

**PREVALENCE OF ANXIETY AND DEPRESSION IN  
HIV POSITIVE MOTHERS WHOSE CHILDREN ARE  
COMPLETING AN HIV INFECTION VACCINE TRIAL**

A DISSERTATION SUBMITTED IN PART  
FULFILMENT FOR THE AWARD OF THE DEGREE  
OF MASTER OF SCIENCE IN CLINICAL  
PSYCHOLOGY

BY

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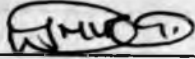
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**Declaration**

I, Dorcas J. Murei, hereby declares that this dissertation is my original work and has not been submitted either wholly or in part to this university or any other institution for the award of any degree or diploma.

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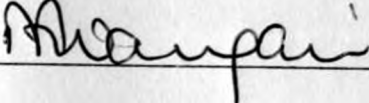
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## Dedication

This is dedicated to my husband Vincent and our children Adrian, Arianne, Alvin and Angel for their encouragement, support and long periods of my absence they endured while I was conducting the research and compiling this thesis.

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## **Abbreviations**

AIDS	Acquired Immune deficiency Virus
BDA	Beck Anxiety Inventory
BDI	Beck Depression Inventory
CDC	Communicable Disease Centre
EDCTP	European Developing Countries Trial Partnership
HADS	Hospital Anxiety And Depression Scale
HIV	Human Immunodeficiency Virus
HIVA	Human Immunodeficiency Virus clade A
MVA	Modified VacciniaAnkra
KNH	Kenyatta National Hospital
KShs.	Kenya Shillings

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## **ABSTRACT**

### **BACKGROUND**

The study was carried out to determine the prevalence of anxiety and depression in HIV positive mothers whose infants were participating in a HIV vaccine study. The participants were interviewed when they were exiting the vaccine study. Many pharmacological interventions and vaccine studies have been conducted which thereafter leave psychological problems unaddressed that necessitated this study to be conducted.

The findings of this study will be used by Researchers to consider and introduce psychological interventions for HIV positive mothers whose infants are participating in HIV infection vaccine trials or any other studies in future.

### **OBJECTIVE:**

To determine the prevalence of anxiety and depression among HIV positive mothers whose infants were participating in an HIV vaccine trial and find out whether there were any differences with the normal population.

### **METHODOLOGY:**

This study was a cross-sectional survey in which all the one hundred participants were eligible to be interviewed but only ninety five of them consented for this study. All the participants were mothers whose infants were participating in a HIV vaccine trial. A standardized questionnaire was administered that had socio-demographic questions as well as the Beck anxiety (BDA) and Beck depression inventory (BDI) were used. The questions also asked about the participants experiences as their infants participated in the vaccine study.

The data collected was analyzed according to the severity of both anxiety and depression. Those who were found to have minimum to mild levels of anxiety and depression were considered to be within normal range that can resolve normally.



For moderate to severe anxiety and depression they required treatment that included referral to Kenyatta National Hospital.

## **RESULTS**

Out of the 95 participants who were intervened, the results can be presented as 4.2% (4) had minimal anxiety, 70.5% (67) had mild anxiety, 10.5% (10) had moderate anxiety and 14.7% (14) had severe anxiety. The findings of this study showed that the participants in the lower age were more affected by anxiety than the older participants ( $P=0.003$ ).

The prevalence of depression in this study population was 31.6%. The breakdown of the categories of depression was as follows: 68.4% (65) had minimal depression, 14.8% (14) had mild depression, and 11.5% (11) had moderate depression while 5.3% (5) and 5.3% (5) had severe depression. The participants who were more educated were more likely to be depressed than the ones who had little or no formal education ( $P = 0.013$ ). Similarly, the participants who were earning less money were more likely to be depressed than their colleagues who were earning more money. ( $P = 0.000$ ).

In conclusion the research showed that the prevalence of anxiety and depression in the study population was higher than that of the normal population.

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### 1.1 Background

The implementation of early human development in an HIV vaccine study on infants in this study the researcher used a case-control study design to identify factors that were significantly associated with the study and provided feeding counseling. Through the case-control study the researcher observed the majority of the mothers had a lot of children of children and were not related to the vaccine study. There were some clinical, mental, physical, financial problems, stigma and many other social factors. The researcher also observed the mothers who were not vaccinated were more likely to be infected with HIV and whether these were significant factors that were not related to the study was not studied.

Since the introduction of the highly active antiretroviral therapy, the incidence of opportunistic infections and death due to HIV infection has declined. As a consequence of these declines, new infectious diseases have become a challenge to public health. The researcher observed that the majority of children who were infected with HIV were born to mothers who were not vaccinated in a HIV vaccine study. The researcher observed that the majority of the children who were not vaccinated were born to mothers who were not vaccinated. The researcher also observed that the majority of the children who were not vaccinated were born to mothers who were not vaccinated. The researcher also observed that the majority of the children who were not vaccinated were born to mothers who were not vaccinated.

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# CHAPTER ONE

## 1.0 INTRODUCTION AND PROBLEM STATEMENT

### 1.1 Background

The researcher was a study Nurse/Counselor in an HIV vaccine study on infants. In this study the researcher was in close contact with mothers of infants who were participating in the study and provided feeding counseling. Through this close contact with the mothers, the researcher observed that most of the mothers had a lot of issues or concerns that were not related to the vaccine study. These issues included marital problems, financial problems, stigma and many other social issues. This prompted the researcher to inquire into whether there were underlying issues and hence this study was conducted.

Since the introduction of the highly active antiretroviral therapy, the incidence of opportunistic infections and death due to HIV infection has declined. As a consequence other conditions associated with chronic diseases have become observable. In particular, the researcher observed signs of anxiety and depression among HIV positive mothers whose infants were participating in a HIV vaccine trial. These conditions appear to affect the mothers. Though the vaccine study was focused on their infants, it appeared that there were signs of anxiety and depression among their mothers whose prevalence needed to be known and appropriate intervention included in the trial or similar trial.

Anxiety is a characteristic feature of most people. In its 'normal' form, it helps with vigilance, learning and general performance. In a short form, anxiety is useful. However, in excess it starts to work against the person. Extremes of self-focus and apprehension quickly reduce attention and performance, perhaps aggravated by that particular blend of emotions such as anger, shame, guilt or

sadness mixing with a dominating fear that make up each person's unique anxiety (Morrison, Sarnquist, Gashi, Osterberg, Maldonado, and Harxhi, 2011).

Depression on the other hand refers to a very wide range of problems, from short periods of low mood to a lifetime of mind-numbing inability to function. The great majority of cases that involve low mood will sort themselves out and do not require medical intervention. However, at any one time, between 5% and 10% of the population are suffering from depression at a level that needs support, and it is likely that 20% of humankind will have a depressive episode of some kind during their lifetime (Anxiety Care UK, 2012).

Anxiety and depression may affect people of all walks of life and under different situations. This includes people suffering from various illnesses and conditions including infection with the Human Immunodeficiency Virus (HIV). Signs of anxiety and depression may be observed both in short periods of illness and may be prevalent for long periods.

In countries which anti-retroviral medications are widely available, HIV/AIDS is a chronic illness requiring management of symptoms caused by disease or its treatment (Kagee & Lind, 2010). Although antiretroviral drugs have enabled those infected to live fairly healthy lives, it can be hypothesized that knowing the risks associated with their status and participating in an HIV vaccine study may be associated with some level of anxiety or depression by HIV positive mothers. Studies assessing anxiety and depression levels among HIV positive mothers who were participating in an HIV vaccine study is lacking in the Kenyan perspective.

It has been argued that psychosocial factors appear to impact upon the development and progression of such chronic diseases as coronary heart disease, cancer and HIV/AIDS (Lopez, Seay, Fekete, Szeto, Mendez, Fletcher, Schneiderman, & Antoni, 2011). It was posited that psychosocial interventions

have been shown to improve the quality of life of patients with established disease and seem to influence biological processes thought to ameliorate disease progression. The Researchers recommends that small-scale studies are useful for specifying the conditions under which psychosocial factors may or may not impact quality of life, biological factors and disease progression (Lopez *et al*, 2011).

This study examined the prevalence and levels of anxiety and depression amongst HIV infected mothers whose infants were participating in an HIV vaccine study. The study has been on-going and was approaching completion.

## **1.2 Problem Statement**

People with anxiety normally feel apprehensive, irritable, or constantly afraid that bad things may happen to them and people close to them like their infant. Depending on its intensity, anxiety can make people feel trapped in their homes, too frightened to even open the door. These feelings normally aggravate and cause depression.

In an on-going HIV vaccine study that is being conducted on infants at The Department of Medical Microbiology, University of Nairobi, it was observed that mothers of infants exhibited signs of anxiety and depression. This was observed during the period when they were expecting, after delivery and as they continued to visit clinics where the progress of the expected baby and infants were monitored and administered trial vaccines.

These signs included fears of what could happen to their babies, withdrawn behaviour, excessive inquisitiveness, general restlessness, amongst others. The researcher observed that some of the mothers were having high levels of anxiety, depression or both. If anxiety and depression had been identified as possible conditions, suitable interventions could have been included in the on-going vaccine study or other similar vaccine studies.

This study examined the prevalence levels of anxiety and depression among these mothers as the infants approach completion of the HIV vaccine trials. While there were studies done that showed people with chronic illnesses like HIV suffered from anxiety and depression (Robert, 2001, Kolva, Rosenfeld, Pessin, Breitbert & Brescia, 2001, Ho, Sambasivam, Chua & Chew, 2011), there was no study done in Kenya showing the prevalence of depression amongst HIV positive mothers whose infants were participating in a vaccine trial. This study filled this gap.

### **1.3 Research Objectives**

#### **1.3.1 Broad Objective**

To determine the prevalence of anxiety and depression among HIV positive mothers whose infants were completing an HIV vaccine trial and whether there were any differences with the normal population.

#### **1.3.2 Specific Objectives**

1. To determine the levels of anxiety among HIV positive mothers whose infants were participating in a HIV vaccine trials.
2. To determine the levels of depression among HIV positive mothers whose infants were participating in an HIV vaccine trials.
3. To describe experiences the mothers went through during their participation in the study.

### **1.4 Research Hypothesis**

Anxiety and depression are high among HIV positive mothers whose infants are participating in HIV infection vaccine trials compared to the normal population.

### **1.5 Justification of the study**

Research into psychological interventions for HIV positive mothers has not been prioritized as many researchers are interested in prevention of mother to child transmission of HIV. Many pharmacological interventions and vaccine studies



have been done leaving the psychological problems unaddressed hence making this area of study essential. Furthermore, findings of this study will inform researchers to consider and introduce psychological interventions for HIV positive mothers whose infants were participating in HIV infection vaccine trials or any other studies.

### 3.1. Introduction

The aim of this study was to assess the psychological and social well-being of HIV positive mothers whose infants were participating in HIV infection vaccine trials. The study was conducted in a rural area of South Africa where the prevalence of HIV is high. The study was conducted in a rural area of South Africa where the prevalence of HIV is high. The study was conducted in a rural area of South Africa where the prevalence of HIV is high.

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## CHAPTER TWO

### LITERATURE REVIEW

#### 2.0 Introduction

Little systematic epidemiological research has been conducted into the prevalence, incidence and duration of psychiatric disorders among Kenyan patients living with chronic illnesses in general and those living with HIV infection in particular. Yet disorders such as major depressive disorder and generalized anxiety disorder appear to be common among patients with HIV infection (Jori, Carlos, Brady, Trezza, Richardson & Keane, 2007). Considerably fewer studies on the prevalence of depression and anxiety have been conducted in non-western countries than in the industrially developed world (Kagee & Lind, 2010). This is despite the disproportionate burden of disease that less developed countries like Kenya bear.

#### 2.1 Anxiety

Anxiety is the most universal of human emotions and is experienced by all persons throughout their entire lifespan (Morrison, Petit, Have, Gettes, Chiappini, Weber, et al, 2002). Despite its all-pervasive nature, however, anxiety cannot be observed directly. Rather, its presence can be inferred only from behavior (Morrison et al, 2002).

Secondly anxiety is simultaneously an adaptation and a stressor. It functions as an adaptation in that it is a response to the system disequilibrium and initially reduces the level of the stress by obscuring the nature of the stressor (Barlow, 2004). In the long run anxiety is a non-productive adaptation because it prevents the system from focusing on and directly dealing with the source of the stress. Nevertheless its existence is a signal that the system is having difficulty maintaining home kinesis, and in that sense it serves a valuable function.

Thirdly anxiety also serves as a stressor in that it unlike any other emotion is always perceived as negative. Thus its presence thrusts the system into a state

of stress, sometimes compounding rather than relieving the original stress. Because anxiety is always perceived as negative the system employs a variety of mechanisms to deal with it that are themselves adaptations (Barlow, 2004).

Anxiety has long been recognized as a prominent symptom of many psychiatric disorders. Anxiety and depression often occur together. Until the last part of the nineteenth century anxiety disorders were not classified separately from mood disorders. It was Freud who first suggested that cases with mainly anxiety symptoms should be recognized as a separate entity under the name of anxiety neurosis (Gelder, Hackmann, Wells, Clark, Sakovskis, & Ludgate, 1999).

Generalized anxiety disorder is excessive anxiety and worry which is occurring more days than not for at least six months and occurring about a number of events or activities such as work or school performance (Guthrie, 1998). Other features include restlessness or feeling keyed up or on the edge, being easily fatigued, difficulty concentrating or the mind going blank, irritability, muscle tension and sleep disturbance. For these symptoms to constitute a disorder there must be evidence of significant distress or impairment in important areas of functioning (Guthrie, 1998).

Anxiety is characterized by a feeling of fear accompanied by physical signs indicative of autonomic nervous system (Bernstein, 2009). When evaluating the anxious patient the clinician must distinguish between normal and pathological anxiety states. Normal anxiety is a universal, possibly advantageous, response to threats challenges or uncertainty. In contrast, Pathologic anxiety with respect to its intensity, duration, or character is an inappropriate response given a particular stimulus in fact often no external stimulus can be identified (Bernstein, 2009).

Studies show that stress management techniques like relaxing the mind and body can help reduce anxiety symptoms, but relaxation techniques alone are not adequate treatment for anxiety disorders (Bernstein, 2009).

There is no doubt question that anxiolytic medication has been helpful in reducing tension and providing the client with the degree of emotional comfort (Mereness & Taylor, 1994). In addition, behavior modification and desensitization are recognized as efficient and effective interventions techniques. The permanent relief for persons suffering from intolerable anxiety and fear lies in discovering the basic cause of the problem and helping the individual understand the actual source of his /her symptoms. This is achieved through the treatment technique of psychotherapy (Mereness & Taylor, 1994).

## **2.2 Depression**

Unlike anxiety, depression has been described as a common disorder that affects about 15% of the population at some time in their lives (Bernstein, 2009). It is characterized by a pervasive and persistent lowering of the mood, sleep disturbance, lowering of the appetite and weight loss. According to Bernstein, (2009) it is not the same as unhappiness and it is not a state people can snap out of it.

The prevalence of major depression according to Bernstein (2009) in the community survey in United Kingdom is about 4% in men and 8% in women. The lifetime risk or the population, or the proportion of people who will suffer one or more episodes or major depression at some time in life is about 15%. Rates increase with age and are high in urban areas. Suicide rates in major depression are about 10% in the long term (Bernstein, 2009).

People with severe depression have a high risk of suicide and it is important they receive appropriate treatment (Barlow, 2004). Severe depressive disorder is best treated with antidepressants medications while moderate to mild disorders can be treated with either psychological treatments or antidepressants or a combination of both (Bernstein, 2009).

### 2.2.1 Depression in HIV positive women

In a study on determinants of depression and HIV- related worry among HIV positive women who have recently given birth in Bangkok, Thailand, Bennetts *et al* (1999) evaluated the predictors of psychological scales from those interviewed and data collected at 18-24 months postpartum. Standardized questionnaires were used to assess depressive symptoms and HIV infection related worry (Bennetts, Shaffer, Manopaibon, Chaiyakul, Siriwasin, Mock, *et al*, 1999).

Depressive symptomatology and HIV infection related worry were common amongst that group of women. Multivariate logistic regression analysis identified several factors that predicted these psychological outcomes. High depression scores were associated with women who were no longer with their partners (5.72 CI), Higher levels of HIV infection related worry were associated with women whose babies were HIV infected (CI 1.28- 10.69), those who had not disclosed their HIV status to others (CI 1.29- 7.24) and those who reported that their HIV status was something about which their family would be ashamed (CI 1.34- 9.77) (Bennetts *et al*, 1999).

Based on these findings psychological interventions were proposed to address issues of disclosure, feelings of shame and coping strategies as well as financial assistance for the single mothers and also group counseling<sup>1</sup>.

Wu *et al* (2008), also undertook a study on the burden of disease among impoverished HIV positive women in Peru and sought to describe the extent, risk factors, and experiences of depression among impoverished HIV positive women living in Lima, Peru. This was a case of serial 78 HIV positive mothers where they measured depression, stigma and social support and performed a multivariable analysis to identify factors associated with depression. Among 78 HIV positive patients 68% were depressed.

Depression and suicidal ideation were rarely diagnosed in multivariable analysis; HIV-related stigma and food scarcity were associated with depression. It was concluded that poverty and socioeconomic vulnerability contributed to depression. The findings highlighted the heavy burden of depression in that cohort of poor women and the need to incorporate mental health services as an integral component of HIV care (Wu *et al*, 2008).

Antelman *et al* (2006), undertook a study on whether depressive symptoms increase risk of mortality among women in Tanzania and examined the effects of depression on HIV infection on disease progression among 996 HIV positive women participating in a trial on micronutrients and outcomes, vertical transmission, and disease progression. Depression and social support were measured 2 months and 6 to 12 months thereafter. Depression measures from pregnancy and more than 12 months postpartum were included in this analysis<sup>18</sup>. They found that depression is common among HIV infected Tanzanian women and increases the risk of disease progression and that screening for depression. They recommended that providing psychosocial interventions should be considered as part of comprehensive HIV care.

Laura, Katalin, Linda & Shelley (1999) undertook a study on disclosure, stress, and psychological adjustment among mothers affected by HIV infection. Participants were followed through a family AIDS clinic at a Midwestern children's hospital. With respect to disclosure, results indicated most common diagnoses included posttraumatic stress disorder and major depression.

### **2.3 Anxiety and depression in HIV positive patients**

A retrospective survey to estimate the point prevalence of anxiety and depression among HIV positive patients and examine its association with various demographic characteristics was undertaken by Ho, Sambasivam, Chua & Chew (2011).

As part of an integrated psychiatric case management programme, they conducted a cross-sectional survey of patients who had lived with HIV infection for 2 years. The patients were screened for anxiety and depressive symptoms using the Hospital Anxiety and Depression Scale (HADS) at the Singapore Communicable Disease Centre (CDC) outpatient clinics from 1 May 2010 to 28 January 2011. Patients with a score of 8 or more in either of the Depression or anxiety subscales were considered symptomatic (Ho *et al*, 2011).

The results were: Data from 140 patients was analyzed. 91% of the respondents were male, age range 21 to 78 years. More than a third of the patients had symptoms of anxiety and/or depression. 17.9% screened positive for symptomatic anxiety, 8.6% depressive symptoms while 10.7% suffered from both anxiety and depression. Of those identified to be symptomatic, only 3 patients (5.5%) were receiving psychiatric treatment. Preliminary analysis showed no gender differences in the presence of anxiety or depressive symptoms (Ho *et al*, 2011).

Among patients who displayed only anxiety symptoms, 63.2% had regular alcohol consumption. They concluded that there was a point prevalence of anxiety and depression at 37% and that clinically significant anxiety and depression were common among HIV infected patients in Singapore and may be overlooked by clinicians. They recommended that recognition of these psychiatric conditions using simple screening tools was therefore an issue of utmost importance. Early detection would ensure that timely interventions were offered to patients in their treatment course (Ho *et al*, 2011).

Morrison, Petito, Have, Gettes, Chiappini, Weber, *et al* (2002) studied depression and anxiety in women with HIV infection, this was to examine whether there were differences in the rate of depressive and anxiety disorders between HIV infected women and a comparison group of HIV uninfected women. The secondary

objective were to examine correlates of depression in HIV infected women – including HIV disease stage and protease inhibitor use – and the associations between symptoms of depression or anxiety and other potential predictor variables.

Their conclusion was HIV seropositive women without substance abuse exhibited significantly higher rates of major depressive disorders and more symptoms of depression and anxiety than the group of seronegative women with similar demographic characteristics.

Morrison, *et al* (2011), undertook a cross-sectional study on the levels of self-reported depression and anxiety among HIV positive patients in Albania and found that the percentage of patients who reported a history of diagnosis of depression or anxiety was high at 62.3% and 82.3 %, respectively. They concluded that mental health problems are widespread among the HIV positive patient population in Albania and suggested the need for more mental health care for HIV positive patients.



## CHAPTER THREE

### RESEARCH METHODOLOGY

#### 3.1 Background

This was carried out on mothers whose infants were participating in an on-going HIV infection vaccine study entitled "An open randomized phase 1/11 study evaluating safety and immunogenicity of a candidate HIV-1 vaccine, MVA, HIVA administered to healthy infants born to HIV-1 – infected mothers". The on-going study targeted infants of HIV positive mothers who were recruited while expectant as they visited the City Council of Nairobi Health Centres for antenatal services.

After recruitment the expectant mothers were followed up in the Department of Medical Microbiology Clinic, University of Nairobi through to delivery when the infants were enrolled into the vaccine study. The Clinic was run by the University of Nairobi in collaboration with City Council of Nairobi with funding by the European Developing Countries Trial Partnership (EDCTP). This research focused on HIV positive mothers whose infants were enrolled in the HIV vaccine study.

The researcher collected data on mothers as they visit the clinic with their infants who had been enrolled in the HIV vaccine trials. The Clinic was located in an area which was near Kenyatta National Hospital. It occupied the second floor of the College of Health Sciences in the paediatric clinic. There were many laboratories, research programmes and training areas which ensures privacy. It was also close to key bus stops improving public transport access to the Clinic.

In the HIV vaccine study, the mothers whose infants were targeted for the study were recruited through purposive sampling. They were recruited by recruitment Nurses who were assisting in mobilization of the clients. At the Clinic the mothers were given information about the vaccine study before signing the consent.

HIV testing was repeated using:

- ELISA method.
- Blood was taken for testing of HB which was expected be 9.5mm.
- CD4 should have been above 350.
- The mother was supposed to start anti-retroviral therapy regimen during pregnancy.
- She was also expected to deliver at Kenyatta National Hospital for proper management and easy enrollment.
- Accept home visits by a community worker to help in tracing and allow for home visits during vaccination.

The mothers and their infants were voluntarily enrolled into the Clinic. One hundred and eighty enrolled at the site and booked at antenatal clinic (Clinic 18) in Kenyatta National Hospital. The mothers were then followed up in the Clinic until delivery. At delivery, the baby would be enrolled into the vaccine study if qualified as per preset criteria comprising weight, without any abnormality and willingness of the parents to continue.

Out of the 180 recruited one hundred qualified and their infants were enrolled in the HIV vaccine trial. The mothers of these one hundred enrolled infants are all targeted in this study.

### **For the Child**

In the HIV vaccine study the child was brought to the Clinic for ten study visits. These were at week two, six, ten, fourteen, nineteen, twenty, twenty one, twenty eight, thirty six and forty eight weeks old. Transport reimbursement was made for at each study scheduled visit. The child also got all the KEPI vaccines at KNH. The children were randomized to receive the study vaccination. Those randomized were to be injected with the vaccines into the child's arm at the twenty week visit. Collection of blood was done at every visit with a maximum of 5 milliliters.

Though this study was not on the children enrolled in the HIV vaccine study, the children being of a vulnerable group would eventually benefit if the mother was diagnosed and treated for anxiety and depression. The child would grow in a healthy environment free of psychological problems that may be associated with the mother hence the children would therefore benefit indirectly.

### **3.2 Study Area/Site**

The study was conducted on the mothers of infants participating in an HIV vaccine study in the Department of Medical Microbiology, University of Nairobi, in an ongoing infant HIV vaccine trial that was running for 3years form August 2009 to April 2012. The mothers the vaccine study were mobilized from September, 2009 and recruitment started in February 2010 from the City Council of Nairobi Health Centres located in Mathare, Kayole, Kariobangi and others Kenyatta National Hospital (KNH).

### **3.2 Study Design**

The study was a cross-sectional study.

### **3.3 Study Population**

All the 100 mothers whose infants were participating in the HIV vaccine study were targeted for this study but only 95 consented and participated in this study. All the mothers were HIV positive and were either exclusively breastfeeding their infants, or formula feeding.

### **3.4 Sampling**

Since the researcher was undertaking this study on mothers whose infants were sampled and enrolled in an on-going HIV vaccine study, the total population of 100 was targeted. The researcher targeted the whole population but only managed to enroll 95 of them. After consenting the researcher administered the questionnaires.

### **3.5 Inclusion criteria**

All the mothers who were enrolled to participate in the on-going HIV vaccine study and had to consent to participant in this study.

### **3.6 Exclusion criteria**

Mothers who do not give consent to participate.

Mothers who are too sick to consent.

### **3.7 Study Instruments**

Three instruments were used:

1. Becks Anxiety Inventory (BAI) Checklist.
2. Becks Depression Inventory (BDI) Checklist.
3. Social demographic Questionnaire designed by the Researcher were used to gather information on mothers and their thoughts and feelings on participation of their infants in the trials. This included age, religion, education, marital status, occupation, year of first diagnosis, spouses status, number of children, and whether other children are HIV positive.

#### **3.7.1 Becks anxiety Inventory (BAI)**

Beck anxiety Inventory was created by Dr Aaron T. Beck. It has twenty one (21) questions. It is a multiple-choice self-report inventory that is used for measuring the severity of a person's anxiety. Each question has the same set of four possible answers choices which are arranged in columns and answered by marking the appropriate one with a cross. These are;

NOT AT ALL

MILD: It did not bother me much.

MODERATELY: It was very unpleasant but I could stand it.

SEVERELY: I could not barely stand it.

The BAI has a maximum score of 63.

0 -7 – Minimal level of anxiety.

8 – 15 - Mild anxiety.

16 – 25 – Moderate anxiety.

26 – 63 – Severe anxiety.

### **3.7.2 Becks Depression Inventory (BDI)**

BDI has three versions. The original was developed by Dr Aaron T. Beck in 1961. BDI is a multiple choice self-report inventory questionnaire and is one of the most widely used instruments for measuring the severity of depression. The questionnaire is designed for adults aged 17 - 80 years. It is composed of items relating to depression symptoms such as hopelessness and irritability cognitions such as guilt or feeling of being punished as well as physical symptoms such as fatigue, weight loss and lack of interest in sex.

#### **Interpretation of BDI**

The score of BDI is a value of 0-3 assigned for each answer and the total score is compared to a key to determine the depression severity.

The score for each of the 21 questions are added to obtain the total score. The highest score for each of the twenty one questions is three (3) and the lowest possible is zero (0). The highest possible total for the whole is sixty three (63) and is compared to a key to determine the level of severity.

There is only one score per question. The standard cutoffs are as follows:

0-13 indicates minimal depression.

14-19 indicates mild depression.

20 – 28 indicates moderate depression.

29 – 63 indicates severe depression.

Higher total scores indicate more severe depressive symptoms.

### **3.8 Procedure**

On exit at visit eleven (with a window period of one month) that is when the participants were picking their results, an explanation of this study was given and

a written informed consent was given. Those who agree to participate were asked to sign an informed consent form. Thereafter they were given a socio-demographic questionnaire, Becks depression inventory and Becks anxiety inventory to fill. It was researcher administered to be able to capture the right information from every participant and minimize error rate.

The instruments were in English language and those with problems of reading were assisted by the Researcher.

### **3.8.1 Data Collection**

Data was collected using standardized Becks Anxiety Inventory (BAI) Checklist and Becks Depression Inventory (BDI) Checklist. A social demographic questionnaire was also administered. The participants were given enough information by the Researcher to enable them to decide on whether to participate. They were then given the social demographic questionnaire, Becks Depression Inventory and Becks Anxiety Inventory.

The participants who required help in completing the questionnaire were assisted by the Researcher who would read out the questions to them without interpreting them.

Although the questionnaires to be filled were in three forms, it would take approximately 30 minutes and therefore the participant would not require a break in between.

Since the participants had their infants enrolled in the completed vaccine study that was being funded by EDCTP and under the University of Nairobi, they had their transport requirements already catered for when they visit the clinic hence the researcher would not need to reimburse their transport costs. The participants were also contacted through the clinic telephone line to ensure that they make their scheduled clinic visits and this study visit. The participants also had the Clinic telephone number to contact in case of any problems. The

researcher thanked each participant for accepting to participate in this research. Transport reimbursement was given as part of the visit to the study clinic.

### **3.9 Ethical Considerations**

The proposal was presented to the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee for approval and was eventually approved. The Researcher observed participants confidentiality and privacy in accordance with KNH and UON Ethics and Research Committee requirements.

Since this study was dealing with human subjects there was no risk for the participants and also no benefit. The Researcher got written informed consent from the participants after giving an explanation pertaining to the study. The Researcher observed participants confidentiality and privacy by avoiding use of names but instead used serialized unique numbers.

There were no material benefits to the study participants. However, those who would be having moderate to severe anxiety and depression were referred to Kenyatta National hospital for treatment. There was some minimal psychological/emotional risk and the researcher managed it before releasing the participant by helping them go through a counseling session. The participant were also be informed that they could withdraw from the study if they felt uncomfortable continuing and no victimization would be meted because of doing so. The participants were also free to contact the Researcher in case of any issues they wish to discuss or clarify.

### **3.10 Data Analysis**

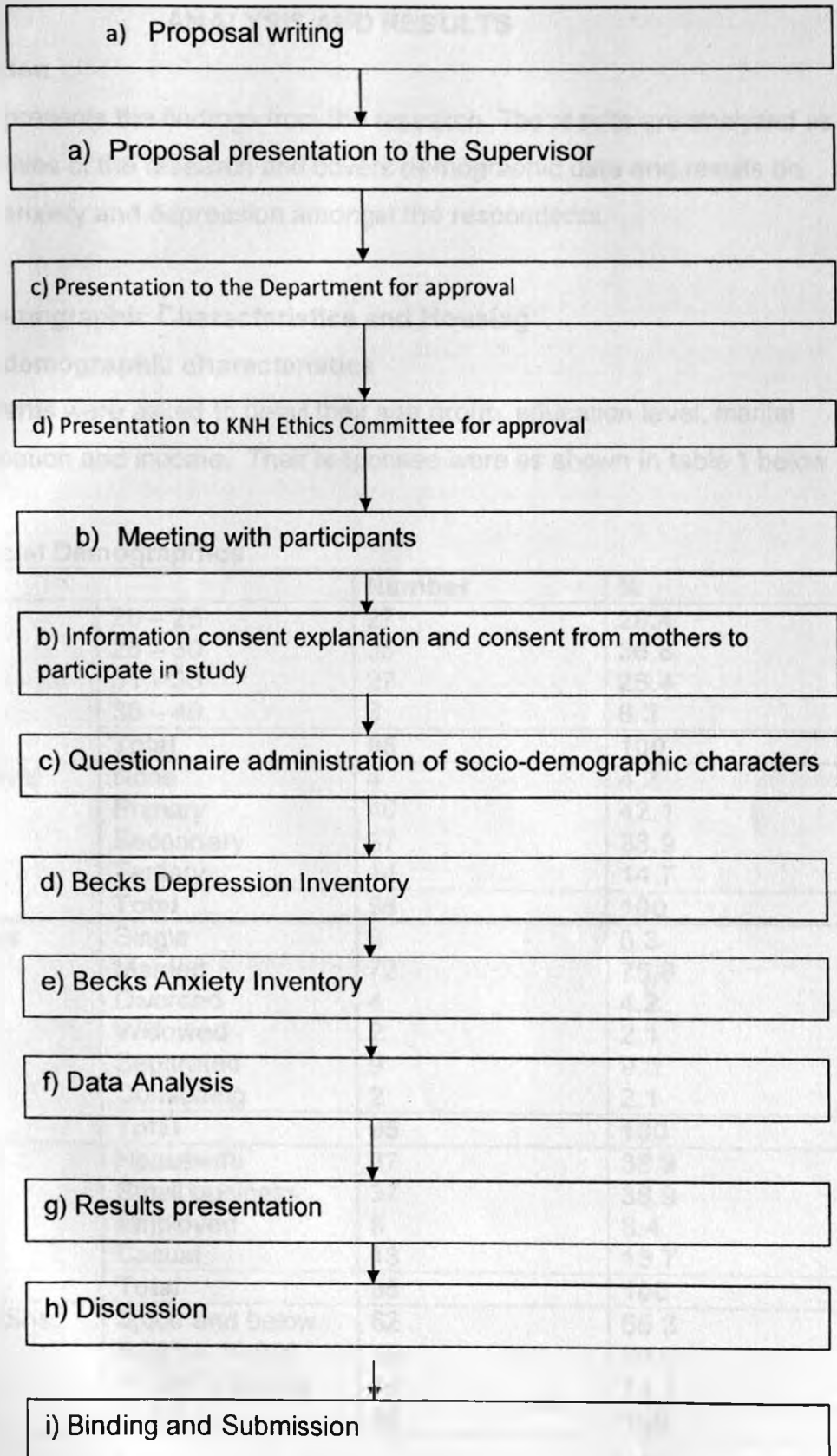
Data collected with the standardized questionnaires was analyzed according to the severity of both anxiety and depression. Those who were found to be having minimum to mild levels of anxiety and depression were considered to be within normal range could resolve normally. For moderate to severe anxiety and depression this would require treatment that includes referral to Kenyatta

National Hospital. Data from socio-demographic questionnaires was analyzed to identify experiences of the participants and their backgrounds.

Data collected will be analyzed using Statistical Package for Social Scientist or excel. The test score which will be compared using the Chi-square test for testing of significance between various variables against depression and anxiety.



## Research Flowchart



## CHAPTER FOUR

### ANALYSIS AND RESULTS

#### 4.0 Introduction

This chapter presents the findings from the research. The results are analyzed as per the objectives of the research and covers demographic data and results on the levels of anxiety and depression amongst the respondents.

#### 4.1 Socio-demographic Characteristics and Housing

##### 4.1.1 Socio-demographic characteristics

The respondents were asked to detail their age group, education level, marital status, occupation and income. Their responses were as shown in table 1 below.

**Table 1: Social Demographics**

		<b>Number</b>	<b>%</b>
Age group	20 – 25	27	28.4
	26 – 30	35	36.8
	31 – 35	27	28.4
	36 – 40	6	6.3
	<b>Total</b>	<b>95</b>	<b>100</b>
Education level	None	4	4.2
	Primary	40	42.1
	Secondary	37	38.9
	Tertiary	14	14.7
	<b>Total</b>	<b>95</b>	<b>100</b>
Marital status	Single	6	6.3
	Married	72	75.8
	Divorced	4	4.2
	Widowed	2	2.1
	Separated	9	9.5
	Cohabiting	2	2.1
	<b>Total</b>	<b>95</b>	<b>100</b>
Occupation	Housewife	37	38.9
	Small business	37	38.9
	Employed	8	8.4
	Casual	13	13.7
	<b>Total</b>	<b>95</b>	<b>100</b>
Income in KShs.	5,000 and below	62	65.3
	5,001 – 10,000	19	20.0
	10,001 – 20,000	14	14.7
	<b>Total</b>	<b>95</b>	<b>100</b>

The study findings showed that the mean age of the participants was 28.6 years, and the median age was 29.0 years with the minimum and maximum ages being 20 years and 30 years respectively. As this study was conducted on mothers whose children were participating in a HIV vaccine trial, this led to the gender of all study participants being female.

Most of the study participants had some formal education 95.8% (91) while 4.2% (4) of them had no formal education. Of the ones that had formal education, only 14.7% (14) had post-secondary education while 42.1% (40) had primary level of education as their highest education level.

Married people constituted more than three quarters of the study participants 75.8% (72), while the least were single and widowed with both having 2.1% (2) each. Single parents were 6.3% (6) whereas those who were separated were 9.5% (9). When asked about their occupation, majority of the participants reported they were housewife 38.9% (37); small business ladies 38.9% (37).

Only 8.4% (8) of the study participant were permanently employed whereas 13.7% (13) were casual workers. When asked about their total income per month, over two thirds of them 65.3% (62) reported an income of less than Kenya Shilling 5,000 per month while only 14.7% (14) said their income was in the range of KShs. 10,000 to 20,000 per month.

#### 4.1.2 Housing

**Table 2: Type of house occupied by respondent**

		No	%
Type of house	Temporary	44	46.4
	Semi-permanent	16	16.8
	Permanent	35	36.8
	<b>Total</b>	<b>95</b>	<b>100</b>
No of bedrooms	One room	54	56.8
	Two room	23	24.2
	One bed roomed house	10	10.5
	Two bed roomed	6	6.3
	Three bed roomed house	2	2.1
	<b>Total</b>	<b>95</b>	<b>100</b>

Lack of proper housing for the participants was evident as majority of them 46.4% (44) were living in temporary houses while 16.8% (16) were living in semi-permanent houses. Only 36.8% (35) reported living in a permanent house.

#### 4.2 Levels of Depression of Respondents

Each respondent filled the standardized Becks Depression Inventory (BDI) Checklist. Their responses are as in table 3 below:

**Table 3: Participants Depression Levels Using BDI**

Depression Levels	Frequency	Percentage
Minimal	65	68.4
Mild	14	14.8
Moderate	11	11.5
Severe	5	5.3
<b>Total</b>	<b>95</b>	<b>100</b>

Table 3 above shows that 68.4 % of the respondents had minimal depression levels. The prevalence of depression in this study population as indicated by the BDI scores was 31.6%.

#### 4.2.1 Relationship between depression and age, education level, occupation and income

Table 4 below shows whether there was any relationship between levels of depression and socio-economic factors like age, education level, occupation and income level.

**Table 4. Relationship between depression and age, education level, occupation and income**

	Age N(95)			
BDI scores	20- 25	26 - 30	31 - 35	36 - 40
Depressed n = 30	9.5%(9)	11.6%(11)	8.4% (8)	2.1% (2)
Not depressed n = 65	18.9% (18)	25.3% (24)	20% (19)	1.2% (4)
P = 0.992 (not significant) r = 0.020				
	Education Level N(95)			
BDI scores	None	Primary	Secondary	Tertiary
Depressed n= 30	0	17.9% (17)	11.6% (11)	2.1% (2)
Not depressed n= 65	4.2% (4)	24.2% (23)	25.3% (24)	14.75 (14)
P= 0.013 <b>Significant</b> ; r = 0.182				
	Occupation N(95)			
BDI scores	Housewife	Business	Employed	Casual
Depressed n = 30	17.9% (17)	9.5% (9)	0	4.2% (4)
Not depressed n= 65	21.1% (20)	29.5% (28)	8.4% (8)	9.5% (9)
P= 0.430 not significant; r = 0.175				
	Income N(95)			
BDI scores	5,000 & below	5,000 – 10000	10,000 – 20,000	
Depressed n = 30	29.5% (28)	2.1% (2)	0	
Not depressed n= 65	35.8% (34)	17.9% (17)	14.7% (14)	
P= 0.00 <b>Significant</b> ; r = 0.404				

The findings showed that there was no relationship between age of the respondents and depression giving a P value of 0.992. Therefore the likelihood of depression happening was similar in all age groups.

Most of the respondents had some formal education; worth noting is that the participants who were more educated were more likely to be depressed than the ones who had little or no formal education (P = 0.013). Whereas education was significant to depression level, occupation did not play any role in one being depressed or not as the occurrence of depression in all categories of occupation was found to be not significant with a P value = 0.430. The respondents who were earning less money in this study were more likely to be depressed than their colleagues who were earning more money. (P = 0.000).

### 4.3 Levels of Anxiety of Respondents

Each respondent filled the standardized Becks Anxiety Inventory (BAI) Checklist. The results are in Table 8 below.

**Table 5: Participants Anxiety Levels Using BAI**

Anxiety levels	Frequency	Percentage
Minimal	4	4.2%
Mild	67	70.5%
Moderate	10	10.5%
Severe	14	14.7%
<b>Total</b>	<b>95</b>	<b>100</b>

From table 5 above 25.2% of the respondents had moderate to severe anxiety. Most respondents (94.8%) had some form of anxiety scoring as mild, moderate or severe levels. The prevalence of anxiety requiring intervention in this study population was 25.2%. This is the group (25.2%) that needed to seek the help of a qualified physician or counselor or urgent treatment.

### 4.3.1 Relationship between Anxiety and age, education level, occupation and income

Table 6 below shows the relationship between anxiety and age, education level, occupation and income.

**Table 6: Relationship between anxiety and age, education level, occupation and income**

	<b>Age N(95)</b>			
BAI scores	20- 25	26 - 30	31 - 35	36 - 40
Anxiety present n = 24	13.4% (13)	9.5%(9)	2.1%(2)	0
No Anxiety n = 71	14.7%(14)	27.4%(26)	26.3%(25)	6.3%(6)
<b>P=0.003 ; r = 0.379</b>				
	<b>Education Level N(95)</b>			
BAI scores	None	Primary	Secondary	Tertiary
Anxiety present n = 24	2.1% (2)	11.6%(11)	8.4%(8)	3.4%(3)
No Anxiety n = 71	2.1%(2)	30.5% (29)	30.5%(29)	11.6%(11)
<b>P= 0.621; r = 0.106</b>				
	<b>Occupation N(95)</b>			
BAI scores	Housewife	Business	Employed	Casual
Anxiety present n = 24	11.6%(11)	7.3%(7)	2.1%(2)	4.2%(4)
No Anxiety n = 71	27.4%(26)	31.6%(30)	6.3%(6)	9.5%(9)
<b>P= 0.708 ; r = -0.008</b>				
	<b>Income N(95)</b>			
BAI scores	5,000 & below	5,000 – 10000	10,000 – 20,000	
Anxiety present n = 24	20%(19)	3.2%(3)	2.1%(2)	

No Anxiety n = 71	45.3%(43)	16.8%(16)	12.6%(12)
P= 0.253 ; r = 0.167			

From table six above, the results revealed that there was no relationship between level of education and anxiety ( $p=0.621$ ). The results also showed that there was no relationship between anxiety and occupation with a P value = 0.708. This finding was also similar with anxiety and income with a P = 0.253. On the contrary the analysis showed that age affected anxiety levels in that the participants with lower age were more prone to anxiety than the older participants  $P=0.003$ .

#### 4.3.2 Relationship between Anxiety and Depression

Table 7 below shows whether there was any relationship between the level of anxiety and depression among the respondents.

**Table 7 : Relationship between Anxiety and Depression**

	Anxiety	
Depression	Yes	No
Yes	10.5% (10)	21% (20)
No	14.7% (14)	53.6% (51)

P= 0.219 is not significant

There was no relationship between levels of anxiety and depression.

#### 4.4 Participants feelings and experiences while their infants were participating in the HIV vaccine Trials

Table 8 below shows the categories of feelings expressed by mothers of infants participating in the HIV vaccine trials.



**Table 8: Feelings and Experiences for Participating in the HIV Trial**

<b>Feeling</b>	<b>Frequency</b>	<b>Percentage</b>
Feels good because the results may help other children when there is a vaccine	85	89.5
Worried about long-term effect of the vaccine	6	6.3
Wished to get the vaccine	4	4.2

The results showed that most (89.5%) of the respondents felt the HIV trials were good because of the expected results in terms of a successful vaccine.

**4.5 Feelings about Infant feeding method in the trial.**

Table 9 below shows how mothers of infants participating in the trial felt about their choice of feeding method.

**Table 9: Feeling about feeding method**

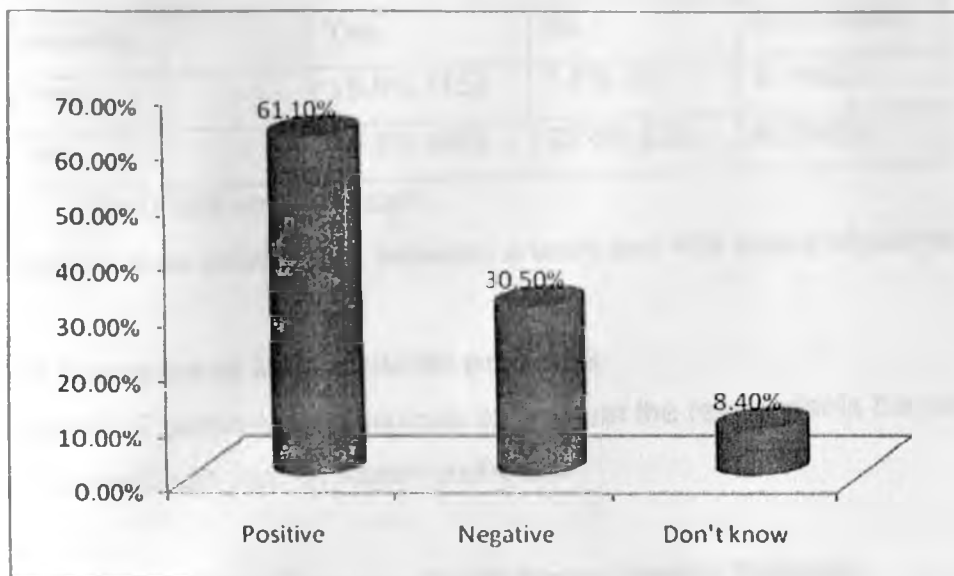
<b>Feeling</b>	<b>Frequency</b>	<b>Percentage</b>
As long as the child is not infected all is well	69	72.7
Fear of infecting the child due to breast milk	21	22.1
Good after being counseled	5	5.3

The results showed 72.7 percent were happy with the method as long as there was no infection of the infant. However, 22.1% feared the method might lead to the child being infected.

**4.6 HIV status of respondents partner**

Diagram 1 below shows the infection categorization of partners of the respondents.

**Diagram 1: HIV Status of Partner**



The results were that 61.1% percent of partners of respondents were HIV positive while a significant 31% were negative.

**4.6.1 Relationship between HIV status of partner and Depression**

Table 10 below examined whether there was any relationship between the HIV status of respondents partner and prevalence of depression.

**Table 10: Relationship between HIV status of partner an depression**

Depression	HIV status of partner		
	Yes	No	Don't know
Yes	20% (19)	7.4% (7)	2.1%(2)
No	41.1% (39)	21.1% (20)	6.3%(6)

P= 0.904 not significant

There was no relationship between prevalence of depression amongst respondents and HIV status of partner.

**4.6.2 Relationship between HIV status of partner and Anxiety**

Table 11 below examined whether there was any relationship between the HIV status of respondents partner and prevalence of anxiety.

**Table 11: Relationship between Status of partner and anxiety**

Anxiety	HIV status of partner		
	Yes	No	Don't know
Yes	15.8% (15)	7.4% (7)	2.1%(2)
No	45.3% (43)	23.4% (22)	6.3%(6)

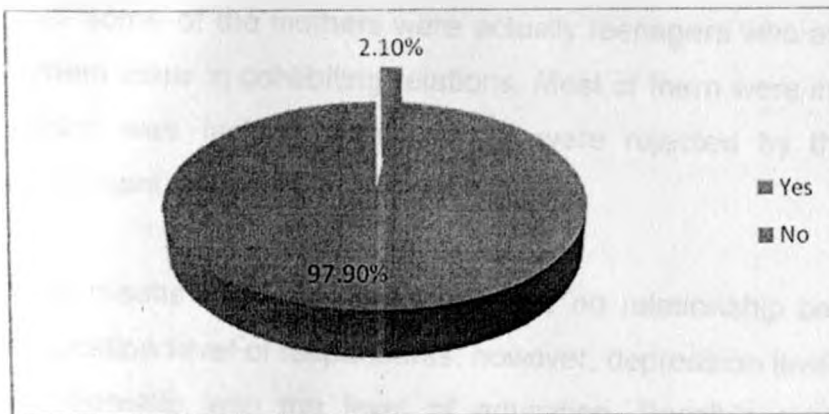
P= 0.985 not significant

There was no relationship between anxiety and HIV status of partner.

#### 4.7 Exposure to Mental health problems

Diagram 2 below shows findings on whether the respondents had been diagnosed with mental health problems.

**Diagram 2: Ever Diagnosed with Mental Health Problem**



An insignificant (2.1%) number of the respondents had been diagnosed with mental problems. The majority of the respondents had not been diagnosed with mental illness.

## CHAPTER FIVE

### DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

#### 5.0 Introduction

This chapter presents the discussion of the findings, conclusions and recommendations.

#### 5.1 DISCUSSION

The results of this study suggested that HIV positive mothers who participated in the HIV vaccine suffered from psychological problems, specifically anxiety and depression. Although there was no relationship between age and depression it clearly showed that anxiety had an impact on age as those who were younger was found to be more anxious than the older ones. Possible explanations include that some of the mothers were actually teenagers who are not yet married while others were in cohabiting relations. Most of them were in need of social support which was lacking because they were rejected by their parents and other significant people in their lives.

The results did show that there was no relationship between anxiety and the education level of respondents, however, depression levels of respondents had a relationship with the level of education. Possible reasons include the wide knowledge by those who were more educated on HIV, stigma associated, and the fact that HIV was previously perceived to be found in the less educated. For the less educated they could be viewing HIV as another disease like the others. For example one respondent said that the disease comes from the human beings so one just has to accept. In a way this perception helps the participant to cope.

While income levels did not seem to have contributed to anxiety levels, the results showed that those who were earning less were more likely to be depressed. Possible reasons being, because they are already depressed they have no energy to work or they have no motivation to look for work to do. A

participant reported that she didn't have energy and that she could wait until the husband comes home in the evening to cook. Failure to work could explain why the income is low. Another possible explanation is that most of mothers were earning less than Kshs. 5 000 per month and with the state of Kenya's economy it is difficult to meet the basic needs with that amount of money.

Although it was evident that most of the respondents were living in temporary houses with majority in single rooms it didn't show that this accommodation had a contribution to either depression or anxiety. Majority of the mothers who were participating in the study were seen to be happy with their participation and this explains why their participation might not have contributed to psychological problems.

Majority of the participants had no previous mental illness. This explains why disease burden, low income levels, stigma and other social issues could have contributed to development of a mental illness.

### **Prevalence of Depression**

The prevalence of depression in this study population as indicated by the BDI scores was 31.6%. This prevalence level is higher compared to a study done by Bernstein *et al* (2009) that showed depression as a common disorder that affect 16.8% of the population at any time. The finding also showed that there was no relationship between age of the respondents and depression hence the likelihood of depression happening was similar in all age groups.

The levels of depression found in the study are consistent with other studies that have been done to determine the levels of depression among HIV positive mothers. Most of the respondents earned below kshs 5000 hence were poor. Ward (1993) found that poverty is associated with psychological morbidity and is a reality for most HIV infected women. Ward (1993) also noted that a substantial number of women seemed to be experiencing depressive symptoms and HIV

related worries. He also observed that socio-demographic and certain health related factors impinged on a persons' wellbeing.

As stated early, most of the respondents had some formal education; worth noting is that the participants who were more educated were likely to be depressed than the ones who had little or no formal education. Whereas education was significant to depression level, the kind of occupation did not play any role in one being depressed or not as the occurrence of depression in all categories of occupation was found to be not significant. The respondents who were earning less money in this study were more likely to be depressed than their colleagues who were earning more money.

### **Prevalence of Anxiety**

Anxiety has for long been recognized as a prominent symptom of many psychiatric disorders and is normally characterized by feeling fearful.

The prevalence of anxiety in this study population was 25.2%. The results also revealed that there was no relationship between anxiety and level of education, type of occupation and income level. However, participants of lower age were more prone to anxiety than older participants.

## **5.2 CONCLUSION**

The purpose of this study was to determine the prevalence of anxiety and depression in HIV positive mothers whose infants were participating in a HIV vaccine study and whether there was any difference with the normal population. The findings showed that the prevalence of anxiety and depression in this group was higher than that of the normal population.

It also indicated that majority of the mothers who had formal education were more depressed and anxious than the others who had low levels of education. This indicated that those who understood HIV/AIDS and what it meant in their

lives were more worried and depressed than those who might not have a good understanding of its nature.

The study also showed that those who were younger precipitated signs of anxiety than the mothers who were older. This could indicate that they did not have adequate social skills to handle issues.

### **5.3 RECOMMENDATIONS**

- Researchers in clinical trials should make a deliberate effort and put in place strategies to include psychological care of their participants.
- The government and non-governmental organizations should come up with strategies and policies that assist this group of persons to generate income and reduce their levels of depression.
- The government and policy makers should come up with a strategy to help the literate people appreciate the knowledge they have and use it to solve their challenges and problems.
- All City Council of Nairobi health Centres should have clinics which handle young mothers and ensure that they have access to services that include psychological care.
- Considering the potential for such a study to serve as the basis for better strategies to towards managing mental illness, it is recommended that a prevalence study that will involve more study areas be conducted.
- Donors should also be made aware that while they are considering the staff to be employed in the study they should also include a psychiatrist/psychologist.

### **5.4 LIMITATIONS OF THE STUDY**

Information / data was collected when the clients were exiting the trial vaccine study and all of them throughout the study period had received at least one session of counseling which could have reduced their levels of anxiety and depression.

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## **CONSENT FORM**

### **Consent form and explanation**

My name is Dorcas J. Murei a Clinical Psychology student in the Department of psychiatry, University of Nairobi.

I am undertaking a research to understand anxiety and depression in mothers whose infants are participating in this HIV vaccine trial.

I have received permission from the Principal Investigator of this project to ask you some questions related to this study.

I am requesting you to participate in the study and if you agree to undertake the same, you will be required to respond to a set of questionnaires in writing under my guidance.

There might be minimal emotional risk associated with the study but the Researcher will be able manage before you are released from the study clinic.

A Study Number will be assigned to you and only that number will be used on the data forms.

All the completed data forms will be kept under lock and key by the Researcher for safe custody.

Your responses will be strictly confidential and there will be no linkage of data by name.

Please answer each question to the best of your ability.

Your participation in this study is purely voluntary and you have the right to withdraw at any time of the study.

There will be no loss of benefit or imposition of any penalty incase you withdraw.

### **Risk of the study**

The risk is that the questionnaires may trigger any emotional feeling you have ever had during your participation in this HIV vaccine study.

### **Benefits**

There is no direct benefit for participation in this study. However, those who will be found to very anxious or very depressed will be referred for treatment at Kenyatta National Hospital. Secondly the results of this study may draw attention to policy makers and researchers to consider having routine screening and treatment for all clients participating in research.

No payments would be forthcoming in agreeing to participate in the study.

Thank you for your assistance

Dorcas J. Murei Msc. Clinical Psychology Student,

Department of psychiatry , University of Nairobi.

Tel . 0722-863658.

**Participants Consent Form**

I, whose signature appears below, confirm that I have been explained the nature of this study and have agreed to participate. I have also been explained that I can stop participating any time and that will not in any way affect any care which the study clinic may deem fit to provide based on the outcome of the study.

Signature.....Date.....  
.....

**Witnessed**

Name.....Signature.....Date.....

Name of the researcher .....

Signature..... Date.....

## FOMU YA WARAKA WA IDHINI

### FOMU YA WARAKA WA IDHINI NA MAELEZO

Jina langu ni Dorcas J. Murei mwanafunzi wa saikolojia ya kliniki katika Idara ya psychiatry, Chuo Kikuu cha Nairobi.

Mimi ninafanya utafiti wa kuelewa wasiwasi na matatizo ya mama wenye watoto wachanga ambao wanashirik: katika jaribio la chanjo dhidi ya virusi vya UKIMWI.

Nimepewa kibali na Mtafiti mkuu wa utafiti huu kukuuliza maswali kuhusiana na utafiti huu.

Mimi nina kuomba ushiriki katika utafiti na kama wewe utakubali na kufanya hivyo, utahitajika kujibu seti ya maswali yaliyoandikwa chini ya uongozi wangu.

Huenda kukawa na hatari ndogo ya hisia zinazohusiana na utafiti lakini Mtafiti atawajibikana nazo kabla ya wewe kuwa huru kutoka kliniki ya utafiti.

Utapeewa nambari ya utafiti ambayo ndiyo pekee itakayotumika kwenye fomu za data.

Fomu zote za data zitakazokuwa zimekamilishwa zitafungiwa na kufuli na Mtafiti ili ziwe salama na chini ya ulinzi.

Majibu yako yatakuwa ni ya siri na hakutakuwa na uhusiano wa data na jina.

Tafadhali jibu kila swali kwa kagiri ya uwezo wako.

Rushiriki kwako kwenye utafiti huu ni kwa hiari na una haki ya kujitoa wakati wowote kwenye utafiti huu. Hautapoteza haki zako au kuadhibiwa kwa aina yoyote ukijiiondoa.

## **Hatari za utafiti**

Hatari ni kwamba maswali yanaweza kusababisha hisia ambazo umeshawahi kuwanazo wakati wa kushiriki kwenye utafiti huu wa chanjo dhidi ya virusi vya UKIMWI.

## **Faida**

Hakuna faida ya moja kwa moja kwa ajili ya kushiriki katika utafiti huu. Hata hivyo, wale ambao watapatikana kuwa na wasiwasi sana au huzuni sana wataelekezwa kuenda kwa matibabu kwenye Hospitali ya Taifa ya Kenyatta. Pili matokeo ya utafiti huu yanaweza kufanya watunga sera na watafiti kuzingatia kuwa na uchunguzi wa mara kwa mara na matibabu kwa wateja wote wanaoshiriki kwenye utafiti.

Hakuna malipo kwa ajili ya kukubali kushiriki kwenye utafiti.

Asante kwa msaada wako.

Dorcas J. Murei Mwanafunzi wa saikolojia ya kliniki,  
Idara ya psychiatry, Chuo Kikuu cha Nairobi.  
Simu 0722-863658

## SOCIO - DEMOGRAPHIC QUESTIONNAIRE

SERIAL NUMBER .....

Code /No. .... Date of birth ..... 19.....

Please answer the following questions by ticking as appropriate.

### Question 1

Educational background.

A) None (B) Primary Level (C) Secondary Level (D) Tertiary Level

### Question 2

4. Marital status

(A) Married (B) Single (C) Divorced (D) Widowed (E) Separated (F) cohabiting

### Question 3

5. Occupation

(A) House wife (B) Small Business (C) Large Business (D) Employed  
(E) Casual Laborer.

### Question 4

Income per month

(A) 2000 and Below (B) Above 2,000 but Below 5,000 (C) Above 5,000 but Below  
10,000 (D) Above 10000 but Below 20,000

### Question 5

Type of house

(A) Temporary (B) Semi Permanent (C) Permanent

### Question 6

Number of rooms in the house.

(A) One (1) Room (B) 2 Rooms (C) One (1) Bedroomed (D) Two (2)  
bedroomed Self Contained (E) Three (3) Bedroomed Self-Contained  
(F) Others ..... (Specify)



**Part II -Questions related to study**

**Question 7**

Is your partner HIV positive?

- (A) Yes (B) No (C) Don't Know.

**Question 8**

Do you have other children?

- (A) Yes (B) No

**Question 9**

If yes, is any of them infected with HIV?

- (A) Yes (B) No (C) Don't Know D) Not applicable

**Question 10**

Is any one else infected in your family?

- (A) Yes (B) No (C) Don't Know

**Question 11**

If your answer to question 10 I YES, who?

- (A) Mother (B) Father (C) Brother (D) Sister (E) Brother  
in law /Sister in-law (F) Others D) Not applicable

**Question 12**

Have you ever been treated for mental illness ?

- (A) Yes (B) No

**Question 13**

If yes, explain

.....  
.....  
.....  
.....

**Question 14**

What are your feelings/experiences about your child participating in the HIV vaccine?

.....  
.....  
.....

**Question 15**

Are you breastfeeding your child or formula feeding?

- A) Breastfeeding.
- B) Formula

**Question 16**

How do you feel about your feeding method?

.....

.....

.....

**Question 17**

Is there anything else which has been bothering you during all this period of your participation which you feel like talking about.

- A) Yes

.....

.....

.....

.....

.....

- B) Nothing.

**THANK YOU SO MUCH.**



Date: \_\_\_\_\_

Name: \_\_\_\_\_ Marital Status: \_\_\_\_\_ Age: \_\_\_\_\_ Sex: \_\_\_\_\_

Occupation: \_\_\_\_\_ Education: \_\_\_\_\_

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including today. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

1. Sadness

- 0 I do not feel sad.
- 1 I feel sad much of the time.
- 2 I am sad all the time.
- 3 I am so sad or unhappy that I can't stand it.

2. Pessimism

- 0 I am not discouraged about my future.
- 1 I feel more discouraged about my future than I used to be.
- 2 I do not expect things to work out for me.
- 3 I feel my future is hopeless and will only get worse.

3. Past Failure

- 0 I do not feel like a failure.
- 1 I have failed more than I should have.
- 2 As I look back, I see a lot of failures.
- 3 I feel I am a total failure as a person.

4. Loss of Pleasure

- 0 I get as much pleasure as I ever did from the things I enjoy.
- 1 I don't enjoy things as much as I used to.
- 2 I get very little pleasure from the things I used to enjoy.
- 3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

- 0 I don't feel particularly guilty.
- 1 I feel guilty over many things I have done or should have done.
- 2 I feel quite guilty most of the time.
- 3 I feel guilty all of the time.

6. Punishment Feelings

- 0 I don't feel I am being punished.
- 1 I feel I may be punished.
- 2 I expect to be punished.
- 3 I feel I am being punished.

7. Self-Dislike

- 0 I feel the same about myself as ever.
- 1 I have lost confidence in myself.
- 2 I am disappointed in myself.
- 3 I dislike myself.

8. Self-Criticalness

- 0 I don't criticize or blame myself more than usual.
- 1 I am more critical of myself than I used to be.
- 2 I criticize myself for all of my faults.
- 3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

- 0 I don't have any thoughts of killing myself.
- 1 I have thoughts of killing myself, but I would not carry them out.
- 2 I would like to kill myself.
- 3 I would kill myself if I had the chance.

10. Crying

- 0 I don't cry anymore than I used to.
- 1 I cry more than I used to.
- 2 I cry over every little thing.
- 3 I feel like crying, but I can't.



11. Agitation

- 0 I am no more restless or wound up than usual.
- 1 I feel more restless or wound up than usual.
- 2 I am so restless or agitated that it's hard to stay still.
- 3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

- 0 I have not lost interest in other people or activities.
- 1 I am less interested in other people or things than before.
- 2 I have lost most of my interest in other people or things.
- 3 It's hard to get interested in anything.

13. Indecisiveness

- 0 I make decisions about as well as ever.
- 1 I find it more difficult to make decisions than usual.
- 2 I have much greater difficulty in making decisions than I used to.
- 3 I have trouble making any decisions.

14. Worthlessness

- 0 I do not feel I am worthless.
- 1 I don't consider myself as worthwhile and useful as I used to.
- 2 I feel more worthless as compared to other people.
- 3 I feel utterly worthless.

15. Loss of Energy

- 0 I have as much energy as ever.
- 1 I have less energy than I used to have.
- 2 I don't have enough energy to do very much.
- 3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

- 0 I have not experienced any change in my sleeping pattern.

---

- 1a I sleep somewhat more than usual.
- 1b I sleep somewhat less than usual.

---

- 2a I sleep a lot more than usual.
- 2b I sleep a lot less than usual.

---

- 3a I sleep most of the day.
- 3b I wake up 1-2 hours early and can't get back to sleep.

17. Irritability

- 0 I am no more irritable than usual.
- 1 I am more irritable than usual.
- 2 I am much more irritable than usual.
- 3 I am irritable all the time.

18. Changes in Appetite

- 0 I have not experienced any change in my appetite.

---

- 1a My appetite is somewhat less than usual.
- 1b My appetite is somewhat greater than usual.

---

- 2a My appetite is much less than before.
- 2b My appetite is much greater than usual.

---

- 3a I have no appetite at all.
- 3b I crave food all the time.

19. Concentration Difficulty

- 0 I can concentrate as well as ever.
- 1 I can't concentrate as well as usual.
- 2 It's hard to keep my mind on anything for very long.
- 3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

- 0 I am no more tired or fatigued than usual.
- 1 I get more tired or fatigued more easily than usual.
- 2 I am too tired or fatigued to do a lot of the things I used to do.
- 3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

- 0 I have not noticed any recent change in my interest in sex.
- 1 I am less interested in sex than I used to be.
- 2 I am much less interested in sex now.
- 3 I have lost interest in sex completely.

Subtotal Page 2

Subtotal Page 1

Total Score

3 4 5 6 7 8 9 10 11 12 A B C D E

## Questionnaire 1 - The Beck Anxiety Inventory

### Instructions:

Think about the past week and then read through the symptoms, giving a number to the amount of bother each symptom gave you over the past week as follows:

Not At All -0	Mildly -1	Moderately-2	Severely -3
---------------	-----------	--------------	-------------

Symptom	Not At All	Mildly	Moderately	Severely
1. Numbness or tingling				
2. Feeling hot				
3. Wobbly legs				
4. Unable to relax				
5. Fear of the worst happening				
6. Dizziness				
7. Pounding heart				
8. Unsteady				
9. Afraid				
10. Nervous				
11. Choking feeling				
12. Trembling hands				
13. Shaky				
14. Fear of losing control				
15. Difficulty breathing				
16. Fear of dying				
17. Scared				
18. Indigestion				
19. Light headed/Faint				
20. Face flushed				
21. Hot/Cold Sweats				
Total of each column				

Now add the totals together

## Measurement/Interpretation (For Researcher)

Now add the totals together to give you a number between 0 and 63.

### Scores:

- 0-7: Minimal level of anxiety. No action required.
- 8-21: Mild anxiety. Look at the sources of anxiety in your life and think about how you can minimize their impact.
- 21-42: moderate anxiety. You are advised to seek the help of a qualified physician or counselor.
- 42-63: severe anxiety. Urgent treatment is needed. Please see a qualified physician or counselor.



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20<sup>th</sup> January 2012

Dorcas J. Murei  
Dept. of Psychiatry  
School of Medicine  
University of Nairobi

Dear Dorcas

Research proposal: "Prevalence of Anxiety and Depression in HIV Positive mothers whose Children are completing an HIV infection vaccine trial" (P471/11/2011)

This is to inform you that the KNH/UON-Ethics & Research Committee has reviewed and **approved** your above revised research proposal. The approval periods are 20<sup>th</sup> January 2012 – 19<sup>th</sup> January 2013.

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given. Clearance for export of biological specimens must also be obtained from KNH/UON-Ethics & Research Committee for each batch.

On behalf of the Committee, I wish you a fruitful research and look forward to receiving an **executive** summary of the research findings upon completion of the study.

This information will form part of the data base that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely

PROF A'N GUANTAI  
SECRETARY, KNH/UON-ERC

cc. The Deputy Director CS, KNH  
The Principal, College of Health Sciences, UON  
The Dean, School of Medicine, UON  
The Chairman, Dept. of Psychiatry, UON  
The HOD, Medical Records, KNH  
Supervisors: Dr. Caleb Othieno, Dept. of Psychiatry, UON  
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