

**ASSOCIATION BETWEEN COMMON MENTAL DISORDERS AND  
ADHERENCE TO HIV CARE AMONG WOMEN ATTENDING A HIV  
CLINIC IN BURNT FOREST, KENYA**

**BY:**

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## DECLARATION

### **Declaration by Student**

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## **DEDICATION**

This thesis is dedicated to my loving family for all their support and especially to my lovely daughter Kaylie Chebet. Also, to Winnie Chebet and Caro Sang, I can never be grateful enough.

## ABSTRACT

**Background:** Mental health disorders have been shown to pose a significant health burden in HIV infected women and are associated with non-adherence to care. It is therefore imperative to diagnose and manage them early to ensure optimal health outcomes.

**Objectives:** This study assessed the prevalence of depression, anxiety and alcohol use disorder and evaluated their association with adherence to clinic appointment and to antiretroviral treatment in women attending a HIV clinic in Burnt Forest, Kenya.

**Methods:** Interviews were conducted with 250 women on ART attending the Burnt Forest HIV clinic over a one-month period. Socio-demographic and adherence information was collected and; PHQ-9, GAD-7 and AUDIT were used to screen for symptoms of depression, anxiety and alcohol use disorder respectively. Descriptive statistics was used to summarize the data and multivariate logistic regression used to model the association between the socio-demographic factors, mental disorders and adherence.

**Results:** The mean age for the respondents was 39.3 years (SD  $\pm$ 9.3 years) with nearly half (49.2%) reporting having ever missed a clinic appointment. The prevalence of depression, anxiety and alcohol use disorder was 24%, 16% and 4% respectively; and the overall adherence to ART was 89%. There was no association between the assessed mental disorders and any of the adherence measures.

**Conclusion:** There is a high prevalence of undiagnosed mental disorders in these women attending a HIV clinic. Their ART adherence was comparatively higher with low rates of adherence to clinic appointment. Depression, anxiety and alcohol use disorder in these women was not associated with clinic appointment or ART adherence.

**Recommendations:**

Although no association was noted between the assessed mental health disorders and the adherence measures assessed, there was a significant burden of undiagnosed mental disorders. Therefore, there is urgent need to build health care worker/system capacity to diagnose and manage mental disorders to ensure optimal health outcomes.

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## LIST OF ABBREVIATIONS

<b>AIDS</b>	Acquired Immunodeficiency Syndrome
<b>AMPATH</b>	Academic Model Providing Access to Healthcare
<b>APA</b>	American Psychiatric Association
<b>ART</b>	Antiretroviral Therapy
<b>ARV/s</b>	Antiretroviral/s
<b>AUDIT</b>	Alcohol Use Disorders Identification Test
<b>BDI</b>	Beck Depression Inventory
<b>BMI</b>	Body Mass Index
<b>CHASE</b>	Coping with HIV/AIDS in Southeast study
<b>DAART</b>	Directly Administered Antiretroviral Therapy
<b>DSM-IV</b>	Diagnostic and Statistical Manual Fourth Edition
<b>DSM-V</b>	Diagnostic and Statistical Manual Fifth Edition
<b>GAD-7</b>	Generalized Anxiety Disorder test
<b>HAART</b>	Highly Active Antiretroviral Therapy
<b>HSCUS</b>	HIV Costs and Service Utilization Study
<b>HIV</b>	Human immunodeficiency Virus
<b>IREC</b>	Institutional Research and Ethics Committee
<b>KAPR</b>	Kenya AIDS Progress Report
<b>LSAD</b>	Leeds Scale for the Self-Assessment of Anxiety and Depression
<b>MDD</b>	Major Depressive Disorder
<b>MOH</b>	Ministry of Health
<b>MPH</b>	Master of Public Health
<b>NACC</b>	National AIDS Control Council
<b>NASCOP</b>	National AIDS and STI Control Programme
<b>NEPHAK</b>	National Empowerment Network of People Living With HIV and AIDS in Kenya
<b>NOK</b>	Ndetei-Othieno-Kathuku scale
<b>PLHIV</b>	People Living with HIV/AIDS
<b>PHQ-9</b>	9 item Patient Health Questionnaire for depression
<b>PTSD</b>	Post- traumatic stress disorder
<b>US/USA</b>	United States of America
<b>WHO</b>	World Health Organization

## DEFINITION OF TERMS

### **Mental Health**

WHO defines mental health as ‘state of well-being in which every individual realizes his or her own potential, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to her or his community.’ (WHO, 2014)

### **Mental Health Disorder/Mental Disorder/Psychiatric Disorder**

This refers to “a syndrome characterized by clinically significant disturbance in an individual’s cognition, emotion regulation, or behaviour that reflects a dysfunction in the psychological, biological and developmental processes underlying mental functioning. The disorders are usually associated with significant distress or disability in social, occupational, or other important activities.” (American Psychiatric Association [APA], 2013)

### **Depression**

Mental disorder characterized by either depressed mood or loss of interest or pleasure during the same two-week period. These symptoms must cause the individual clinically significant distress or impairment in social, occupational, or other important areas of functioning. The symptoms must also not be a result of substance abuse or another medical condition. (DSM-V)

### **Anxiety**

Mental disorder characterized by excessive worry that is experienced as very challenging to control and accompanied by physical or cognitive symptoms that cause the individual clinically significant distress or impairment in social, occupational, or other important areas of functioning. (DSM-V)

### **Alcohol Use Disorder**

A maladaptive pattern of drinking, leading to clinically significant impairment or distress, occurring within a 12-month period (DSM-V)

### **Adherence**

WHO defines adherence as “the extent to which a person’s behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider.” This requires the patient’s agreement to the recommendations. (WHO, 2003)

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## CHAPTER ONE

### INTRODUCTION

#### 1.1 Background Information

WHO defines health as “state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (WHO, 2014a). Mental health is more than the mere lack of mental disorders (WHO, 2014b). Mental health concepts include perceived self-efficacy, subjective well-being, autonomy, competence, intergenerational dependence and recognition of the ability to realize one’s emotional and intellectual potential (WHO, 2001a). It has also been defined as a state of well-being whereby individuals are able to cope with the normal stresses of life, recognize their abilities, work and fruitfully and productively and contribute to their communities (WHO, 2008).

Mental illness is a well-known co-morbidity in HIV/AIDS infection, with high prevalence of mental illness being detected in this population (Chibanda *et al.*, 2016; Kendall *et al.*, 2014; Kinyanda, Hoskins, Nakku, Nawaz & Patel, 2011; Shacham *et al.*, 2008a; Whetten, Reif, Wheeter & Murphy-McMilla, 2008; Too *et al.*, 2021). Co-occurrence of mental illness with substance use is also found at higher levels among HIV infected individuals as compared to the general population (Remien *et al.*, 2019). In a study to assess HIV costs and service utilization (HCSUS), 13% of participants were found to have both mental health and substance abuse problems (Galvan, Burnam & Bing, 2003). A study of psychiatric co-morbidities among HIV-infected individuals receiving care at infectious disease clinics in North Carolina found even higher levels of co-morbid mental illness and substance abuse, as 23% experienced symptoms of both disorders (Wheeten *et al.*, 2008). Mental illness has been steadily on the rise especially with the increase in life expectancy due to the availability of

highly active antiretroviral therapy and especially in the Sub-Saharan Africa with the initiation of programs to care for persons infected with HIV and the rapid scale up of these services (Kinyanda, *et al.*, 2011). Thus, advances in treatment have resulted in people living longer with the disease and this increased population of individuals infected with HIV is dealing with complex psychological and social demands of this life-threatening illness (Matacotta, 2010; NIH, 2020). Psychiatric and substance abuse disorders among people infected with HIV may interfere with quality of life, negatively affect the need for and utilisation of health services, impact health outcomes and compromise adherence with complicated medication regimens (Abas *et al.*, 2014; Bing *et al.*, 2001; NIH, 2020; Shacham *et al.*, 2008b; Tran *et al.*, 2014; Yehia *et al.*, 2015).

Neuropsychiatric disorders are very common in HIV infected individuals and it has been associated with HIV disease since the beginning of the AIDS epidemic (Evans, Mason, Bauer, Leserman & Pettito, 2002; Remien *et al.*, 2019). It is attributed to a number of factors such as direct effects of the virus, pre-existing psychiatric conditions, personality vulnerabilities, affective disorders, addictions, or responses to the social isolation and disenfranchisement that are frequently associated with the diagnosis of HIV (Bing *et al.*, 2001; Deribew *et al.*, 2010; Kagee, 2008; NIH, 2020; Pence, Miller, Gaynes, & Eron, 2007a).

The most common psychiatric disorders include anxiety disorders, depression and alcohol use disorders with substance use and depression being the most common (Bing *et al.*, 2001; Abas *et al.*, 2014; Too *et al.*, 2021; Whetten *et al.*, 2008). There is an association between depressive disorders and HIV/AIDS with high levels of depression being seen in people living with HIV/AIDS (PLHIV) attended to in primary care clinics and in HIV medical clinics (Abas *et al.*, 2014; Petrushkin,

Boardman & Ovunga, 2005). As AIDS develops there seems to be a sustained rise in depressive symptoms (Petrushkin *et al.*, 2005). Disorders of alcohol use are frequently seen together with anxiety, depression and severe mental illness (Castillo-Carniglia *et al.*, 2019; Chander, Himelhoch & Moore, 2006).

Research done previously suggests that rates of drug and psychiatric disorders vary depending on the population studied and the groups for comparisons used. Depression in HIV-infected clinic populations has been found to range from around 22% to 32%, which is 2 to 3 times higher than the prevalence of depression in general community populations (Bing *et al.*, 2001), to as high as 46% to 54% in some studies (Nakimuli-Mpungu, Musisi, Natabira, Nachenga & Bass, 2011a; Petrushkin *et al.*, 2005; Whetten *et al.*, 2008) or as low as 8.1% (Kinyanda *et al.*, 2011). Depression is a common and often impairing problem resulting from the various stressors involved with being HIV positive such as minimised social support, being isolated and increased exposure to violence, as well as adjustment to antiretroviral treatment that is complicated (Abas *et al.*, 2014; Bengston *et al.*, 2016; Daughters, Magidson, Schuster & Safren, 2010). In the HIV cost and service utilization study (HCSUS), 36% of HIV infected individuals screened positive for depressive symptoms in the previous year (Bing *et al.*, 2001) and similar levels were found in the coping with HIV/AIDS in the Southeast (CHASE) study where 35% of participants screened positive for depression (Pence *et al.*, 2007b). Kinyanda *et al.* (2011) found that factors associated with major depressive disorder (MDD) at univariate analysis only were family history of mental illness, female gender, alcohol dependency disorder, negative coping style, stress and food security; those not associated with MDD were neurocognitive impairment, social support, CD4 counts and BMI. Factors independently associated with MDD were adverse life events, psychosocial impairment, generalised anxiety disorder, post-

traumatic stress disorder and life-time attempted suicide (Kinyanda *et al.*, 2011). In a study in western Kenya among adults living with HIV/AIDS to assess the validity and reliability of the nine item patient health questionnaire (PHQ-9) and the two item patient health questionnaire (PHQ-2) for diagnosing depressive disorders based on the diagnostic statistical manual fourth edition (DSM- IV) (Monahan *et al.*, 2008); MDD, other depressive disorder and any depressive disorder were 13%, 21% and 34% respectively with 53% having mild- moderate depression severity. In this study, depression was associated with female gender but not CD<sub>4</sub> which is a type of white blood cell involved in immunity infected by the HIV virus (Monahan *et al.*, 2008). Another study in Kenya reported 75% of HIV infected individuals living with a psychiatric morbidity as compared to 36% in those not infected with the virus (Kiima, Njenga, Okonji, & Kigamwa, 2004), while a study conducted in the country several years earlier did not show any significant difference in the psychiatric morbidity comparing adults based on their HIV status (Carson, Sandler, Owino, Matete, & Johnstone, 1998). Slightly more than a quarter of the sampled patients (27.2%) reported depressive symptoms in a study conducted at an outpatient clinic offering HIV services at a private hospital in Kenya (Karanja-Mbugua, 2011). In a study to assess factors associated with depressive symptoms among people living with HIV (PLHIV) receiving care and treatment in Kenya, Namibia, and Tanzania it was noted that 28% of the respondents reported mild to severe depressive symptoms; with women reporting more depressive symptoms indicating the need to intervene with women who are depressed, have low social support, or consume alcohol (Kidder *et al.*, 2012).

Anxiety is a concern for patients living with HIV/AIDS as it creates disruption and uncertainty in all aspects of a patient's life (Matacotta, 2010). In the HCSUS study,



16% of participants had generalised anxiety disorder (Bing et al., 2001) while the CHASE study found 29.5% had significant levels of anxiety (Pence et al., 2007b). In the HCSUS study, anxiety symptoms were only slightly higher in females with no differences being noted in the CHASE study. A study in Tanzania found depression or mixed anxiety and depression in 15.5% of subjects and that 4.5% were suffering from other anxiety disorders (Marwick & Kaaya, 2010). In HIV/AIDS, post-traumatic stress disorder (PTSD) may be particularly relevant due to the trauma of knowing that one is infected; which consists of many points of crisis such as learning one's HIV positive status, being diagnosed with AIDS, beginning new treatment, discontinuing treatment, developing new symptoms and terminal illness (Matacotta, 2010). Matacotta (2010) also found that despite prevalence rates of post-traumatic stress disorder (PTSD) in HIV/AIDS ranging from 30% to 64%, looking into the nature of this relationship and assessing how the diagnosis of HIV/AIDS impacts mental health has been problematic. The study also noted that for a PTSD diagnosis to be valid, one must suffer intrusive and recurrent recollections, dreams, or physiological reactivity from cues about the informer, and being informed (e.g., place, time, etc.) of the HIV positive status (Matacotta, 2010).

In a study on PTSD among HIV infected women, no differences were noted by race/ethnicity or any other demographic characteristics but PTSD was associated with reduced social support and a greater number of traumatic experiences (Whetten *et al.*, 2008). A study in Kenya to assess the symptoms of psychological distress being presented by individuals living with HIV in western Kenya who were engaged with a large HIV treatment and prevention initiative, women reported significantly higher symptoms of distress, specifically anxiety and depression (Reece *et al.*, 2007; Shacham *et al.*, 2008b).

A recent study in East Africa on adult patients enrolled for HIV care to assess the prevalence of alcohol consumption and its impact on HIV care both at patient and program level found that of all study participants, 42% consumed alcohol with 27% and 16% respectively being classified as hazardous and hyper drinkers respectively. Compared to women, men were 3 to 4 times more likely to consume alcohol and the use of alcohol was associated with a lower probability of starting ART in a comparison between those who consumed alcohol and those who did not (aSHR = 0.77, p-value = 0.008) and higher likelihood of non-retention to care (aSHR = 1.77, p-value = 0.023) (Patsis *et al.*, 2020).

Most persons with mental health problems in HIV/AIDS do not receive any care for it (Matacotta, 2010; UNAIDS, 2018; Wainberg *et al.*, 2017); for example, the HCSUS study showed that 45% of those with mental disorder did not have documentation of the diagnosis in their medical records (Whetten *et al.*, 2008). Limited research has been done in sub-Saharan Africa with regards to mental health and more specifically in the HIV population and effects on adherence including mental disorder treatment effects on HIV outcomes (Myer *et al.*, 2008; Reece *et al.*, 2007; Shacham, *et al.*, 2008a; Remien *et al.*, 2019). Estimates of national burden of mental disorders in the HIV population are not currently available. Population-based estimates of the prevalence of these disorders among people with HIV and factors associated with them are important for the development and improvement of policies and programs that will enhance access to appropriate care, enhance individual well-being, and reduce the costs of care (Bing *et al.*, 2001; Kwobah *et al.*, 2017; Lake & Turner, 2017; Matacotta, 2010).

Currently, there is no standard clinical definition of adherence that is agreed-upon (American Public Health Association, 2004; Garrison & Haberer, 2017). Several

definitions for adherence exist and include those mentioned herein. Adherence as defined by the Stedman's medical dictionary is "the extent to which the patient continues the agreed-upon mode of treatment under limited supervision" (Stedman, 2013). This is similar to the Federal Drug and Food Agency (FDA) which defines adherence as the extent to which patients take medications as prescribed in agreement with their health care provider (FDA, 2019). Ickovics & Meisler (1997) defined medication adherence as the percentage of prescribed doses taken. In a study to define medication adherence, adherence was defined pharmacokinetically as the serum level of the drug from the patient's pattern of medicine use (Morrison *et al.*, 2015).

Medication regimen adherence is generally defined as the extent to which patients take medications as prescribed by their health care providers. Rates of adherence are usually reported as the proportion of the prescribed doses of the medication actually taken by the patient over a specified period. The definition of adherence can be further refined to include data on the timing of doses (taking pills within a prescribed period) in addition to dose taking (taking the prescribed number of pills each day). In acute disorders, patients usually report higher adherence rates compared with those having chronic disorders; persistence in those with chronic disorders is lamentably low dropping drastically after the first few months of therapy. Adherence is typically reported as: adherence or non-adherence. However, it can range from 0 to more than 100 percent when patients take more than the prescribed amount of medication. (Osterberg & Blanschke, 2005).

WHO (2003) defines adherence as "extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider." Patient participation is crucial in adherence and involves their active, voluntary and collaborative involvement in a

mutually acceptable course of behaviour to produce a therapeutic result; implying that the patient has a choice and that both patients and providers work mutually to establish treatment goals and the medical regimen (Ho, Bryson & Rumsfeld, 2009, Nafradi *et al.*, 2017). Adherence to medication and to clinic visits may therefore be taken as: adherence to medication - taking the prescribed medication in the right dose, at the right time and in the right environment for example without the use of alcohol, before or after meals, with lots of water, storing it correctly and doing this consistently and with minimal supervision during the duration of treatment. Adherence to clinic – keeping all scheduled appointments for due follow-up during the course of treatment and is done to ensure that the patient is taking the medications as they should be, with the dosing and frequency being changed if need be, to check for any adverse drug reactions or any other complication that may arise and to intervene as early as possible.

All these are essential as it ensures that the best possible conditions are given for the treatment to work and with reduced incidence of side effects, drug resistance and lead to overall improvement in outcomes.

Adherence involves both the active participation of the care giver as well as the patient and the instruction/ education given to the patients have to be sufficient and relevant to them as their understanding of the regimen is crucial to the sustenance of adherence especially for long term treatment regimens (WHO, 2003). Care providers need to be vigilant and to maintain continued assessments to ensure adequate adherence is maintained and they should also be equipped to address the concerns of the patient regarding their treatments.

## 1.2 Problem Statement

Worldwide, neuropsychiatric disorders remain among the top causes of disability accounting for a significant proportion of years lost to disability in those aged 15 years and over with the burden of anxiety and depression disorders being higher in females (IHME, 2018, 2020; WHO, 2008). In women aged 15–59 years in Africa, the single most important cause of burden of disease is HIV/AIDS and the per capita burden of HIV is 40% higher for women than for men (WHO, 2008).

The 2018 Kenya AIDS Progress Report (KAPR) showed a declining HIV prevalence (4.9%) as compared to 5.9% and 6.0% respectively in 2014 and 2013 among adults aged 15-49 years; and continued to indicate that disproportionately more women (6.2%) than men (3.5%) aged 15-49 years are infected (National AIDS Control Council [NACC], 2018). Adherence to ART still remains a concern to clinicians since a significant number of patients are still non-adherent to care even with routine adherence counselling and adequate ART counselling done prior to treatment initiation (American Public Health Association, 2004; Ford *et al.*, 2019; NASCOP, 2018; Talam, Gatongi, Rotich & Kimaiyo, 2009). This is worrying given the infectiousness of the virus and the transmissibility of these resistance strains to naïve patients or those already on treatment. Given the high burden of mental disorders and HIV/AIDS combined on the population; and the associated high co-morbidity of mental disorders in the HIV infected populations, it is paramount to recognise and treat them early to ensure that non-adherence due to mental disorders are minimised. Such treatment of mental disorders has been shown to improve overall medical outcomes (APA, 2021; Harvey, 2015; IHME, 2018; Papas *et al.*, 2020; WHO, 2008). Increased understanding and awareness as well as management that is comprehensive and integrated may alleviate the burden caused by co-morbid mental disorders on the

individual, society and the health services (APA, 2021; WHO, 2008). If persons affected with HIV/AIDS do not adhere to treatment it will lead to premature drug resistance with resultant increase in the incidence of drug resistant strains and its subsequent transmission leading to poor outcomes, increased prevalence of disease and higher strain on the resources at the family and society levels.

### **1.3 Justification**

Information on the effect of mental health and/ or disorders and its effect on chronic disorders and specifically HIV/AIDS is mostly available for developed countries especially in Europe and North America and even then is not exhaustive (Remien *et al.*, 2019). Locally, there is limited information on mental health burden in our HIV population and more so on the effect of these mental disorders on treatment adherence and maintenance. This information maybe insightful given the different context in the developed and developing countries and even the differences seen locally. Treatment and adherence in psychiatric disorders have been shown to reduce symptom of disease and allowed those affected to lead relatively normal lives for example, research has consistently demonstrated the efficacy of mental disorder treatment in patients with chronic medical illness and co-morbid mental disorders (IHME, 2018; WHO, 2008), all the more reason to identify them as they are manageable. This study will therefore aim to estimate the prevalence of depression, anxiety and alcohol use disorder in women attending a HIV care clinic and the effect of these disorders on adherence.

### **1.4 Research Questions**

What is the prevalence of depression, anxiety and alcohol use disorder among women attending the Burnt Forest HIV clinic?

What is the adherence rate to clinic appointment and ART among women attending the Burnt Forest HIV clinic?

What is the association between depression, anxiety and alcohol use disorder and adherence among women attending the Burnt Forest HIV clinic?

## **1.5 Objectives**

### **1.5.1 Broad Objective**

1. To determine the association between anxiety, depression, alcohol use disorder and adherence to clinic appointment and to antiretroviral therapy among women attending the Burnt Forest HIV clinic

### **1.5.2 Specific Objectives**

1. To estimate the prevalence and distribution of anxiety, depression and alcohol use disorder among women attending the Burnt Forest HIV clinic
2. To determine the rate of adherence to clinic appointment and ART among women attending the Burnt Forest HIV clinic
3. To determine the association between the mental disorders and adherence among women attending the Burnt Forest HIV clinic

## **CHAPTER TWO**

### **LITERATURE REVIEW**

#### **2.1 Introduction**

Adherence to care in HIV/AIDS is extremely crucial especially with the high rate of drug resistance that occurs when drug regimens are not strictly adhered to. Primary resistance occurs in those who are infected with already resistant strains while secondary resistance will occur in those that are on medication due to viral mutations. The time it takes to occur varies from one individual to another and depends on adherence to medication and time on treatment. Resistance in non-adherence occurs due to the exposure of the virus to sub-optimal levels of drugs (Ekstrand *et al.*, 2012; Yam *et al.*, 2008) that can occur in triple therapy, quadruple therapy, mono or duo therapy. The consequences of missed doses or non-adherence to ARVs appear to be grave, with evidence of increase in viral load after missing only two days and the development of mutant viral strains (American Public Health Association, 2004), though newer HIV drug regimens are associated with lower rates of drug resistance development due to non-adherence compared to the older regimens (WHO, 2021).

#### **2.2 Clinic Appointment and Antiretroviral Therapy Adherence**

Adherence may mean adherence to medication, clinic visits or both. Adherence to medication can be measured by self-reporting, remaining pill count, clinical assessment, directly observed therapy, measuring drug levels or devices that record the times and number that it has been used (Al-Hassany *et al.*, 2019; American Public Health Association, 2004; Castillo-Mancilla & Haberer, 2018; Lam & Fresco, 2015; Osterberg & Blaschke, 2005; WHO, 2003). It can also be measured through pharmacy refills, HIV RNA, drug levels in plasma, urine and saliva and additionally through ART concentrations in dry blood spots and in hair (Castillo-Mancilla *et al.*, 2018).



There is however no gold standard for measuring ARV adherence (American Public Health Association, 2004; Garrison & Haberer, 2017). Adherence to clinic means keeping clinical appointments as these visits support close monitoring of drug adherence, identification of opportunistic infections for treatment, continued health education, identification and treatment of adverse drug reactions with substitution of drugs in the regimen, assessment of patients' overall health status, checking for drug efficacy and switching regimen in cases of failure.

Of the prescribed regimens, few are as complicated and challenging to an individual's daily life as HIV medication therapies (Iacob, Iacob & Jugulete, 2017). Because of the need for sustained viral suppression, adherence to HIV therapy is of paramount importance. Given the long-term survival of HIV reservoirs within treated patients and the high rate of viral replication, it has been estimated that a high level of consistent adherence with medication is required to maintain HIV viral suppression and to prevent the emergence of drug resistance (American Public Health Association, 2004; Schaecher, 2013). Thus the need to maintain a near perfect adherence especially in the Sub Saharan region where there has been roll out of ART to ease the burden of disease and to ensure the success of these programs in curbing the morbidity and mortality wrought by its prevalence and to reduce its incidence.

Before studies were done on HAART adherence, authors had written that if pills taken reached a level of 80%, one could label the patient as being adherent (American Public Health Association, 2004). However, recent evidence suggests that with HAART adherence, an 80% level may be inadequate to prevent the development of drug resistant viral strains (American Public Health Association, 2004; Schaecher, 2013). This is important in light of studies that suggest most individuals on treatment with HAART are not 100% compliant (Heestermans *et al.*, 2016). In fact, data from

some studies suggest that in the preceding two to three days, patients who reported missing a dose or more were as many as 30% (American Public Health Association, 2004), with another study among patients suffering from HIV/AIDS reporting only about one third take their medications as prescribed while the rest do not (Talam *et al.*, 2009). A study in Eldoret, Kenya showed only 43.2% of the subjects were adherent to the prescribed time of taking ART and that while all the participants claimed to be adherent to clinical appointments, a review of hospital records showed that only 93.5% kept their clinical appointments (Talam *et al.*, 2008). In a study conducted in Western Kenya to determine the relationship between adherence to clinic appointments and year-one mortality for newly enrolled HIV infected patients found that 44% of the participants had ever defaulted their clinic appointment. Defaulters were categorised into two; those who had missed only one clinic appointment and those who had missed more than one. Of those reported to have ever defaulted their clinic appointment, 32% were repeat defaulters (Kimeu *et al.*, 2016).

Another study at an urban private hospital in Kenya showed that patient self-report of adherence being greater than 95% was 82%. However, when correlated with pharmacy data on refill, only 52% of these same patients had greater than 95% medication possession ratio (Karanja-Mbugua, 2011). ART adherence rate was found to be 74% in central province Kenya in a study to assess factors that influence non-adherence to ART among HIV and AIDS patients (Wanjohi, 2009). In a cross-sectional community-based study in Machakos county to assess factors contributing to ARV drug adherence among adults living with HIV or AIDS, using pill count, only 59% of the respondents had reached  $\geq 95\%$  level of adherence (Kioko & Pertet, 2017). Additionally, a study to assess adherence and barriers to ART in Kiambu county, only 53% of patients were adherent to their medication regimen (Bashti *et al.*, 2021).

Another study in Mombasa, Kenya reported a rate of greater than 95% adherence in a study on HIV infected individuals who were on the Directly Administered Antiretroviral Therapy (DAART) program (Sarna *et al.*, 2005). It is important to note that while patients may take the total number of prescribed doses, they may not take them at the appropriate times. It was also noted that within a subgroup of patients who took more than 90% of the doses, there was a significant dosing fluctuation in 50% of patients during the first two months of treatment. This dosing fluctuation ranged from taking within 2 hours to more than 2 hours of the defined time (American Public Health Association, 2004).

### **2.3 Mental Health Disorders and Adherence**

Mental health has been shown to have a significant impact on adherence to ARV's in people infected with HIV (Nakimuli-Mpungu *et al.*, 2011b; Remien *et al.*, 2019). Among HIV infected individuals, mental illness has been associated with lower likelihood of receiving ARV's and among those receiving antiretroviral medications; mental illness has been consistently related to poorer medication adherence (Nakimuli-Mpungu *et al.*, 2011b; Remien *et al.*, 2019; Whetten *et al.*, 2008). Depression in HIV infected individuals has been associated with poor drug adherence (Heestermans *et al.*, 2016; Marwick *et al.*, 2010) and faster disease progression (Yousuf *et al.*, 2019; Whetten *et al.*, 2008). The likelihood of attaining good adherence was 42% and 55% lower among those with depressive symptoms as compared to those without in two studies on mental health and adherence outcomes (Nakimuli-Mpungu *et al.*, 2011b; Uthman *et al.*, 2014). Several studies have shown that anxiety symptoms are associated with sub-optimal HIV medication adherence (Remien *et al.*, 2019; Whetten *et al.*, 2008; Willie *et al.*, 2016). Severe anxiety was found to be a predictor for non-adherence to ART during follow up period in a study

in Brazil (Campos, Guimaraes & Remien, 2010). In a study in Denmark to assess the prevalence of depression in HIV positive persons in an out-patient clinic, it was found that patients at risk of major depression were nearly 6 times more likely to have missed at least 1 dose of HAART in the 4 days prior to assessment (Rodkjaer, Laursen & Sodemann, 2010). Only depression contributed significantly unique variance suggesting its primary role and post-traumatic stress disorder (PTSD) playing a secondary role in poor adherence in HIV in a study to assess the relationship of PTSD and depression to ART adherence in persons with HIV (Vranceanu *et al.*, 2008). A study on medication adherence and related factors among those newly initiating on ART found that having depression and non-disclosure of HIV status were associated with poor adherence (Yu *et al.*, 2018).

In a study in Nigeria to assess for adherence in depression, 63.6% of the participants with depression had poor adherence compared to 21.1% of those without depressive disorder (Olisah, Baiyewu & Sheikh, 2010). Olisah *et al.* (2010) also noted that 27% of all the participants had poor adherence. Poor adherence in this study was attributed to patients forgetting, getting tired of taking the pills, lack of energy, hopelessness, cognitive impairment in depression that can cause impaired attention, concentration and memory and in severe cases dementia like syndrome. Olisah *et al.* (2010) further noted that about 30% with depression disorder did not use (the medication at the right time) ten or more pills in the previous week, compared to only 8.65% in patients without depression. The significant association that was seen between depressive disorder and poor adherence suggests that depression is associated with poor medication adherence. This was so in terms of missed doses and the wide variations in dose timing. An Ethiopian study found that non-depressed patients were 2 times more likely to be adherent to medication than those who were depressed (Ambebir,

Woldemicheal, Getachew, Girma & Deribe, 2008). Ammassari *et al.* (2004) found that non adherence to HAART was independently associated with worse depression score rating. In comparison to non-depressed patients, Namukuli-Mpungu *et al.* (2011a) noted that those with subclinical depression were more likely to be using ART for less than 1 year, less likely to have high levels of self-efficacy, had advanced HIV disease and current alcohol use disorder. In a multisite study on depression as a predictor for non-adherence to ART in India and Kenya, patients in India that had severe depression were 4 times more likely to report less than 90% adherence [OR 4.84 (1.63-12.26);  $p = 0.003$ ] while patients in Kenya with depression were more likely to have less than 95% adherence [OR: 1.8 (1.0-13.1) per increase in depression category;  $p = 0.049$ ] (Sarna, 2008). A study to assess factors related to adherence to ART in an HIV outpatient clinic found that although this did not reach significant levels, patients who were non-adherent were 1.3 times more likely to be depressed. However, on multivariable analysis there was no significant association between depression and levels of adherence (Karanja-Mbugua, 2011).

In about 77% of HIV infected persons with history of alcohol problem receiving HAART in a study to assess adherence and alcohol consumption in HIV infected persons with alcohol problems, alcohol was the most significant predictor of adherence, with better adherence being associated with recent abstinence from alcohol compared to at risk level usage or compared to moderate usage (Samet, Horton, Meli, Freedberg & Palepu, 2004). Samet *et al.* (2004) therefore concluded that any alcohol use among HIV infected persons with history of alcohol problems is associated with worse HAART adherence and therefore addressing alcohol use may improve adherence and ultimately clinical outcomes. A study by Kim *et al.* (2007) noted that among HIV infected adults with alcohol problems, depression symptoms but not use

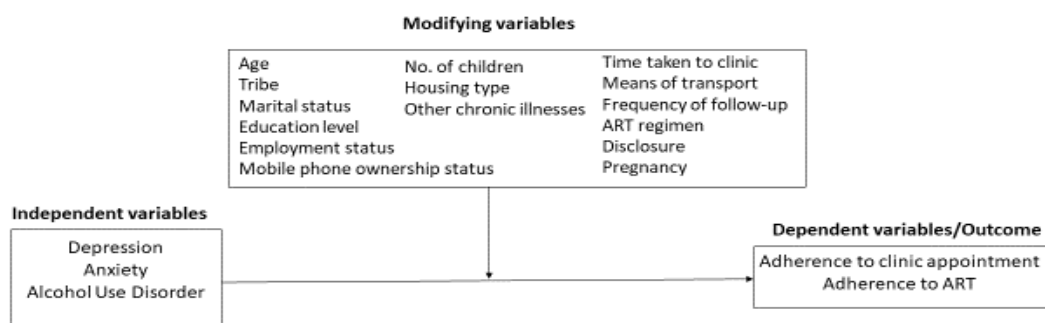
of substance predicted subsequent ART discontinuation. In a study seeking to understand the characteristics of patients who remained on ART compared to those who those who were lost to care, 63% had drug and/or alcohol use as a reason for attrition. In those who wanted to return to antiretroviral treatment, 36% provided cessation of alcohol use or reduced intake as the reason. For those lost to care, significantly more reported use of alcohol and other substances in the past 30 days, drinking several times per week or daily and that use of drug/alcohol use had ever prevented them from taking ART (Pecoraro *et al.*, 2015). Additionally, in a systematic review and meta-analysis to assess determinants of adherence to ART among HIV positive adults in SSA, non-adherence was associated with alcohol use (OR=1.78; 95% CI 1.51-2.09;  $I^2=39\%$ ), binge drinking (OR=2.25; 95% CI 1.92-2.65;  $I^2 =18\%$ ) alongside other sociodemographic factors (Heestermans *et al.*, 2016).

Mental illness is grossly under diagnosed among HIV positive patients (Rodkjaer *et al.*, 2009; UNAIDS, 2018). Brief screening procedures to assess symptomatology at baseline, before starting ART and conducted regularly during clinic visits may help identify indications for ways to improve quality of life and adherence (Campos *et al.*, 2010; Remien *et al.*, 2019; Rodkjaer *et al.*, 2009). It has been shown that those with psychiatric diagnoses can still effectively maintain HAART adherence with dose monitoring by care providers (Karina, 2010; Sikkema *et al.*, 2015; van Luener *et al.*, 2018). Research on providing treatment for mental illness in HIV positive individuals has demonstrated its effectiveness in reducing psychiatric symptoms, improving adherence and reducing cost of care (Sikkema *et al.*, 2015; Whetten *et al.*, 2008).

## 2.4 Conceptual Framework

A conceptual framework is a process layout which an investigator best believes can explain the outcome of the study (Camp, 2001). It explains how the investigator will approach the study problem. It is associated with important theories, concepts and empirical research used in promoting and organising the knowledge adopted by the investigator (Peshkin, 1993). Statistically speaking, a conceptual framework helps to describe the relationship between the main concepts of a study. It provides a visual representation of these relationships (Grant & Osanloo, 2014).

This study adopted the WHO analysis diagram of possible factors contributing to adherence of ART (WHO, 2003).



**Figure 1: Conceptual Framework**

## CHAPTER THREE

### METHODOLOGY

#### 3.1 Study Area

The study was conducted at the Burnt Forest sub-county hospital which is located in the Rift Valley region in Kesses sub-county, Uasin Gishu County. It is about 35kms south east of Eldoret town and approximately 450kms North West in relation to Nairobi city. Kesses sub-county has five wards: Racecourse, Cheptiret/Kipchamo, Tulwet/Chuiyat, Tarakwa and Ngeria. It has an estimated population of 221,000 according to the census figures of 2009 (Kenya National Bureau of Statistics, 2010). The HIV prevalence for Uasin Gishu county stands at 4.3% (National AIDS and STI Control Programme [NASCOP], 2014).

The Academic Model Providing Access to Health care (AMPATH) comprehensive care clinic, located in the sub- county hospital offers HIV care in this catchment area. The AMPATH Burnt forest clinic was staffed by 4 consultants (i.e. physician, paediatrician, obstetrician gynaecologist and psychiatrist) who covered the clinic once or twice a month but were always on call for any consultations; and a medical officer who covered the clinic weekly. The rest of the staff manned the clinic on a daily basis: 4 clinical officers, 3 nurses, 2 outreach workers, 2 social workers and 2 psychosocial workers, 1 nutritionist, 1 pharmacy technologist, 1 phlebotomist, 1 data clerk and 1 records clerk. The services provided there included: HIV testing services, nutritional services, social support services, outreach services, psychosocial support services, treatment for opportunistic infections and provision of ART and follow up by regular appointments to the clinic. The major economic activity is farming, both small and large scale. The centre in which the clinic is located is on the main highway (Mombasa - Malaba) in the northern corridor and has been built partly on trading



especially as it is a stopover for truck drivers who ply that route. The area around the main clinic is cosmopolitan. The locals are drawn from several tribes in the country although the major tribe representation is by the Kalenjin community.

### **3.2 Population**

This consisted of the about 700 HIV positive women who received treatment and/ or follow up at the Burnt Forest AMPATH comprehensive care clinic.

#### **3.2.1 Inclusion criteria**

- Adult women 18 and above years of age
- On ART

#### **3.2.2 Exclusion criteria**

- Those who were too ill to respond

### **3.3 Study Design**

A cross-sectional study design was used to collect baseline information on socio-demographic characteristics, depressive symptoms, anxiety symptoms, alcohol use disorder and adherence. This design was chosen as we did not know the extent of adherence to clinic or ART or mental illness at the time and these were what we sought to determine in the study and further the association between the assessed mental disorders and the assessed adherence measures.

### **3.4 Sample Size Determination**

The sample size required was determined by using a 95% confidence interval and a sampling error of 5%.

The Fisher's formula was used to calculate the sample size.

$$n_0 = \frac{Z_{\alpha}^2 (pq)}{d^2}$$

Where:

$n_0$  = sample size

$Z_{\alpha}$  = statistical constant that represented 95% confidence interval, thus  $Z = 1.96$

$p$  = probability of success (was taken as 50% since we did not have an estimate of mental health prevalence = 0.5)

$q$  = probability of failure (1 -  $p$ )

$d$  = sampling error = 5% = 0.05

$$n_0 = \frac{(1.96)^2(0.5 \times 0.5)}{0.05^2}$$

$$n_0 = 384$$

This was adjusted for the population size of 700 women using the formula:

$$n^* = \frac{n_0}{1 + n_0/N}$$

To get  $n^*$  = minimal sample size

$$n^* = \frac{384}{1 + 384/700}$$

$$n^* = 248 \text{ women}$$

### 3.5 Sampling Procedure

Consecutive sampling was applied in selecting participants to the study to constitute a minimal sample size of 248, as long as they met the eligibility criteria. The participants were identified starting from the first eligible patient seen and subsequently every eligible patient seen. The total number of patients seen in a day was determined by the time it took to fill in the individual questionnaires and the number of eligible patients seen on that particular day and would average 15 - 18.

Recruitment to the study was done by the clinical officers and nurses after administration of informed consent.

### **3.6 Data Collection Procedure**

#### **3.6.1 Tools**

An interviewer administered questionnaire was used to obtain the information. The schedule featured: socio-demographic data, HIV/ART characteristics including adherence information, and screening tools for depression, anxiety and alcohol use. The questionnaire schedule featuring socio-demographic and HIV/ART characteristics was researcher designed and the screening tools for assessing depression, anxiety and alcohol use were validated tools and are further described in detail below. The interviews were carried out in English or Kiswahili under the supervision of the investigator by trained research assistants (clinical officers) in private rooms in the clinic. Information on adherence to ART was by self-report and assessed the rate and the indicators were dosing and timing in the last month. Self-report was used as it was the standard of care for patients on ART and also for mentally ill adult patients whose adherence to medication is assessed by self-report (especially if they live alone); and when accompanied their responses were corroborated with their guardians. Studies done previously have found self-report to be a useful tool in measuring adherence and is very reliable when a patient reported non-adherence (Talam *et al.*, 2009). Participants were requested to produce/show their ART medication and explain how they took them. The rate of adherence to ART was then determined by assessing missed drugs and/or delayed dosing in the last month. Those who missed drugs (more than 2 times as per MOH guidelines) and additionally those who delayed dosing (more than 2 hours) more than 2 times in the last month were categorised as non-adherent. Dose timing is an essential component in adherence to ART especially for drugs that are less forgiving e.g. the non-nucleoside reverse transcriptase inhibitors that formed the back-bone of treatment for the women in this study as compared to newer boosted protease inhibitors and integrase inhibitors.

Delay in dosing has been associated with increased risk of development of drug resistance due to the variations in drug levels that when low still allow for viral replication to occur but high enough to create selection pressure and consequently development of drug resistant strains. [Gill *et al.*, 2010; Vrijens *et al.*, 2003]

Adherence to clinic appointments was corroborated using the clinic appointment card and patient file. The mental disorders symptoms were assessed using the patient health questionnaire (PHQ-9) for depression, generalised anxiety disorder questionnaire (GAD-7) for anxiety and alcohol use disorders identification test (AUDIT) for alcohol use. These tools are for screening purposes and those screening positive require to further undergo diagnostic processes to confirm the diagnosis. The PHQ-9 is a multipurpose tool used for screening, diagnosing, monitoring and measuring the severity of depression in clinic settings. It consists of 9 items on depression symptoms based on the diagnostic criteria for major depressive disorder in the Diagnostic and Statistical Manual Fourth Edition (DSM-IV). Frequencies of symptoms are rated into a severity index between 0-3 and the minimum and maximum range is 0-27. It also contains a non-scored question which tries to assess how the symptoms experienced affect the patient's functional ability (Kroenke & Spitzer, 2002). Its psychometric properties include: validity through various studies which noted that scores equal to or greater than 10 had sensitivity and a specificity of 88% for major depression (Kroenke & Spitzer, 2002). Mild, moderate, moderately severe and severe depression are scored as 5, 10, 15 and 20 respectively (Kroenke *et al.*, 2002; Kroenke, Spitzer & Williams, 2001). It was validated for use in the HIV/AIDS population in western Kenya (Monahan *et al.*, 2008). Anxiety symptoms were assessed using the generalised anxiety disorder questionnaire (GAD-7). It is useful for identifying probable cases of generalised anxiety disorders and assessing the severity. Like the PHQ-9, symptoms of anxiety are rated into a severity index

between 0-3 with a maximum score of 21 and minimum score of 0. Psychometric properties include: Sensitivity and specificity of greater than 80% at cut point greater or equal to 10 with sensitivity being nearly maximized (Spitzer, Kroenke, Williams & Lowe, 2006). Alcohol use was assessed using the WHO AUDIT tool. It is an instrument used to screening for problems with alcohol use. It focuses on recent alcohol use and is able to identify dependence (alcoholism) and harmful or hazardous alcohol use. It consists of 10 items that assess the frequency and amount of alcohol intake: hazardous use (items 1-3), alcohol dependence (item 4-6) and problems related to alcohol consumption- harmful use (items 7-10). Scores range from 0 to 40, and the generally accepted cut-off point of the scale to identify potentially hazardous alcohol intake is 8. At cut of point of 8, sensitivity for the AUDIT for various indices of problematic drinking were generally in the mid 90's%. The specificity across countries and across criteria averaged in the 80's% (Meneses-Gaya, Zuardi, Loureiro & Cripa, 2009; WHO, 2001b). This tool has been used in several studies within the international community and in primary health care settings, including several African countries (Daughters *et al.*, 2010; Kidder *et al.*, 2012; Talam *et al.*, 2008).

Scoring cut offs for each instrument is as indicated in the appendices.

### **3.6.2 Data Collection**

The eligible patients who consented were interviewed using an interviewer administered questionnaire to collect information of the sociodemographic and clinical characteristics. The interview was conducted by a clinical officer and the responses recorded in individual questionnaires. The interviews were conducted privately after the patients had received their regular appointment clinical service.

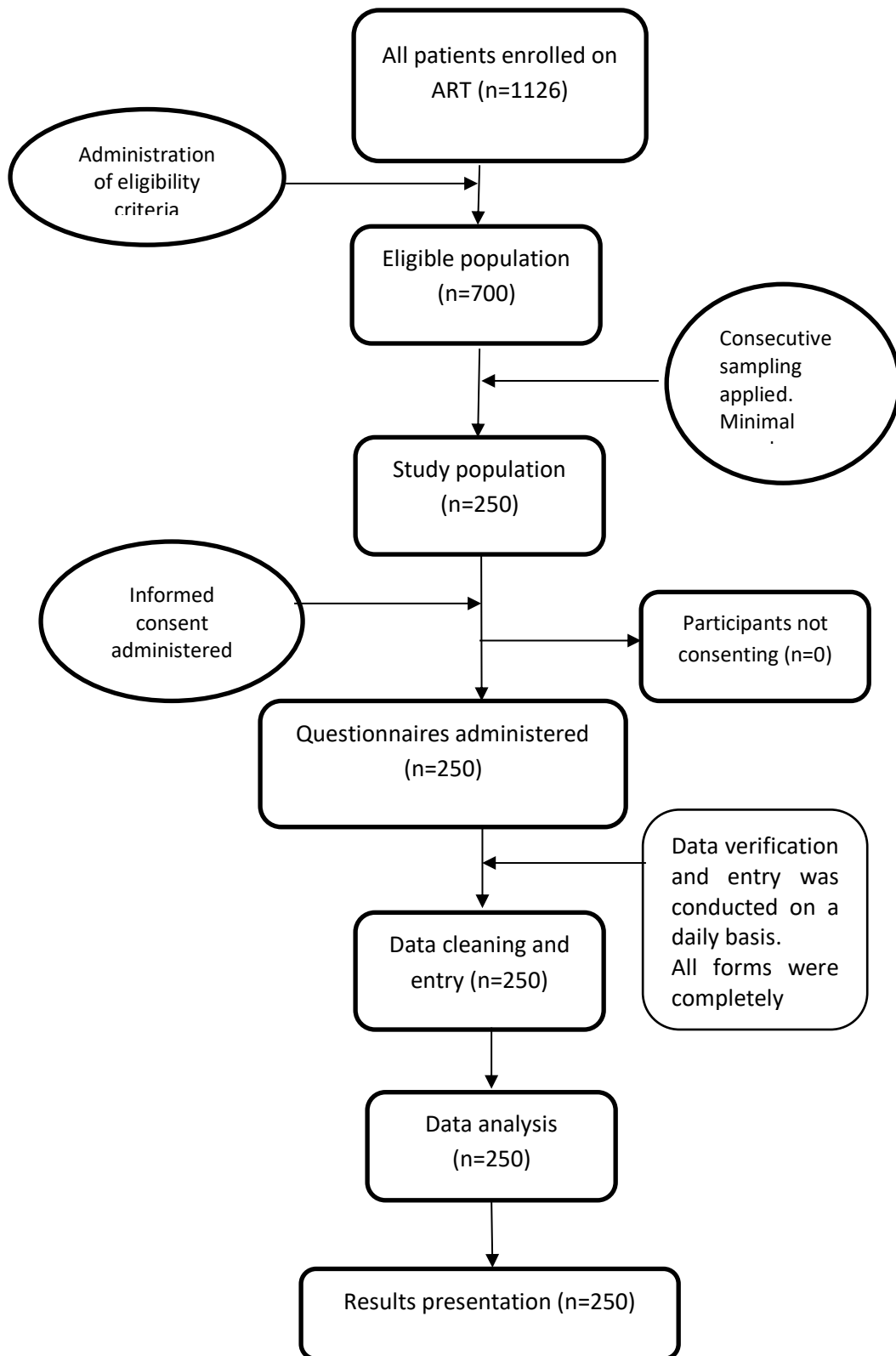
### **3.7 Pilot Study**

A pilot study was carried out at the Turbo HIV clinic. This was done to pre- test the data collection tools, determine the feasibility of the study and to allow for corrections to be made before the main data collection. It was done on 10% of the minimal sample size (248) that is 25. We found that the questionnaire was easy to be administered and was also easily understood by the participants.

### **3.8 Data Analysis and Presentation**

Data from the questionnaire were entered into Microsoft Excel 2010 and then imported to the statistical software package SPSS version 22.0 for analysis. Three measures were looked at, i.e.: socio-demographic characteristics, HIV- related characteristics and mental health characteristics. The nature of the data collected was both numerical and categorical. Numerical data included: age, number of children, pregnancy duration, adherence percentage, duration of ARV use, number of drugs, number of times used a day, duration of follow up at the clinic. Categorical data included: marital status, educational level, housing, employment status, time to clinic, reasons for missed appointments, reasons for missed/delayed ARV use, disclosure status, symptoms of depression, anxiety and alcohol use. Exploratory data analysis was conducted to check for missing data, goodness and meaningfulness of data collected. Descriptive statistics was used to summarize the data into frequency tables. Measures of central tendency used for numerical data were mean and median. The dependent variable was adherence and the independent variables were: age, education level, number of children, marital status, employment, pregnancy, use of other medications, tribe, housing, time to clinic, means of transport, duration of clinic follow up, duration of ARV use, number of ARV drugs, other chronic illness, disclosure status, depression, anxiety and alcohol use disorder. The prevalence of

depression, anxiety and alcohol use disorder was analysed and presented as proportions with 95% confidence interval. Pearson Chi-square and Fischer's exact test were used as appropriate to test the association between the independent variables: socio-demographic factors, mental health factors and adherence. Significant factors from the bivariate analysis were entered into a multivariate logistic regression model to control for potential confounders. Probability values of less than 0.05 were considered significant.



**Figure 2: Study Flow**



### **3.9 Limitations**

We may not have got accurate information on true alcohol consumption. In a study by Shaffer, Njeri, Justice, Odero, & Tierney (2004), at multivariate analyses adjusting for age, sex, site of care, men remained 9 times likely to report hazardous drinking behaviour compared to women.

The GAD-7 only focuses on one anxiety disorder i.e. generalised anxiety disorder whereas there are many other anxiety disorders e.g. PTSD, obsessive compulsive disorder, social phobia. However, generalised anxiety disorder is one of the most common anxiety disorder seen in outpatient clinic settings.

We may not have captured true adherence to ART as we relied on self-report. It is difficult to measure adherence in the outpatient setting with absolute precision and accuracy (American Public Health Association, 2004). Self-report tends to overestimate actual adherence. However, researchers studying HAART adherence agree that self-report asking about missed doses within a very short timeframe i.e. within 1-4 days are more valid and reliable than those asking within a week or greater (Daughters *et al.*, 2010). Self-report will still be used as it is the standard of care. It may be improved by creating a comfortable trusting environment.

### **3.10 Ethical Considerations**

Approval was sought from Moi University/ Moi Teaching and Referral Hospital Institutional Research Ethics Committee (IREC), approval number FAN: IREC 000902. Permission was also sought from the AMPATH and the facility management; and were granted to carry out the study.

Researchers obtained informed written consent from the participants before conducting the study. The study participants were informed about the nature and

purpose of the study, procedures to be used, expected benefits to the individual participants and/or society, the potential of reasonably foreseeable risks/potential stresses/discomforts and that they were free to withdraw at any time at their discretion without prejudice. The participants were also assured of confidentiality and anonymity for any information they gave. Participation in the study was entirely voluntary, free of any coercion or promises of benefits unlikely to result from taking part. All study participants were educated on the importance of adherence to ART, challenges and coping strategies to the challenges to ARV adherence following the conduct of the individual interviews.

Participants found to have depression, anxiety or alcohol use disorders were referred for further psychiatric evaluation. This was contained in the information on the content of the research (appendix) and the participants were made aware that there would be referrals for further evaluation as part of the benefits and ethical considerations of the study should they be found to have the mental disorders above mentioned.

All data was de-identified following initial data collection and was handled with utmost confidentiality. This included password protection for all computer records and locking up forms in a secure location. Paper records will be kept for 12 months after the study is concluded and shredded afterwards. This information will only be accessible to the investigator, her supervisors and the academic committee that will be involved with the student thesis and only upon approved written request.

### **3.11 Dissemination of Results**

The results of this study will be shared with the AMPATH and facility management for appropriate action. It will also be presented to the defence panellist of Moi University, College of Health Science. The results shall also form part of the thesis

which will subsequently be available to the university community and to the public and will also be used to author a manuscript that will be submitted for publication in peer- reviewed journals.

### **3.12 Time Frame**

The proposal development was done between January to June, 2012. It was then submitted to the Moi Teaching and Referral Hospital/ Moi University Institutional Research and Ethics Committee (IREC) in July, 2012 with corrections incorporated from the review within the same month. IREC Approval was received in September, 2012 with training of research assistants and the pilot study conducted in the following month (October, 2012). Data collection was then conducted in December, 2012 with analysis and report writing being conducted between September, 2018 to October, 2019.

## CHAPTER FOUR

### RESULTS

#### 4.1 Socio-demographic characteristics

Two hundred and fifty HIV infected women on ART were recruited into the study. The age range was 18 to 82 years (Mean  $\pm$ SD, 39.3 $\pm$ 9.3 years). Majority of the women were of the Kalenjin tribe (44.4%), followed by the Kikuyu (30.4%) and the Luhya (17.2%). Most of the women were either married (35.6%) or single (34.8%), unemployed (90.0%), lived in semi-permanent housing (91.6%), owned a mobile phone (76.4%) and slightly over two thirds (68%) had primary level of education. The median number of children reported per woman was 3.0 (IQR 2.0-5.0) with 4 (1.6%) women being pregnant at more than 23-weeks gestation. The main mode of transport to the clinic was by use of a vehicle (60.8%) and it took most women less than 2 hours to get to the clinic. (**Table 1**).

#### 4.2 HIV and Medical Factors

A majority of the women (40%) took 3 ARV pills and 96.4% had a dosing of twice daily. Nearly half (48.4%) of the women had been on ART for more than 3 years and 11.6% had been on treatment for less than 1 year. The median duration of follow up at the clinic was 4.0 years (IQR 2.0 – 6.0) and the frequency of follow up was mostly two monthly (36.4%) and monthly (32.8%). Twelve women (4.8%) reported being on medication for other chronic illness with 75% of them being on treatment for hypertension. (**Table 2**)

**Table 1: Socio-demographic characteristics**

<b>Variable</b>	<b>N (%)</b>
<b>Mean age in years (SD)</b>	39.3 (9.3)
<b>Tribe</b>	
Kalenjin	111 (44.4)
Kikuyu	76 (30.4)
Luhya	43 (17.2)
Luo	5 (2.0)
Other	15 (6.0)
<b>Marital status</b>	
Single	87 (34.8)
Married	89 (35.6)
Divorced	4 (1.6)
Separated	24 (9.6)
Widowed	46 (18.4)
<b>Education level</b>	
None	18 (7.2)
Primary	172 (68.8)
Secondary	55 (22.0)
Post-secondary	5 (2.0)
<b>Employment</b>	
Employed	25 (10.0)
Not employed	225 (90.0)
<b>No. of children (IQR)</b>	3.0 (2.0-5.0)
<b>Pregnant</b>	
No	246 (98.4)
Yes	4 (1.6)
<b>Weeks of gestation</b>	
24	1 (25.0)
30	1 (25.0)
32	2 (50.0)
<b>Housing type</b>	
Semi-permanent	229 (91.6)
Permanent	21 (8.4)
<b>Time to clinic</b>	
<1 hour	106 (42.4)
1-2 hours	104 (41.6)
>2hours	40 (16.0)
<b>Transport to clinic</b>	
Walking	70 (28.0)
Vehicle	152 (60.8)
Motorbike	26 (10.4)
Other	2 (0.8)
<b>Mobile phone</b>	
Yes	191 (76.4)
No	59 (23.6)

**Table 2: HIV and other medical characteristics**

<b>Variable</b>	<b>N (%)</b>
<b>No. of ARVs taken</b>	
1	62 (24.8)
2	88 (35.2)
3	100 (40.0)
<b>Daily dosing</b>	
Once	9 (3.6)
Twice	241 (96.4)
<b>Treatment Duration (years)</b>	
<0.5 years	19 (7.6)
0.5-0.9 years	10 (4.0)
1.0-1.9 years	24 (9.6)
2.0-3.0 years	76 (30.4)
> 3 years	121 (48.4)
<b>Follow up (years)</b>	
Mean (SD)	4.3 (2.6)
Median (IQR)	4.0 (2.0-6.0)
<b>Frequency of follow up</b>	
<1 monthly	18 (7.2)
Monthly	82 (32.8)
Two monthly	91 (36.4)
Three monthly	55 (22.0)
Other	4 (1.6)
<b>Chronic Illness</b>	
Yes	12 (4.8)
No	238 (95.2)
<b>Type of Chronic Illness</b>	
Hypertension	9 (75)
Asthma	2 (16.67)
TB	1 (8.33)

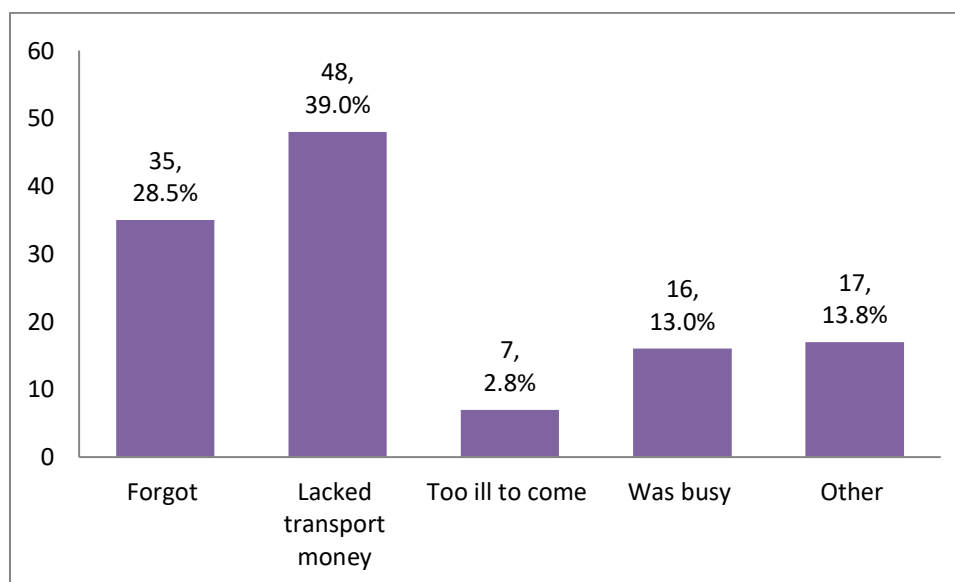
### 4.3 Adherence Rates

#### 4.3.1 Clinic appointment adherence

Nearly half (49.2%) of the women had ever missed a clinic appointment with 8.9% of those missing more than or equal to 5 times (see Table 3). The most common reasons given for missed appointment were the lack of money for transport (39.0%) and forgetfulness (28.5%). (Table 3a and Figure 2)

**Table 3a: Clinic appointment adherence**

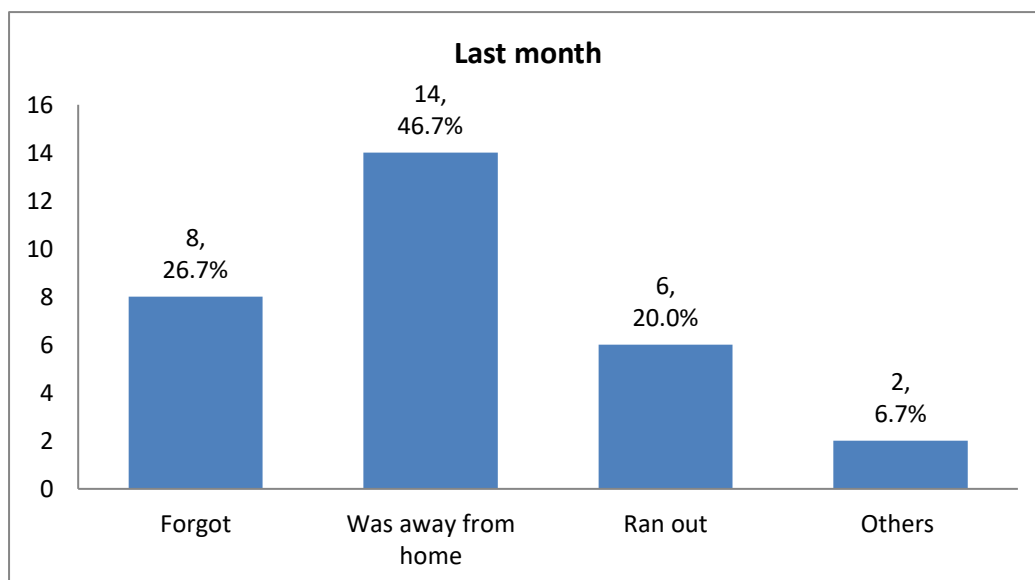
Variable	N (%)
<b>Missed appointment</b>	
No	127 (50.8)
Yes	123 (49.2)
<b>No. of missed appointments</b>	
<5	112 (91.1)
5-10	9 (7.3)
>10	2 (1.6)

**Figure 3: Reasons for missed appointments****4.3.2 ART adherence**

In the last month, 30 women (12%) reported missed doses with 50% being more than or equal to 3 times and the most common reason for missing doses in the last month was being away from home (46.7%). Thirty-two percent of the women reported delayed ARV dosing in the last month with 23.5% reporting that the delay was more than 2 hours and 79.0% of those reporting that the delay was more than or equal to 3 times. Nearly 90% of the women reported having disclosed their HIV status. The adherence rate was 89.2%. (Table 3b and Figure 2).

**Table 3b: ART Adherence**

<b>Variable</b>	<b>N (%)</b>
<b>Missed ARV's in the last month</b>	
No	220 (88.0)
Yes	30 (12.0)
<b>No. of times</b>	
1-2	15 (50.0)
3-4	13 (43.3)
≥5	2 (6.7)
<b>Delayed ARV's in the last month</b>	
No	169 (67.6)
Yes	81 (32.4)
<b>Delayed by</b>	
<2 hours	62 (73.5)
>2 hours	19 (23.5)
<b>No. of times delayed &gt; 2hours</b>	
1-2	4 (21.1)
3-5	12 (63.2)
>5	3 (15.8)
<b>Disclosure</b>	
Yes	218 (87.2)
No	32 (12.8)
<b>Adherence (by dose and timing)</b>	
Yes	223 (89.2)
No	27 (10.8)

**Figure 4: Reasons for missed doses**



#### **4.4 Prevalence of Mental Disorders**

The prevalence of the three mental disorders assessed was: depression (24.0%), anxiety (15.6%) and alcohol use disorder (3.6%). Several women had comorbid mental health disorders with 29 (11.6%) having both depression and anxiety and 6 (2.4%) having all three. Of those who had depressive symptoms, 11 (18.3%) reported having been bereaved in the last 3 months and 2 (3.3%) reported previous history of mental illness. Majority of the women had mild severity for depression (78.3%) and anxiety (76.9%). Of those who reported current alcohol use, 9 (39.1%) had hazardous and harmful use, 2 (8.7%) had high level of alcohol problems and 14 (60.9%) experienced alcohol related harm. One woman reported suicidal ideation nearly every day and was promptly referred for further evaluation. All those who were found to have mental disorders were booked for the psychiatric clinic for further evaluation.

**(Table 4)**

**Table 4: Prevalence of mental disorders**

<b>Variable</b>	<b>N (%)</b>	<b>95 % CI</b>
<b>Depression</b>		
Yes	60 (24.0)	18.4-29.6
No	190 (76.0)	70.8-81.6
<b>Depressive severity (n=60)</b>		
Mild	47 (78.3)	68.3-88.3
Moderate	10 (16.7)	8.3-26.7
Moderately severe	1 (1.7)	0-6.7
Severe	2 (3.3)	0-8.3
<b>Anxiety</b>		
Yes	39 (15.6)	10.8-20.4
No	211 (84.4)	79.6-89.2
<b>Anxiety severity (n=39)</b>		
Mild	30 (76.9)	61.6-89.7
Moderate	4 (10.4)	2.6-20.5
Severe	5 (12.8)	2.6-25.6
<b>Alcohol use</b>		
Yes	23 (9.2)	5.6-12.8
No	227 (90.8)	87.2-94.4
Hazardous and harmful alcohol use	9 (3.6)	1.6-6.4
<b>Co-morbid mental disorders</b>		
Depression and anxiety	29 (11.6)	7.6-16.0
Depression and Alcohol use	7 (2.8)	0.8-5.2
Anxiety and Alcohol use	7 (2.8)	0.8-4.8
Depression, Anxiety and Alcohol use	6 (2.4)	0.8-4.8

## **4.5 Association between Socio-demographic, HIV/Medical factors and Adherence**

### **4.5.1 Socio-demographic, HIV/Medical factors and Clinic appointment adherence**

The mean age for women who adhered to clinic appointment was significantly lower (38.1 years) than those who did not (40.6 years),  $p=0.029$ . Similarly, those with primary education [OR 4.0 (95% CI 1.3-12.7),  $p=0.018$ ] and secondary education [OR 3.6 (95% CI 1.1-12.6),  $p=0.040$ ] were more likely to adhere to clinic appointments than those with no education. Those women who reported less than 1 hour to get to clinic [OR 0.5 (95% CI 0.2-0.99),  $p=0.048$ ] and 1-2 hours [OR 0.4 (95% CI 0.2-0.9),  $p=0.023$ ] to get to the clinic were less likely to adhere to clinic appointment than those who reported taking more than 2 hours. Women who owned mobile phones were more likely [OR 1.9 (95% CI 1.03-3.4),  $p=0.039$ ] to adhere to clinic than those who did not. HIV/Medical factors were not significantly associated with clinic appointment adherence. Only time to clinic was independently associated with clinic appointment adherence. Shorter time to the HIV clinic was associated with poor adherence to clinic appointments. As compared to those who took more than 2 hours to get to the clinic, there was reduced likelihood of adherence to appointments for patients taking 1 to 2 hours [aOR 0.4 (95% CI 0.2-0.9),  $p=0.026$ ]. **(Table 5a and 5b)**

**Table 5a: Socio-demographic, HIV/Medical factors associated with clinic appointment adherence**

	Clinic appointment adherence		OR (95% CI)	p value
	Yes (%)	No (%)		
<b>Mean age (SD)</b>	38.1 (9.1)	40.6 (9.4)	-	<b>0.029</b>
<b>Marital status</b>				
Married	45 (50.6)	44 (49.4)	1.0	
Single	41 (47.1)	46 (52.9)	0.9 (0.5-1.6)	0.649
Divorced	3 (75.0)	1 (25.0)	2.9 (0.3-29.3)	0.359
Separated	10 (41.7)	14 (58.3)	0.7 (0.3-1.7)	0.440
Widowed	28 (60.9)	18 (39.1)	1.5 (0.7-3.1)	0.256
<b>Education level</b>				
None	4 (22.2)	14 (77.8)	1.0	
Primary	92 (53.5)	80 (46.5)	4.0 (1.3-12.7)	<b>0.018</b>
Secondary	28 (50.9)	27 (49.1)	3.6 (1.1-12.4)	<b>0.040</b>
Post-secondary	3 (60.0)	2 (40.0)	5.3 (0.6-43.1)	0.123
<b>Employment</b>				
Employed	10 (40.0)	15 (60.0)	0.6 (0.3-1.4)	0.258
Not employed	117 (52.0)	108 (48.0)	1.0	
<b>Pregnant</b>				
No	124 (50.4)	122 (49.6)	1.0	
Yes	3 (75.0)	1 (25.0)	3.0 (0.3-28.8)	0.352
<b>Housing type</b>				
Semi-permanent	118 (51.5)	111 (48.5)	1.4 (0.6-3.5)	0.449
Permanent	9 (42.9)	12 (57.1)	1.0	
<b>Time to the clinic</b>				
<1 hour	52 (49.1)	54 (50.9)	0.5 (0.2-0.99)	<b>0.048</b>
1-2 hours	48 (46.2)	56 (53.8)	0.4 (0.2-0.9)	<b>0.023</b>
>2hours	27 (67.5)	13 (32.5)	1.0	
<b>Transport to clinic</b>				
Walking	39 (55.7)	31 (44.3)	1.0	
Vehicle	74 (48.7)	78 (51.3)	0.8 (0.4-1.3)	0.331
Motorbike	14 (53.8)	12 (46.2)	0.9 (0.4-2.3)	0.870
Other	0	2 (100.0)	-	0.999
<b>Mobile phone</b>				
Yes	104 (54.5)	87 (45.5)	1.9 (1.03-3.4)	<b>0.039</b>
No	23 (39.0)	36 (61.0)	1.0	
<b>Median duration of follow up in years (IQR)</b>	4 (2-6)	4 (3-6)	-	0.110
<b>Median duration of ARV use in years (IQR)</b>	3 (2-6)	3 (2-6)	-	0.607
<b>No. of ARVs taken</b>				
1	28 (45.2)	34 (54.8)	0.6 (0.3-1.2)	0.180
2	43 (48.9)	45 (51.1)	0.8 (0.4-1.3)	0.328
3	56 (56.0)	44 (44.0)	1.0	
<b>Daily dosing</b>				
Once	4 (44.4)	5 (55.6)	0.8 (0.2-2.9)	0.746
Twice	123 (51.0)	118 (49.0)	1.0	
<b>Treatment duration</b>				
<0.5 years	10 (52.6)	9 (47.4)	1.1 (0.4-3.0)	0.805
0.5-1 year	7 (70.0)	3 (30.0)	2.4 (0.6-9.6)	0.215
1-2 years	14 (58.3)	10 (41.7)	1.4 (0.6-3.5)	0.434
2-3 years	36 (47.4)	40 (52.6)	0.9 (0.5-1.6)	0.762
> 3 years	60 (49.6)	61 (50.4)	1.0	

**Table 5b: Socio-demographic, HIV/Medical factors independently associated with adherence to clinic appointment adherence**

<b>Variable</b>	<b>Adjusted OR (95% CI)</b>	<b>p value</b>
<b>Age in years</b>	0.99 (0.96-1.02)	0.362
<b>Education level</b>		
None	1.0	
Primary	3.2 (0.9-11.5)	0.068
Secondary	2.9 (0.7-11.3)	0.130
Post-secondary	4.4 (0.5-39.6)	0.182
<b>Time to clinic</b>		
<1 hour	0.5 (0.2-1.1)	0.066
1-2 hours	0.4 (0.2-0.9)	<b>0.026</b>
>2hours	1.0	
<b>Mobile phone</b>		
Yes	1.6 (0.8-3.0)	0.152
No	1.0	

#### **4.5.2 Socio-demographic, HIV/Medical factors and ART adherence**

The women who had been on ART between 6 and 12 months were less likely [OR 0.2 (95% CI 0.0-0.8), p=0.021] to be adherent than those who had been on ART for more than 3years. Inversely, those who were on a single pill ART were more likely [OR 4.9 (95% CI 1.1-22.3), p=0.041] to be adherent than those who were on a 3 pill ART regimen. Socio-demographic characteristics were not significantly associated with ART adherence. In multivariable analysis, ART adherence was only independently associated with the number of drugs taken by the patient. When compared to those who took 3 pills per day, those who took a single pill were more likely to report good adherence to treatment, aOR 5.2 (95% CI 1.1-24.3), p=0.038. **(Table 6a and 6b)**

**Table 6a: Socio-demographic, HIV/Medical factors associated with ART adherence**

	ART adherence		OR (95% CI)	p value
	Yes (%)	No (%)		
Mean age (SD)	39.5 (9.4)	38.0 (8.8)	-	0.428
<b>Marital status</b>				
Married	76 (85.4)	13 (14.6)	1.0	
Single	82 (94.3)	5 (5.7)	2.8 (1.0-8.2)	0.061
Divorced	4 (100.0)	0	-	0.999
Separated	19 (79.2)	5 (20.8)	0.7 (0.2-2.1)	0.462
Widowed	42 (91.3)	4 (8.7)	1.8 (0.6-5.9)	0.332
<b>Education level</b>				
None	16 (88.9)	2 (11.1)	1.0	
Primary	151 (87.8)	21 (12.2)	0.9 (0.2-4.2)	0.892
Secondary	51 (92.7)	4 (7.3)	1.6 (0.3-9.5)	0.609
Post-secondary	5 (100.0)	0	-	0.999
<b>Employment</b>				
Employed	23(92.0)	2 (8.0)	0.7 (0.2-3.1)	1.000
Not employed	200 (88.9)	25 (11.1)	1.0	
<b>Pregnant</b>				
No	220 (89.4)	26 (10.6)	2.8 (0.3-28.1)	0.369
Yes	3 (75.0)	1 (25.0)	1.0	
<b>Housing type</b>				
Semi-permanent	204 (89.1)	25 (10.9)	0.9 (0.2-3.9)	0.844
Permanent	19 (90.5)	2 (9.5)	1.0	
<b>Time to the clinic</b>				
<1 hour	93 (87.7)	13 (12.3)	0.4 (0.1-1.8)	0.213
1-2 hours	92 (88.5)	12 (11.5)	0.4 (0.1-1.9)	0.249
>2hours	38 (95.0)	2 (5.0)	1.0	
<b>Transport to clinic</b>				
Walking	62 (88.6)	8 (11.4)	1.0	
Vehicle	135 (88.8)	17 (11.2)	1.0 (0.4-2.5)	0.957
Motorbike	24 (92.3)	2 (7.7)	1.6 (0.3-7.8)	0.597
Other	2 (100.0)	0	-	0.999
<b>Mobile phone</b>				
Yes	170 (89.0)	21 (11.0)	0.9 (0.4-2.4)	0.858
No	53 (89.8)	6 (10.2)	1.0	
Median duration of follow up in years (IQR)	4.0 (2.0-6.0)	3.0 (2.0-6.0)	-	0.083
Median duration of ARV use in years (IQR)	4.0 (2.0-6.0)	2.0 (1.0-5.0)	-	0.095

<b>No. of ARVs taken</b>				
1	60 (96.8)	2 (3.2)	4.9 (1.1-22.3)	<b>0.025</b>
2	77 (87.5)	11 (12.5)	1.1 (0.5-2.7)	0.763
3	86 (86.0)	14 (14.0)	1.0	
<b>Daily dosing</b>				
Once	8 (88.9)	1 (11.1)	1.0 (0.1-8.6)	0.976
Twice	215 (89.2)	26 (10.8)	1.0	
<b>Treatment duration</b>				
<0.5 years	17 (89.5)	2 (10.5)	0.6 (0.1-3.1)	0.542
0.5-1 year	7 (70.0)	3 (30.0)	0.2 (0-0.8)	<b>0.021</b>
1-2 years	21 (87.5)	3 (12.5)	0.5 (0.1-2.2)	0.328
2-3 years	65 (85.5)	11 (14.5)	0.4 (0.2-1.1)	0.075
> 3 years	113 (93.4)	8 (6.6)	1.0	

**Table 6b: Multivariable analysis of socio-demographic and HIV/Medical factors on ART adherence**

<b>Variable</b>	<b>Adjusted OR (95% CI)</b>	<b>p value</b>
<b>Age in years</b>	1.01 (0.96-1.06)	0.684
<b>Education level</b>		
None	1.0	
Primary	0.8 (0.1-5.0)	0.831
Secondary	1.2 (0.2-9.6)	0.847
Post-secondary	-	0.999
<b>No. of ARVs taken</b>		
1	5.2 (1.1-24.3)	<b>0.038</b>
2	1.5 (0.6-3.7)	0.401
3	1.0	
<b>Duration of treatment (years)</b>	1.15 (0.96-1.39)	0.135

#### 4.6 Association between Mental Disorders and Adherence

In this section, we performed multivariate logistic regression to determine the association between adherence as dependent variable and other independent variables (mental health disorders, and socio-demographic variables)

##### 4.6.1 Mental Disorders and Clinic appointment adherence

Multiple variate logistic regression model with clinic appointment as dependent variable and mental disorders as independent variables indicated that; depression, anxiety and alcohol use disorder were not significantly associated with clinic appointment adherence. (Table 7a)

#### 4.6.2 Mental Disorders and ART adherence

Women who had no depression reported higher adherence rates (92.1%) compared to those with depression (80.0%), OR 2.9 (95% CI 1.3-6.7),  $p=0.008$ . Also, those with no anxiety were more adherent (91.9%) than those who had anxiety (74.4%), OR 3.9 (95% CI 1.6-9.4),  $p=0.003$ . There was no association noted between alcohol use disorder and ART adherence. Adjusting for age, education, pill burden and duration of ART, depression and anxiety were not independently associated with ART adherence. (Table 7b)

**Table 7a: Association of socio-demographic factors, mental disorders and clinic appointment adherence**

	Clinic appointment adherence		Crude OR (95% CI)	p value	Adjusted OR (95% CI)	p value
	Yes (%)	No (%)				
<b>Mean Age (SD)</b>	38.1 (9.1)	40.6 (9.4)	-	<b>0.029</b>	0.99 (0.96-1.02)	0.385
<b>Education</b>						
None	4 (22.2)	14 (77.8)	1.0		1.0	
Primary	92 (53.5)	80 (46.5)	4.0 (1.3-12.7)	<b>0.018</b>	3.1 (0.9-10.9)	0.082
Secondary	28 (50.9)	27 (49.1)	3.6 (1.1-12.4)	<b>0.040</b>		0.162
Post-secondary	3 (60.0)	2 (40.0)	5.3 (0.6-43.1)	0.123	2.7 (0.7-10.4)	0.188
					4.3 (0.5-38.7)	
<b>Time to clinic</b>						
<1 hour	52 (49.1)	54 (50.9)	0.5 (0.2-0.99)	<b>0.048</b>	0.5 (0.2-1.1)	0.070
1-2 hours	48 (46.2)	56 (53.8)	0.4 (0.2-0.9)	<b>0.023</b>	0.4 (0.2-0.9)	<b>0.027</b>
>2hours	27 (67.5)	13 (32.5)	1.0		1.0	
<b>Mobile phone</b>						
Yes	104 (54.5)	87 (45.5)	1.9 (1.03-3.4)	<b>0.039</b>	1.5 (0.8-2.9)	0.209
No	23 (39.0)	36 (61.0)	1.0		1.0	
<b>Anxiety</b>						
Yes	23 (59.0)	16 (41.0)	1.0		1.0	
No	104 (49.3)	107 (50.7)	0.7 (0.3-1.4)	0.266	0.4 (0.2-1.0)	0.054
<b>Depression</b>						
Yes	29 (48.3)	31 (51.7)	1.0		1.0	
No	98 (51.6)	92 (48.4)	1.1 (0.6-2.0)	0.661	1.5 (0.7-3.1)	0.278
<b>Alcohol use</b>						
Yes	2 (22.2)	7 (77.8)	1.0		1.0	
No	125 (51.9)	116 (48.1)	3.8 (0.8-18.5)	0.081	2.9 (0.5-15.8)	0.209



**Table 7b: Multivariable analysis of socio-demographic factors and mental health disorders on ART adherence**

	ART adherence		Crude OR (95%CI)	p value	Adjusted OR (95% CI)	p value
	Yes (%)	No (%)				
<b>Mean Age (SD)</b>	39.5 (9.4)	38.0 (8.8)	-	0.428	1.01 (0.96- 1.07)	0.653
<b>Education</b>						
None	16 (88.9)	2 (11.1)	1.0		1.0	
Primary	151 (87.8)	21 (12.2)	0.9 (0.2- 4.2)	0.892	0.8 (0.1-4.9)	0.806
Secondary	51 (92.7)	4 (7.3)	1.6 (0.3- 9.5)	0.609	1.2 (0.1-9.5)	0.874
Post- secondary	5 (100.0)	0	-	0.999	-	0.999
<b>ARVs taken</b>						
1	60 (96.8)	2 (3.2)	4.9 (1.1- 22.3)	<b>0.025</b>	5.1 (1.1-24.1)	<b>0.039</b>
2	77 (87.5)	11 (12.5)	1.1 (0.5- 2.7)	0.763	1.5 (0.6-3.8)	0.383
3	86 (86.0)	14 (14.0)	1.0		1.0	
<b>ART duration</b>						
<0.5 years	17 (89.5)	2 (10.5)	0.6 (0.1- 3.1)	0.542	0.9 (0.2-5.4)	0.937
0.5-1 year	7 (70.0)	3 (30.0)	0.2 (0-0.8)	<b>0.021</b>	<b>0.1 (0-0.3)</b>	<b>0.002</b>
1-2 years	21 (87.5)	3 (12.5)	0.5 (0.1- 2.2)	0.328	0.6 (0.1-2.6)	0.476
2-3 years	65 (85.5)	11 (14.5)	0.4 (0.2- 1.1)	0.075	<b>0.3 (0.1-0.9)</b>	<b>0.036</b>
> 3 years	113 (93.4)	8 (6.6)	1.0		1.0	
<b>Depression</b>						
Yes	48 (80.0)	12(20.0)	1.0		1.0	
No	175(92.1)	15 (7.9)	2.9 (1.3- 6.7)	<b>0.008</b>	1.8 (0.6-5.1)	0.292
<b>Anxiety</b>						
Yes	29 (74.4)	10(25.6)	1.0		1.0	
No	194(91.9)	17 (8.1)	3.9 (1.6- 9.4)	<b>0.003</b>	2.6 (0.8-8.1)	0.111
<b>Alcohol</b>						
Yes	7 (77.8)	2 (22.2)	1.0		1.0	
No	216(89.6)	25(10.4)	2.5 (0.5- 12.5)	0.261	1.3 (0.2-8.7)	0.754

## CHAPTER FIVE

### DISCUSSION

#### 5.1 Introduction

Adherence to care and to ART is crucial to success of management of HIV infection. Adherence in the context of chronic care is particularly challenging and more so in HIV disease given the threshold for development of resistance in the most commonly used ARVs and the standard of care practice of scheduling clinic appointment to coincide with drug refill. Factors affecting adherence should therefore be explored and addressed to achieve the goals of treatment and improve the overall wellbeing of those receiving treatment.

Few studies in our context examine mental health disorders specifically in HIV infected women and their effect on adherence. Most studies on ART adherence assess dose adherence whereas dose timing is also crucial for successful treatment outcomes (Nieuwkerk *et al.*, 2001; Schonnesson, Diamond, Michael, Williams & Bratt, 2006). This cross-sectional study examined the association of depression, anxiety and alcohol use disorder with adherence in women attending a HIV clinic in a rural setting.

The results indicated that the prevalence of depression and anxiety was considerable at 24% and 16% respectively compared to alcohol use at 9% with 39% of the women currently using alcohol reporting hazardous and harmful alcohol use. A majority of the women (89%) were adherent to ART by both dosing and timing while nearly half (49%) of the women had ever missed a clinical appointment. At multivariable analysis, this study noted no significant association between the mental health disorders assessed and adherence. Despite the higher level of ART adherence levels noted (89%), the prevalence of the mental health disorders is of concern given that

these were undiagnosed and could potentially worsen and lead to poor health outcomes.

The ages of the women included in the study appear to be similar to what was reported at the time in the Kenya National AIDS Indicator Survey (NASCOP, 2014). The survey showed that the prevalence of HIV was highest (12.3%) in women between the ages of 35-39 years corresponding to the mean age of 39.3 years in this study (NASCOP, 2014). This was attributed to improved survival of HIV infected persons over time due to enhancements in interventions and wider availability of ART (NASCOP, 2014).

## **5.2 Prevalence of Mental Disorders**

The prevalence of depression in this study was 24% and is comparable to other studies in South Africa, Cameroon, Tanzania, Kenya, Namibia and Tanzania that noted depression rates of between 21% and 28% [Belenky *et al.*, 2014; Gaynes *et al.*, 2012; Kibera, Kuria & Kokonya, 2018; Ngum, Fon, Ngu, Verla & Luma, 2017; Pappin, Wouters & Booysen, 2012; Seth *et al.*, 2014). Other studies in Western Uganda and Kenya noted much higher rates of depression at between 30% - 65% (Nakimuli-Mpungu & Munyaneza, 2011c; Ndeti *et al.*, 2009; Ng'ang'a, (2011). The differences may be explained by the diverse study populations, study settings and the instruments used to screen for depression. One study in Kenya (Ndeti *et al.*, 2009) determined the prevalence of depression in adult (aged 18 years and over) inpatients and outpatients seen in public, private and faith-based general hospitals, health centres and specialised clinics and units of general hospitals located in both urban and rural settings. Ndeti *et al.* (2009) utilized 3 different psychometric instruments [Beck Depression Inventory (BDI), Ndeti-Othieno-Kathuku scale (NOK) and Leeds Scale for the Self-Assessment of Anxiety and Depression (LSAD)] to assess for depression.

It was conducted at time when the stigma and discrimination associated with HIV/AIDS was higher (NEPHAK, 2011) and this may have contributed to the higher prevalence of depression reported in the study. The study population included adults both HIV and non-HIV infected accessing care in the sampled health facilities and only excluded those attending psychiatric and maternity units (Ndetei *et al.*, 2009). The other study in Kenya by Ng'ang'a (2011) was conducted in a national tertiary hospital HIV clinic, recruited adult 18 years and older and utilized the Beck's Depression Inventory to assess for depression. The higher prevalence of depression (47%) in this population may largely be attributed to the fact that it is a tertiary referral hospital HIV clinic handling advanced and/or complicated cases and referrals and therefore likely catering to patients with a substantial burden for psychiatric disorders due to their WHO staging for HIV infection and/or comorbidities. Nakimuli-Mpungu *et al.* (2011c) in the study in Western Uganda recruited HIV infected individuals attending an outpatient HIV clinic and utilized the DSM-IV symptom criteria for depression. Those who endorsed five or more symptoms of depression and indicated that these symptoms had caused significant problems at home, at work, socially, or at school or in some other important way were diagnosed as having depression (Nakimuli-Mpungu *et al.*, 2011c).

The prevalence of anxiety is similar to what was observed in an epidemiological study in western Kenya and in different level general medical facilities in Kenya that both reported 12% prevalence of generalised anxiety disorder (Jenkins *et al.*, 2012; Ndetei *et al.*, 2009); and a study in Ethiopia which reported a 17% prevalence of adherence (Bedaso, Belagavi, Bekele & Mekonnen, 2016). It however differs from other studies conducted in South Africa that reported prevalence rates of 7% and 30% (Pappin *et al.*, 2012; Olley, Seedat & Stein, 2006). As with depression, the varying prevalence

may be explained by the differences in study location and population; and by the instruments and study methods used to assess for anxiety. In one study, 65 recently diagnosed HIV patients were assessed for anxiety using the MINI International Neuropsychiatric Interview at presentation to a hospital-based HIV clinic and then 6 months later (Olley *et al.*, 2006). The other study conducted interviews with 716 patients initiating ART at twelve public health care facilities in the Free State, South Africa (Pappin *et al.*, 2012). Pappin *et al.* (2012) utilized the Hospital Anxiety and Depression Scale to measure anxiety and cut-off levels of 8+ was used to identify possible cases of anxiety. Higher anxiety prevalence here is consistent with recent diagnosis of HIV (Matacotta, 2010) as compared to the findings from this study in which all the participants were already on ART and a majority (79%) had been on treatment for more than or equal to 2 years. Other studies in Ethiopia and Kenya also reported slightly higher prevalence of anxiety at 22% and 23% respectively (Belete, Andaregie, Tareke & Azale, 2014; Ng'ang'a *et al.*, 2011). Both utilized the Beck's Anxiety Inventory to assess for anxiety, had a study population that included HIV infected individuals both on ART and not on ART and were both conducted in the context of referral hospitals.

The prevalence of alcohol use disorder in this study was similar to that in a Kenyan study which reported an alcohol use disorder prevalence of 5.5% (Kibera, Kuria & Kokonya, 2017). Other studies in Uganda and Nigeria reported slightly higher prevalence of 7% (Farley *et al.*, 2010) and 8% (Nakimuli-Mpungu *et al.*, 2011c) respectively. This may be attributed to the differences in study population and setting which included both male and female ART and non-ART individuals and one utilizing the DSM-IV criteria for alcohol abuse. The alcohol use reported in this study of 9% is much lower than studies from US (Lazo *et al.*, 2007) which reported alcohol

use of 41% in women from 2 prospective ART adherence studies and another study in Lao which reported 20% (Hansana, 2013). The lower prevalence of alcohol use and alcohol use disorder noted in this study could be due to the rural setting of the study site and cultural restrictions placed on women and alcohol use that influence its ingestion and likely impacts the consumption rates and subsequently patterns of use reported by the women who took alcohol.

### **5.3 Adherence**

Keeping scheduled clinical appointments is crucial in achieving good treatment outcomes and may be used as a proxy for medication adherence (McClure, Catz & Brantley, 1999; NASCOP, 2018; Park *et al.*, 2007). It allows for review of progress of current management, addressing concerns with new symptoms and adverse events associated with treatment; and also serve as a point for drug prescription refills especially for those with chronic illnesses among other interventions.

In the Kenyan HIV program, clinical appointments are scheduled to coincide with ART refills (NASCOP 2018). This study found that close to half of the women (49%) reported having missed a clinic appointment which may have been associated with missed drug intake as reported in a study in Uganda (Shumba, Atuhaire, Imakit, Atukunda & Memiah, 2013). We however did not assess whether the missed appointments were associated with missed doses nor did we assess the average time taken to return to clinic after a missed appointment.

The most common reasons given for missing clinic appointments were lack of transport money (39%) and forgetting (29%). This is comparable to what was reported in a study in Nigeria where before intervention of the use of mobile phone as reminders in reducing missed appointments, the rate of missed appointment was 44% (Ekeleme, Onwasigwe & Onymachi, 2019.); and in Kenya where 47% reported

having ever missed a scheduled clinical appointment (Ronoh, 2018). It however differs from a study in Lao (Hansana *et al.*, 2013) that reported only 12% of participants missed at least one clinical appointment with the commonest reasons given for missing appointments given as being busy (42%) and lacking money for transport (38%). Our study subjects were predominantly unemployed (90%) while the Lao study had predominantly employed (76%) subjects and this could explain the differences noted in both the adherence to clinic rates and the commonest reasons for missing appointments.

Some studies have reported association between missed appointments with age with some reporting younger age (Bofill, Waldrop-Valverde, Metsch, Pereyra & Kolber, 2011; Kunutsor *et al.*, 2010; Perron *et al.*, 2010) and others with older age (Howe, Cole, Napravnik & Eron, 2010; Nagata & Gutierrez, 2015) with increased likelihood of keeping appointment. A higher level of education has also been reported to be associated with increased likelihood of keeping appointments (Bigna, Noubiap, Plottel, Kouanfack & Koulla-Shiro, 2014). This can be attributed to a greater appreciation of the benefits of engaging in care based on the understanding of the health education and treatment preparations done by the clinical team. In our study, bivariable analysis showed age, level of education and time to clinic were associated with clinic appointment adherence; with younger women, those with primary and secondary education; and those taking more than 2 hours to the clinic being more likely to adhere to clinic appointment. Only time to clinic retained significance in multivariable analysis. This is unlike previous studies that have reported those living further from the care facility as less likely to adhere to clinic appointments (Geng *et al.*, 2010; Rabkin, Austin & Nash, 2010; Ochieng-Ooko *et al.*, 2010). We postulate that in our study, those women who lived further away from the clinic because of the

time taken to get to the clinic prepared earlier for convenience as was routinely advised by the clinical care team due to the risks of missing medication and being lost to follow-up whereas those who lived closer may have been passive in their preparations to attend clinic because of proximity and because it was much easier for them to be followed up in their homes should they miss appointments by the clinic outreach team.

The ART adherence rate reported in this study is comparable to studies conducted in Ethiopia (Letta, Demissie, Oljira & Dessie, 2015) and in the US (Beer & Skarbinski, 2014) that reported ART adherence rates of 85% and 86% respectively. This may be attributed to the efforts by the clinical team in treatment preparation of patients by providing effective education and on-going support during clinic visits and through phone consultations. It was higher than reported in some studies conducted in Ethiopia (Ambebir *et al.*, 2008), 5 African countries (Etienne, Hossain, Redfield, Stafford & Amaroso, 2010), Lao (Hansana *et al.*, 2013) and US (Lazo *et al.*, 2007) which reported adherence rates of between 61% - 77%. The difference noted may be attributed to the methods used to assess adherence, context variations and ART use characteristics for example: number of ARVs taken, dosing and duration on treatment. In the Ethiopian study (Ambebir *et al.*, 2008), the study population comprised both men and women receiving ART in the context of a large specialized university hospital prospectively followed up. Information on adherence was collected at baseline and then at the follow up visit in the third month and it assessed adherence by the number of missed doses in the last seven days, dose timing and adherence to dietary instructions agreed upon with the providers. The study conducted in 5 African countries (Etienne *et al.*, 2010) to assess indicators of adherence to ART among HIV infected persons reviewed medical charts for adult male and female HIV infected



individuals who had been on ART for at least twelve months. Adherence was defined as missed doses in the past week or missed appointments in the past three months. The American study (Lazo *et al.*, 2007), assessed adherence in women prospectively and defined it as taking all meds in the past 3 days (100% adherence) versus not taking all meds in the past 3 days (less than 100% adherence).

The main reasons for missed doses in the last month in our study were being away from home, forgetting and running out of drugs. These are similar to other studies in Kenya (Wanjohi, 2009), Nigeria (Bello, 2011; Erah & Arute, 2007) and Ethiopia (Ambebir *et al.*, 2008; Markos, 2008). Women who had been on ART between 6 months and 1 year were 80% less likely to be adherent compared to those who had been on treatment for more than 3 years. This is similar to a study in US (Hansana *et al.*, 2013) that found longer time from diagnosis was associated with better adherence. This finding differs from another study in the US (Beer *et al.*, 2014) that found longer time since HIV diagnosis was associated with lower adherence. In our study, it is likely that these women were not yet settled on ART and were now on multi-month follow up which meant less frequent contact with the health care providers to provide on-going support.

We also found that those who took 1 ARV drug taken once a day were 5 times more likely to be adherent to ART than those who took 3 ARV drugs taken twice a day. This is in keeping with literature on the impact of dosing; a study in the US (Beer *et al.*, 2014) found that greater than once-daily dosing was associated with lower adherence levels.

#### **5.4 Mental Health Disorders and Adherence**

In bivariate analysis, our study did not find association between any of the assessed mental health disorders (depression, anxiety and alcohol use disorder) and clinic

appointment adherence. We found higher likelihood of ART adherence in those who did not have depression or anxiety but on multivariate analysis, neither depression nor anxiety retained significant association with ART adherence. This is similar to studies in Kenya (Karanja-Mbugua, 2011; Waititu, Mwangangi, Amugune, Bosire & Makanyengo, 2016) which did not find any association between depression and ART adherence. The lack of association between depression and ART adherence is unlike other studies conducted in Cameroon (Ngum *et al.*, 2017), US (Kacanek *et al.*, 2010) and; 2 global review and meta-analysis studies (Gonzalez, Batchelder, Psaros & Safren, 2011; Uthan, Magidson, Safren & Nachenga, 2014), which found an association between them. The findings of no association in our study may suggest that the symptoms of depression assessed could be due to adverse events associated with ART use (e.g. feeling tired or having little energy, poor appetite, trouble falling or staying asleep, or sleeping too much).

Anxiety was also not associated with ART adherence and this was similar to a study in Columbia (Cardona-Duque, Medina-Pérez, Herrera-Castaño, Orozco-Gómez, 2017), US (Pruitt, 2013) and Ethiopia (Tesfaw *et al.*, 2016). Some studies in Brazil (Campos *et al.*, 2010) and Italy (Ammassari *et al.*, 2001) however, showed association between anxiety and ART adherence. The lack of association here too is unlike what is reported in many studies that showed a strong association between mental illness comorbidities to ART non-adherence among many different populations and settings (Hicks *et al.*, 2007; Mellins *et al.*, 2009) suggesting that other factors in this population may be predictors of adherence to ART for example: ART side effects, social support and health system factors among others.

No association was found between alcohol use disorder and adherence. This finding differs from studies in Lesotho (Cerutti *et al.*, 2016) and South Africa (Magidson,

Saal, Nel, Remmert & Kagee, 2017). It is likely attributed to the few numbers of women who reported alcohol use in this study and that men were also included in the compared studies.

A strength of this study was the utilization of both missed doses and timing of doses in the assessment of adherence as opposed to the standard of care at the time that assessed missed doses only. There were some limitations in this study. Firstly, due to the utilization of self-report as was the standard practice to assess adherence, this may not have been entirely accurate. Secondly, due to cultural and other social factors associated with women taking alcohol, its use may have been under-reported by the participants in this study. Thirdly, due to the rural nature of the study environment, the findings may not be generalizable to other populations that are not similar to it. Fourthly, we were unable to relate the obtained adherence rate to CD4 cell count and/or viral count due to financial, logistic and policy barriers which prevented frequent laboratory monitoring and confined viral count testing to restricted subpopulations on ART. Fifthly, we did not assess whether the missed appointments were associated with missed doses nor did we assess the average time taken to return to clinic after a missed appointment.

## CHAPTER SIX

### CONCLUSION AND RECOMMENDATIONS

#### 6.1 Conclusion

From the results of this study, we conclude that there was:

- A high prevalence of undiagnosed depression, anxiety and alcohol use disorder in women attending a HIV care clinic
- A high rate of ART adherence in these women compared to reported studies in similar settings and it was associated with the number of ARV pills taken
- A low rate of clinic appointment adherence and we noted an effect between clinic appointment adherence and the time it took to reach the clinic
- No significant effect of depression, anxiety, and alcohol use on clinic appointment adherence nor ART adherence on these women

#### 6.2 Recommendations

- There is need to explore and address other causes of non-adherence in this population. Special focus should be made to assess socio-demographic factors associated with adherence to clinic appointments for those attending care there since as highlighted in this study, women who took less than 2 hours to the clinic were less likely to adhere to clinic appointments contrary to widely reported better adherence to appointment schedules for those who lived closer to the care facility.
- There is urgent need to build the capacity of health care workers/health system to diagnose and manage mental health disorders including effective referrals and should include brief screening tools incorporated at each visit.
- Alternative strategies for appointment management should be explored including the use of mobile phones reminders as a significant proportion of

women had a mobile phone whereas over a quarter of them reported forgetfulness as a reason for missing clinic appointments. Use of a simplified ART regimen (one pill taken once a day) will likely facilitate adherence to ART as noted by the higher levels of adherence in those women on one pill with once a day dosing.

- Further research is required to evaluate the impact of interventions for management of depression and anxiety in HIV co-infection in our setting and where available this information on mental health assessments and their management should be reviewed regularly to assess effectiveness of interventions in our setting
  - These studies should additionally examine clinical outcomes (viral suppression, retention in care, mortality) to correlate ART adherence and include both men and women; and special groups like children, adolescents and the youth.

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## APPENDICES

### APPENDIX I: Research Consent Information

#### **TITLE: MENTAL HEALTH FACTORS ASSOCIATED WITH ADHERENCE TO ANTIRETROVIRALS IN WOMEN ATTENDING AHIV CLINIC IN BURNT FOREST, KENYA**

This is a study conducted by Moi University School of Public Health student as part of partial fulfilment of her Master of Public Health degree.

Investigator: Kenei R.K. Chemutai

Supervisors: Prof. Joseph Rotich

Dr. Atwoli Lukoye

This study aims to assess the association of depression, anxiety and alcohol use disorder among HIV positive women at the Burnt Forest AMPATH clinic and their effect on adherence to HIV care.

Permission is hereby requested for your participation in the study. Should you consent, the following should be understood by you:

#### **Procedure**

A questionnaire will be administered to you. You are not obliged to answer any question.

You will be asked questions on socio-demographic data, adherence, symptoms of depression, anxiety and alcohol use disorder.

The questionnaire will take about 25-30 minutes to complete.

No invasive procedures will be involved.

**Rights**

Participation is voluntary

You are free to quit at any time during the study.

You are free to seek an explanation on anything involving the study.

There are no right or wrong answers; what is important is that you try and be as honest as you can with your responses.

There will be no penalties of any nature incurred as a result of your participation or declining to participate in this study.

**Benefits**

There are no direct benefits to you as part of this research. However, this project may benefit patients in general because it may help us to understand more about mental disorders and their effect on adherence.

Participants found to have depression, anxiety or alcohol use disorders will be referred for further psychiatric evaluation.

**Risks**

There is a risk of loss of confidentiality.

However, to minimise this:

- All data collected will be treated as confidential and stored safely and securely.

- This information will only be accessible to the investigator, supervisors and the academic committees that will be involved with the student thesis and only upon approved written request.
- Your name will not appear anywhere on the final report and it will not be possible to know which responses came from which individual.

### **Participation**

Participants in the study will be selected at random and everyone has an equal chance at being included.

### **Ethical Considerations**

Approval will be sought from both Moi University/ Moi Teaching and Referral Hospital IREC. Researchers will obtain informed written consent from the participants before conducting the research and they (participants) will be informed that they are free to withdraw at any time at their discretion.

Participants found to have depression, anxiety or alcohol use disorders will be referred for further psychiatric evaluation.

All data shall be de- identified following initial data collection and will be handled with utmost confidentiality. This will include password protection for all computer records and locking up all forms in a secure location. Paper records will be kept for 12months once study is concluded and shredded afterwards. This information will only be accessible to the investigators, their supervisors and the academic committees that will be involved with the student thesis and only upon approved written request.

**APPENDIX II: Consent Form**

I, the undersigned, willingly accept to participate in this study. The nature of the study and what it entails has been explained to me.

I understand that there are no direct benefits to me as part of the research. However, this project will be beneficial to patients in general as it will help in the understanding of burden of depression, anxiety and alcohol use disorder and how they affect adherence to care among HIV patients.

I understand that the risk involved in the study is the loss of confidentiality of the information given but the researcher has assured me that utmost care will be taken to ensure that the information is kept safe and that no names will appear in the final report.

I also understand that I reserve the right to refuse participation at any stage of the study.

SIGN \_\_\_\_\_ Date \_\_\_\_\_

INVESTIGATOR/ WITNESS:

SIGN \_\_\_\_\_ Date \_\_\_\_\_



**APPENDIX III: Questionnaire****PART A****DEMOGRAPHICS**

AMRS/ AMPATH No: \_\_\_\_\_

1. Name \_\_\_\_\_
2. Age \_\_\_\_\_
3. Tribe \_\_\_\_\_
4. Marital status- (circle appropriate)
  - 1 Single
  - 2 Married
  - 3 Divorced
  - 4 Separated
  - 5 Widowed
5. Educational Level
  0. None
  1. Primary
  2. Secondary
  3. Post secondary
6. Employment: are you?
  - 1 Employed
  - 2 Not employed
7. How many children do you have? \_\_\_\_\_
8. Are you pregnant?
  - 1 No
  - 2 Yes. How many weeks \_\_\_\_\_
9. Housing type
  - 1 Semi-permanent
  - 2 Permanent
10. How long does it take you to get to the clinic?
  - 1 < 1 hour
  - 2 1 – 2 hours
  - 3 > 2 hours

What means of transport do you mainly use?

- 1 Walking
- 2 Vehicle
- 3 Motorbike
- 4 Other

11. Do you own a mobile phone?

- 1 Yes
- 2 No

## **PART B**

### **ADHERENCE**

12. Have you ever missed an appointment?

- 1 No
- 2 Yes

If yes, how many times? (Corroborate with the file and appointment card)

- 1 <5
- 2 5-10
- 3 >10

why?

- 1 Forgot
- 2 Lacked transport money
- 3 Too ill to come
- 4 Was busy
- 5 Other (specify)\_\_\_\_\_

13. How long have you been followed up at the clinic (in years)\_\_\_\_\_

14. How often are you seen at the clinic?

- 1 <1 Monthly
- 2 Monthly
- 3 2 Monthly
- 4 3 Monthly
- 5 other (specify)\_\_\_\_\_

15. How many ARV drugs do you take? \_\_\_\_\_

- How many times a day do you take them? \_\_\_\_\_
- For how long have you taken them (in years)? \_\_\_\_\_

16. Have you missed taking your ARV's in the last month?

- 1 No
- 2 Yes.

How many times?

- 1 1-2
- 2 3-4
- 3  $\geq 5$

Why?

- 1) Forgot
- 2) Was away from home
- 3) Ran out
- 4) Other (specify)\_\_\_\_\_

17. Have you delayed taking your ARV's in the last month?

- 1 No
- 2 Yes.

Delayed by?

- 1) < 2 hours
- 2) > 2hours

If delayed > 2hours. How many times?

- 1) 1- 2
- 2) 3-5
- 3) >5

18. Have you disclosed your status?

- 1 No
- 2 Yes

If yes, to whom?

- 1 Spouse/ Partner
- 2 Family/ Relative
- 3 Friends/ Neighbour
- 4 Other (specify)\_\_\_\_\_

19. Are you on any other medications for chronic illness?

- 1 No  
2 Yes

If yes, what illness? \_\_\_\_\_

**PART C DEPRESSIVE AND ANXIETY SYMPTOMS AND ALCOHOL USE**

Have you recently been bereaved (within 3 months)? \_\_\_\_ If so, whom \_\_\_\_\_

Have you ever had a history of any mental illness? \_\_\_\_\_

**PHQ-9**

Over the **last 2 weeks**, how often have you been bothered by any of the following problems? (use “✓” to indicate the answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
	Not at all	Several days	More than half the days	Nearly every day
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3

TOTAL \_\_\_\_ + \_\_\_\_ + \_\_\_\_

<b>10.</b> If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	0) Not difficult at all _____
	1) Somewhat difficult _____
	2) Very difficult _____
	3) Extremely difficult _____

### **GAD-7**

Over the **last 2 weeks**, how often have you been bothered by the following problems?

Circle the response.

0=Not at all sure

1= Several days

2= Over half the days

3= Nearly every day

1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it's hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Total Score = \_\_\_\_\_ (Sum of the circled responses)

If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people?

0) Not difficult at all \_\_\_\_\_

1) Somewhat difficult \_\_\_\_\_

2) Very difficult \_\_\_\_\_

3) Extremely difficult \_\_\_\_\_

### **AUDIT**

Have you ever drunk alcohol?

1 No. (If no, end at this point)

2 Yes

If yes, have you used alcohol in the last year?

- 1 No
- 2 Yes

If no, when did you stop?\_\_\_\_\_

If yes, then proceed to the answer the questions below.

Now am going to ask you about your alcohol use in the last year. (Circle the response)

1. How often do you have a drink containing alcohol?
  - (0) Never [skip to questions 9-10]
  - (1) Monthly or less
  - (2) 2-4 times a month
  - (3) 2-3 times a week
  - (4) 4 or more times a week
2. How many drinks containing alcohol do have on a typical day when you are drinking?
  - (0) 1 or 2
  - (1) 3 or 4
  - (2) 5 or 6
  - (3) 7, 8 or 9
  - (4) 10 or more
3. How often do you have six or more drinks on one occasion?
  - (0) Never
  - (1) Less than monthly
  - (2) Monthly
  - (3) Weekly
  - (4) Daily or almost daily

Skip to Q9 and 10 if the total scores for 2 and 3 = 0
4. How often in the last year have you found that you were not able to stop drinking once you had started?
  - (0) Never
  - (1) Less than monthly
  - (2) Monthly
  - (3) Weekly
  - (4) Daily or almost daily
5. How often during the last year have you failed to do what was normally expected from you because of drinking?
  - (0) Never
  - (1) Less than monthly
  - (2) Monthly
  - (3) Weekly
  - (4) Daily or almost daily

6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?
  - (0) Never
  - (1) Less than monthly
  - (2) Monthly
  - (3) Weekly
  - (4) Daily or almost daily
7. How often during the last year have you had a feeling of guilt or remorse after drinking?
  - (0) Never
  - (1) Less than monthly
  - (2) Monthly
  - (3) Weekly
  - (4) Daily or almost daily
8. How often during the last year have you been unable to remember what happened the night before because had been drinking?
  - (0) Never
  - (1) Less than monthly
  - (2) Monthly
  - (3) Weekly
  - (4) Daily or almost daily
9. Have you or someone else been injured as a result of your drinking?
  - (0) No
  - (2) Yes, but not in the last year
  - (4) Yes, during the last year
10. Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down?
  - (0) No
  - (2) Yes, but not in the last year
  - (4) Yes, during the last year

Total for the specific items \_\_\_\_\_

## **APPENDIX IV: Scoring**

### **PHQ-9**

For initial tentative diagnosis of depression:

Need to rule out normal bereavement and history of manic/hypomanic episode.

If there are at least 4 ✓s in the highlighted section (including Questions #1 and #2), consider a depressive disorder. Add score to determine severity.

#### ***Consider Major Depressive Disorder***

If there are at least 5 ✓s in the highlighted section (one of which corresponds to Question #1 or #2)

#### ***Consider Other Depressive Disorder***

If there are 2 to 4 ✓s in the highlighted section (one of which corresponds to Question #1 or #2)

The last item 10 needs to be endorsed as somewhat difficult, very difficult or extremely difficult.

### **Interpretation of Total Score**

#### **Total Score Depression Severity**

0-4 None

5-9 Mild depression

10-14 Moderate depression

15-19 Moderately severe depression

20-27 Severe depression

When screening for depressive disorders, a recommended cut-point for further evaluation is a score of 10 or greater. All who respond 1,2 or 3 to item 9 should be evaluated further as they may be at a higher risk for suicide.

### **GAD-7**

#### **Total Score Anxiety Severity**

0-4 Minimal anxiety

5-9 Mild anxiety

10-14 Moderate anxiety

15-21 Severe anxiety



When screening for anxiety disorders, a recommended cut-point for further evaluation is a score of 10 or greater.

### **AUDIT**

The response scores from all the items should be added and recorded in as the “Total”.

Total scores of 8 or more are recommended as indicators of hazardous and harmful alcohol use, as well as possible alcohol dependence. (A cut-off score of 10 will provide greater specificity but at the expense of sensitivity.)

More detailed interpretation of a patient’s total score may be obtained by determining on which questions points were scored. In general, a score of 1 or more on Question 2 or Question 3 indicates consumption at a hazardous level. Points scored above 0 on questions 4-6 (especially weekly or daily symptoms) imply the presence or incipience of alcohol dependence. Points scored on questions 7-10 indicate that alcohol-related harm is already being experienced.

AUDIT scores in the range of 8-15 represented a medium level of alcohol problems whereas scores of 16 and above represented a high level of alcohol problems. AUDIT scores of 20 or above clearly warrant further diagnostic evaluation for alcohol dependence.