you and your child?

Stigmatized ( ) Not stigmatized ( )

q. How many doctors/clinic appointments have you missed?

.....

If yes, please state the reason why

.....

.....

.....

.....

.....

Name of person completing form: …….. .....

Appendix 3: Ethical clearance letter

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200 NAIROBI, Kenya
Tel: (254) (020) 2722541, 2713349, 0722 205901, 0733-430033; Fax: (254) (020) 2720032
E-mail: director@kemri.org irm@kemri.org Website: www.kemri.org

KEMRI/RES/7/3/1 **April 22, 2014**

TO: **SOPHIA MUSENJERI,**
PRINCIPAL INVESTIGATOR

THROUGH: **MS. FREDA ANDAYI,**
ACTING DIRECTOR, CIPDCR,
BUSIA

Dear Madam,

RE: **SSC PROTOCOL NO 2656 (*RESUBMISSION*): FACTORS AFFECTING ENTRY INTO CARE AND TREATMENT FOR HIV IN PRE-EXPOSED INFANTS IN MUMIAS DISTRICT, WESTERN KENYA**

Reference is made to your letter dated 7th March 2014. The ERC Secretariat acknowledges receipt of the revised proposal on 12th March 2014.

This is to inform you that the Ethics Review Committee (ERC) reviewed the document listed above and is satisfied that the issues raised at the 224th meeting held on 18th February, 2014 have been adequately addressed.

The study is granted approval for implementation effective this **22nd day of April 2014**. Please note that authorization to conduct this study will automatically expire on **21st April, 2015**. If you plan to continue with data collection or analysis beyond this date, please submit an application for continuing approval to the ERC Secretariat by **10th March 2015**.

Any unanticipated problems resulting from the implementation of this protocol should be brought to the attention of the ERC. You are also required to submit any proposed changes to this protocol to the ERC prior to initiation and advise the ERC when the study is completed or discontinued.
You may embark on the study.

Yours faithfully,

Appendix 4: Scientific steering committee clearance lette

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200, NAIROBI, Kenya
Tel: (254) (020) 2722541, 271 3349, 0722-205981, 0733-400000; Fax: (254) (020) 2720030
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KEMRI/SSC/102429 9th January, 2014

Sophia Muscinjuri

Thro'
Director, CIPDCR
BUSIA (K)

REF: SSC No. 2656 (Revised) – Impact Of Early Infant Diagnosis On Access To Treatment And Care In Selected Health Facilities In Mumias District, Western Kenya

I am pleased to inform you that the above mentioned proposal, in which you are the PI, was discussed by the KEMRI Scientific Steering Committee (SSC), during its **210th** meeting held on **6th January, 2014** and has since been approved for implementation by the SSC.

Kindly submit 4 copies of the revised protocol to SSC within 2 weeks from the date of this letter i.e., 23rd January, 2014 for onward transmission to the ERC office.

We advise that work on this project can only start when ERC approval is received.

Sammy Njenga, PhD
SECRETARY, SSC

Appendix 5: Publication

Science Journal of Public Health
2015; 3(3): 366-372
Published online April 24, 2015 (http://www.sciencepublishinggroup.com/j/sjph)
doi: 10.11648/j.sjph.20150303.20
ISSN: 2328-7942 (Print); ISSN: 2328-7950 (Online)

Factors Affecting Adherence to Treatment of HIV in Exposed Infants in Mumias Region, Western Kenya

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To cite this article:
Sophia Musenjeri, Serah Mbatia, Joseph Nganga, Matilu Mwau. Factors Affecting Adherence to Treatment of HIV in Exposed Infants in Mumias Region, Western Kenya. *Science Journal of Public Health.* Vol. 3, No. 3, 2015, pp. 366-372. doi: 10.11648/j.sjph.20150303.20

Abstract: *Objective*: To determine social-demographic and economic factors affecting adherence to treatment of HIV in exposed infants in Mumias region, Western Kenya. *Methods*: The study was a descriptive cross sectional study carried out among parents of HIV exposed infants in selected health facilities in western Kenya. Through random sampling, the study recruited three hundred and eighty four (384) parents aged between 15-66 years old. The parents who were recruited were seeking HIV testing, treatment and care for their infants. The laboratory procedure involved automated assay: Abbott Real-time HIV-1. Secondly, structured interviewer administered questionnaire was used to collect information from parentsof the affected infants. Data was analyzed using SPSS version 20. *Results*: 5.2% (20) of the participants tested positive while 94.8% (364) tested negative. Married participants were more likely to adhere to treatment (Odds ratio (OR) =1.062, 95%CI 0.628-1.796 P<0.05). Educated participants were more likely to attend their clinical appointments compared to the non-educated (0R=1.140, 95% C.I 0.949-1.369 P<0.05). Participants aged above 35 years old were more likely to adhere to treatment compared to those below 35 years old (OR=1.029, 95% C.I 0.985-1.074 P<0.05). Participants whose children tested negative at 6 weeks were more likely to adhere to treatment (OR=0.652, 95% C.I 0.185-2.305 P<0.05). Parentsunder the support of Community Health Workers (CHW) were more likely to adhere to treatment (OR=1.226, 95%C.I 0.419-3.581 P<0.05). Non-stigmatized mothers were more likely to adhere to treatment (OR=1.101, P<95% C.I 0.545-2.223). *Conclusion:* Adherence to treatment and care of HIV in exposed infants appears to be a significant challenge for HIV diagnostic and preventive services. To forestall the consequences, the stakeholders and government have to support the parents both financially and socially especially through public awareness campaigns to encourage them to adhere to treatment and care services.

Keywords: Adherence HIV, Infants, Diagnosis, Stigma, CHW

1. Introduction

In Sub-Saharan Africa,Human Immunodeficiency Virus (HIV) infection is prevalent in women who are in their reproductive age[1, 2]. In 2009, the Kenya National AIDS and STD Control Programme (NASCOP) estimated that 5.6% of pregnant women were HIV positive while in 2010 more than 80,000 pregnant women were HIV positive. Mother to Child Transmission (MCT) of HIV accounted for 10,390 infants' deaths in 2013[3, 4]. The Ministry of Health (MoH) in Kenya established an Early Infant Diagnosis (EID) program to reduce HIV infection in infants. All exposed infants start taking septrine immediately after birth. The HIV DNA Polymerase Chain Reaction (PCR) determines HIV infection in infants aged between 6 weeks and 24 months. The EID program uses the dried blood spots technology and automatedAbbott real time HIV-1 or automated Cobas® AmpliPrep / Cobas® TaqMan® HIV-1 to determine the HIV status of exposed infants [5, 6]. Therapeutic and prophylactic medications are initiated timely for infants[7].

Infants who are HIV positive start on cotrimoxazole prophylaxis at six weeks[8]. Due to continuous exposure, infants who test negative but their mothers are positive are also initiated on cotrimoxazole prophylaxis[4, 9]. Follow up is done on the exposed infants under medication. At the age of

twenty-four months, the infants are re-tested to ascertain their HIV status.

Prevention of MCT of HIV relies heavily on consistence in antiretroviral therapy[10]The speculation is that at least 50% of the mothers of the exposed infants get their results almost timely; however, some of them do not. Although those who receive positive results can get into free treatment and care, not all do. Unfortunately, the reasons, which motivate an individual to either get into treatment or not are yet to be known. The Ministry of Health in Kenya has established many EID sites to increase access. Therefore, many exposed infants are tested for HIV and treatment initiated immediately. However, new child infections of HIV and negligence in treatment have serious implications on reducing the disease burden and child mortality.

The aim of the study was to establish the factors affecting entry into care and treatment for HIV in exposed infants in Mumias District, Western Kenya.

2. Methods and Materials

2.1. Study Design and Setting

An institution based quantitative cross-sectional study was carried out in major EID sites in Mumias region, Western rural Kenya. Mumias is situated about 416km from Nairobi. Ideally, the ministry of health has picked a few health facilities to serve as Early Infant Diagnosis (EID) sites, which include St.Marys Mission hospital, Matungu sub-district hospital, Mumias sugar clinic, and Mumias model dispensary, Bukaya dispensary, Makunga dispensary and Malaa health centre. The health facilities in the region combine both child wellness and Early Infant Diagnosis program.

2.2. Study Participants

The participants were both male and female aged 15-66 years old. All the participants were HIV positive parents whose infants had been exposed to HIV in *utero*. The infants were attending HIV testing, treatment and care.

2.3. Sample Size and Sampling Techniques

To calculate the sample size, Cochran 1963 formula[$n = Z^2P(1-P)/e^2$] was used. Proportion of 0.5 was applied and a confidence interval of 95%

Whereby n was the sample size,

Z^2 was the abscissa of the normal curve that cuts off an area at the tails (1– equals the desired confidence level, which was 95%),

e was the desired level of precision (80%)

p was the estimated proportion of an attribute that is present in the population.

The value for Z was found in statistical tables, which contain the area under the normal curve (1.96); therefore, a sample of 384 was used during the study. The first 384 parent-infant pair who agreed to participate in the study were interviewed one after the other regardless of the health facility.

2.4. Data Collection

Data was collected using self-administered close-ended questionnaire. The questionnaire was prepared in English and the local dialect (luhya) commonly used in the region. The contents of the questionnaire included social, economic and demographic characteristics that may affect adherence to treatment and care of infants under EID. Before the commencement of the study, the questionnaire was pretested on at least 8% of the population attending EID treatment and care.The importance of the pretesting was to check on the ability of participants to comprehend the questions, the duration the interview will take, language comprehension and structuring of the questions. After pretesting, the questionnaire underwent slight modification to fit the study population. In addition, Cronbach's alpha test was used to validate and confirm the data collection tool. The data was collected everyday for a period of six months.

2.5. Clinical Specimens

Using filter papers, dotted blood spots (DBS) were collected from the participant's infants by the nurse in-charge.

2.6. Laboratory Analysis

For automated PCR assay, Abbott Real time HIV-1 tested the HIV status of the infants. Using a clean, disinfected pair of forceps, two 2mm discs were excised from the pre-cut Dried Blood Sample and carefully placed into labeled sterilized tubes[11]. The procedure was done inside a biosafety class II cabinet. Disinfection of the pair of forceps was done using 10% sodium hypochlorite, distilled water and 70% ethanol respectively. Disinfection was done after cutting each sample to prevent cross-contamination between samples. The above procedure was repeated until all samples had been transferred into their respective falcon tubes. Approximately, 1760 microlitres of the bulk lysis (specimen extraction buffer) was added in each falcon tube-containing sample. The prepared sample was incubated for 30 minutes. After incubation, reaction tubes were labeled in correlation with the falcon tubes. Approximately 1760 microlitres of the extracted specimen was transferred into the respective reaction tubes placed in Abbott racks. The Abbott instrument has six racks, each with ability to hold 16 samples. Thus, the total samples tested at a time were 96. However, the last two slots of the last rack were placements for positive and negative controls. The racks were then loaded onto the Abbott sample preparation instrument fully loaded with the reagents, consumables for proviral DNA extraction. Amplification and detection was through manual transfer of extracted DNA to Abbott real time amplification instrument. Results were indicated as either target detected for positive or target not detected for the negative results. All positive samples were re-tested for confirmatory purposes.

2.7. Data Analysis

Data was entered and analyzed using statistical package for windows SPSS version 20. 0. Descriptive statistics was used to summarize and present data in form of percentages or frequencies. Odds ratio (95%CI) was used to analyze the association between social-demographic variables and level of adherence of the participants.

2.8. Ethical Considerations

Participants signed consent forms as per the guidelines of the Kenya National Ethical Review Committee. Scientific approval was sought from the Scientific Steering Committee at Kenya Medical Research Institute (KEMRI).

3. Results

The study was carried out in a period of 6 months, from June 2014 to December 2014. 5.2% (20) of the infants tested were positive while 94.8% (364) tested negative. 75 (20.6%) of the Infants who tested negative missed at least one or more appointments while 30% (6) of those who tested positive missed one or more of their monthly appointments.

3.1. Social and Demographic Features of the Participants

Using random sampling, 384 participants whose infants had been tested for HIV during the study period were recruited into the study. All the participants responded to the questionnaire. The sample was composed of 97.9% females and 2.1% men. The participants had a mean age of 32.82 and standard deviation of 6.870 and standard error of 0.351. Furthermore, the median age was 33 while mode age 32, the age ranged from 15-66. In terms of marital status, at least 92.7% of the participants were married while the rest were single, divorced or widowed (Table 1). More than half of the participants had at least attended primary school with the rest either lacking formal education or having not completed primary education. More details in Table 1. Nearly half of the 43.75% participants were either in self/informal employment or in formal employment while the rest were casual workers or not employed (Table 1). The participants were either Christians 66.66% (256) or Muslims 33.33% (122) (Table 1).

Table 1. Social-economic and demographic characteristics.

Characteristic		N=384	Percentage
Marital status	Never married	28	7.3%
	Married	328	85.4%
	Separated	12	3.1%
	Widowed	16	4.2%
Level of education	No formal education	48	12.5%
	Primary incomplete	118	30.7%
	Primary complete	89	23.2%
	Secondary incomplete	50	13.0%
	Secondary complete	48	12.5%
	Tertiary complete	31	8.1%
	No answer	1	0.3%
Occupation	Salaried formal employment	31	8.1%
	Informal employment	40	10.4%
	Self employment	97	25.3%
	Casual worker	48	12.5%
	Unemployed/Housewife	167	43.5%
How does the society treat you and your child	Stigmatized	276	71.9%
	Supportive	108	28.1%
Financial challenges you incur as a parent under this program.		3	0.8%
	Yes	322	83.9%
	No	59	15.4%
Do you have other children	Yes	368	95.8%
	No	16	4.2%
How much do you earn in KShs?	No income	191	49.7%
	Below 500	17	4.4%
	501-1000	35	9.1%
	1001-2000	35	9.1%
	2001-3000	26	6.8%
	Above 3001	80	20.8%
		2	0.5%

3.2. Factors Affecting Adherence to Treatment of HIV in Exposed Infants

Various factors either positively or negatively affect the uptake treatment and care.

The major challenges that face the primary care givers include financial constraints whereby 83.9% (322) attributed it as the reason to why they sometimes have to miss their clinic appointments. 76.3% (293) of the interviewees had to have at least Ksh.50 and above in order to access treatment in the nearest health centre.

Secondly, societal stigma is a problem that affects 276 (71.88%) of the participants while 108 (28.12%) of the interviewees attribute their success to the community and

family members support. Similarly, support from community health workers encouraged participants to seek treatment and care. Only Matungu Sub-district hospital employed the services of community health workers (CHW). Ironically, only 22 participants in Matungu health centre acknowledged being visited by CHW.

Due to inconsistent supply of ARV's 25% (29) Participantsof the interviewees at St.Mary's Mission Hospital missed their doses during the study period. The nurse in-chargeadvised them to divide adult NVP into half and give to the infants.

Nearly half of the participant 191 (49.7%) have 0% monthly income while 113 (79.13%) of the participants earn less than 3000 Kenyan shillings in a month. The rest of the participants 80 (20.87%) earn more than 3000 shillings in a month.

At least 94% (361) of the participant had received education on the important of Early Infant Diagnosis. However, 5.2% (20) admitted to not having any knowledge about the program, more details given in Table2.

Table 2. Factors affecting adherence to treatment and care.

Variable	FrequencyN=384	Missed appointments	Odds ratio (95%CI)
Age <15	1	None=1(100%)	
16-25	53	8 (15.1%)	
26-35	210	46 (21.9)	
36-46	109	21 (19.3%)	
47-56	6	4 (66.7%)	
57+	5	1 (20%)	1.029(0.985,1.074)
Female	376	77 (20.5%)	
Male	8	4 (57.1%)	0.253 (0.050,1.278)
No formal education	48	11(22.9%)	
Primary incomplete	118	21(17.8%)	
Primary complete	89	20 (22.5%)	
Secondary incomplete	50	7 (14%)	
Secondary complete	48	13 (27.1%)	
Tertiary education	31	9 (29%)	1.140 (0.949, 1.369)
Salaried employment	31	1 (3.2%)	
Informal employment	40	11 (27.5%)	
Self employment	97	25 (25.8%)	
Casual employment	48	7 (14.6%)	
Unemployed	167	37 (22.22%)	1.101 (0.545,2.223)
Never married	28	4 (14.3%)	
Married	256	72 (22%)	
Separated	12	2 (16.7)	
Widow	16	3 (18.8)	1.062 (0.628,1.796)
No income	197	44 (23%)	
>500	17	3 (17.6)	
501-1000	35	5 (14.3%)	
1001-2000	35	5 (14.3)	
2001-3000	26	6 (23.1%)	
Above 3000	80	18 (22.5%)	0.955 (0.839,1.087)
Catholic	128	27 (21.1%)	
Muslim	122	26 (21.3%)	
Pentecostal	128	27 (21.1)	
Tradition	2	1 (50%)	
others	4	None=4	0.466 (0.221,0.981)

P value=0.5

A chi-square test was used to test the independence between socio-demographic factors and the number of missed appointments. The significance level was reported when $p<0.05$. Table 3 shows the socio-demographic factors that were significant relation to adherence level of the participants.

3.3. Level of Adherence Among Participants

Adherence level was measured in terms of number of missed appointments recorded in a period of six months during the study. At least 21.1% (81) of the participants missed either one or more appointments. The participant with the poorest level of adherence missed all thefour appointments (1.23%)

4. Discussion

In Kenya, the prevalence of HIV in women is estimated by NASCOP to be 7.6%, which translates to new HIV infections in newborns. Although EID has reduced PMTCT to approximately 3.5% in developed countries [12], there is limited data showing its impact among infants and children in developing countries including Kenya. The Kenya AIDSIndicator Survey estimated in 2013 that 12,940 children were newly infected[4]. In relation to these reasons, interventions to encourage parents to enroll in EID will reduce new HIV infections in children. Timely management

of HIV exposed infants minimizes the risk of vertical transmission. Maternal adherence to treatment during pregnancy plus consistent use of neonate zidovudine greatly reduces infection of HIV to newborns[13]. On the other hand, social, demographic and economic factors work synergistically to make adherence to treatment and care of HIV in infants difficult. This study established a strong correlation between socio-demographic factors and uptake of treatment. From the results above, there is a significant relationship between stigmatization, EID education, occupation, presence of other infected children and the frequency of missed appointments (see table 3).

Table 3. Association between social-demographic factors and adherence to treatment.

Chi-Square Tests				
Characteristic	Value	df	Frequency	Asymp. Sig. (2-sided)
Stigmatization	8.082	1	N=276(71.9%)	0.004
Presence of other children	8.819	2	N=368 (95.8%)	0.012
Other children (HIV+)	8.381	1	N= 43 (11.2%)	0.004
Education on EID	6.379	2	N=361 (94%)	0.041
Occupation	9.525	4	N= 216 (56.3%)	0.049
Total sample size=384				

From the study,most of the participants were female 97.1%. This is evident that the responsibility and burden of taking care of a sick child is always left to the mother. Various studies have established that men rarely seek health care unless they are in critical condition[14]. Due to AIDS related deaths, some of the infants had been orphaned and thus the responsibility of taking care of them had been left to their grandmothers.

The age of participants directly affected their level of adherence to treatment. For instance, an increase in age increased the chances of a mother-infant pair getting into treatment and care by at least 2.9% (OR=1.029, 95% C.I 0.985-1.074 P<0.05). However, this was not the case for the old, poor and weak grandmothers. Mothers below 35 years of age were more likely to miss clinical appointments when compared to their older counterparts. Married mothers were 6% more likely to adhere to clinical appointments compared to non-married ones.

A study conducted inKakamega district by the University of Nairobi, established that educationstatus, economic ability of the HIV positive mothers and their occupation affects entry into care and treatment [15]. Education status of the caregiver boosts the adherence level of positive mothers. However, from the study only 56.7% of the caregivers had completed their primary education. Consequently, parents who had at least completed their primary education were 13.1% more likely to adhere to clinical appointments and treatment compared to those who had little or no formal education at all. The ministry of health in Kenya ensures that every person who seeks HIV treatment undergoes training on how to treat and manage the disease. This study established that (361) 94% of the participants had knowledge about EID. Therefore, participants who had knowledge on EID were 3.9% less likely to miss their clinical appointments (OR=0.962, 95% P<0.05 0.296-3.130).Lack of knowledge on EID promotes ignorance and poor attitude towards accessing and adherence to treatment and care of HIV[16].

Participants who earn between KSh. 0 to 1000 per month are 4.6% more likely to miss an appointment compared to those who earn KSh. 1000 and above monthly (OR=0.955 95% C.I 0.839-1.087 P<0.05). Similarly, according to Muchedzi et al., the economic status of the family determined their priority to access basic needs like food, shelter and health is not among them [17]. In 2010, UNICEF stated high poverty levels as a factor that negatively contributes to accessibility to health centers [18].

At least 71.88% of the participants in the study face stigmatization;this hindered them from enrolling into treatment and care. Adherence to treatment and clinical becomes poor yet the children have to take their drugs to minimize chances of drug resistance[19]. Parents, who receive some form of support from either the extended family or community, are 19.1% more likely to comply with their clinic appointments without failure compared to their counterparts who received no form of support from their surrounding (OR=1.211, 95% P<0.05 C.I 0.886-1.654). Other issues stated include cultural and behavioral practices, which forces them to keep their HIV status a secret.

Any form of support from the health centre other than treatment produced positive effects in compliance with enrollment into care and treatment. For instance, a community health worker visit to the home of a respondent was significant; this increased their chance of attending to all the scheduled clinic appointment by 20.3% unlike their counterpart respondents who never had any community health worker's visit to their homes. Thus, CHW motivate parents to enroll infants in EID.

Muchedzi et al, mentions the quality of services offered to mother-infant pair as either a motivating or demoralizing factor [17]. According to health workers, poor turnaround time (more than 2 months), and communication breakdown with the reference laboratories has contributed to low turn up of patients after EID. Shortage of medical supplies forces the health workers to turn away the patients, which eventually demoralizes them from enrolling into treatment and care. This has also contributed to high number of defaulters.

Health workers ascertained that more than 50% of mothers come back for results. This is due to their anxiety to know the HIV status of their children. Similarly, according to NASCOP, in 2010, only 64% of HIV exposed infants received PCR test. Furthermore, only 7% of them proceed to

treatment [2, 20]. In the study at least, 10 defaulters were interviewed during the study and they pointed at various social and economic factors that hinder them from seeking their results from the health centers. For instance, they raised delay of results and lack of communication as to when the results will be delivered from KEMRI as a demoralizing factor. Lack of support from spouse and otherfamily members leaves all the burden ofcaring for a HIV positive child to the mother yet she is unable to cater for all the family needs. A visit by a health worker increased enrollment and consistency in adhering to treatment and care by 20.3% (Table 2). In 2010 UNICEF, Kenya stated lack of education awareness on HIV, communication barriers, poverty, behavioral and cultural as factors that negatively affect enrollment of infants into EID [18]. In addition, other issues stated include cultural and behavioral practices, which forces care givers especially a mother to keep their HIV status a secret.

5. Conclusion

In 2013, HIV accounted for 10390 infants' deaths in Kenya. Although the ministry of health in Kenya provides free treatment to HIV exposed infants, the mortality rates are yet to drop. The study established a significant correlation between social, demographic and economic factors versus adherence to treatment and care. Some of these factors include education level, marital status, occupation, income level, gender, presence of other children, support from the communities and stigmatization among others. Support from the CHW and family motivated the participants to seek and be consistency in EID. The quality of services offered to EID participants ensured either consistence or inconsistency in treatment. Furthermore, a breakdown of social relationships in the society has left the responsibility of taking care of HIV affected infants to mothers. Due to the burden, mothers shun health services, which include EID. In terms of education only 12.4% of the participants at least attended secondary school. Due to ignorance, most parents take EID education less seriously, which contributes to poor enrollment into treatment and care after EID. Whilst antiretroviral therapy drugs are readily available, the uptake of drugs and adherence to treatment is yet to reach 100%. There is need by policy makers to understand the impact of the social description of an individual to EID

The greatest limitation of the study resulted from the fact that most of the defaulters could not be traced. This study highlights the major setbacks the EID stakeholders should focus on.

Acknowledgment

We appreciate everybody who participated in the study especially the participants. The study was conducted in conjunction with Kenya Medical Research Institute, Centre for Infectious and Parasitic Diseases.

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