IMPACT OF SOCIO-DEMOGRAPHIC AND PSYCHOSOCIAL FACTORS ON ADHERENCE TO ANTIRETROVIRAL THEPARY AMONG MOTHERS ATTENDING ANTENATAL CLINICS AT MBAGATHI AND KENYATTA NATIONAL HOSPITALS

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Abbreviations and acronyms

AIDS: Acquired Immunodeficiency Syndrome

ANC: Antenatal clinic

ART: Antiretroviral therapy

ARV: Antiretroviral

EPDS: Edinburgh Postnatal Depression Scale

GAD-7: Generalized Anxiety Disorder-7

HAART: Highly active antiretroviral therapy

HIV: Human Immunodeficiency Virus

KNH: Kenyatta National Hospital

MSPSS: Multidimensional scale for perceived social support

MTCT: Mother to child transmission

OR: Odds ratio

PHQ-9: Public Health Questionnaire-9

SD: Standard deviation

U.o.N: University of Nairobi

Definition of operational terms

Incident cases: new infection cases in a given population over a specified period of time.

Optimal adherence: Taking 95% of the prescribed ARVs on time.

Prophylaxis: Action taken, or treatment given to prevent occurrence of a given disease.

Seropositive: Positive result for an infection such as a virus in a sample of blood serum.

Vertical transmission: Transmission of an infection from mother to the child.

Abstract

Background: Studies have indicated that adherence to antiretroviral therapy is associated with improved treatment outcome. In expectant mothers, it also ensures reduced viral load prior to delivery and during breastfeeding, both of which reduce chances of vertical transmission. Conversely, reduced adherence is associated with development of resistance to the antiretroviral therapy and poor clinical outcomes. Adherence level is affected by various psychosocial factors such as anxiety, depression and social support. There are limited published studies to find out the impact of psychosocial factors on the level of adherence among the pregnant HIV infected women in Kenya.

Objectives: The main objective of this study was to determine the impact of socio-demographic and psychosocial factors on adherence to antiretroviral therapy among mothers attending antenatal clinics at Mbagathi and Kenyatta National Hospitals.

Methodology: This was a cross-sectional descriptive study carried out at the antenatal clinics of Kenyatta National Hospital and Mbagathi County Hospital from 1st April to 30th July 2023. The study population comprised of 70 HIV infected antenatal clinic mothers who were on antiretroviral therapy. Participants who met the inclusion criteria and who gave written informed voluntary consent were enrolled into the study. A pre-tested standardized questionnaire was used to collect information on the socio-demographics, anxiety, depression, and perceived social support. Adherence to antiretroviral therapy was determined using the 8- scale Morisky tool.

Data management: Data analysis was done using IBM SPSS Chicago Illinois version 23. Prevalence and severity of anxiety, depression and perceived social support were computed and presented as percentages. Association between adherence and various psychosocial factors were determined by use of chi square or Fischer's exact test. Binary logistic regression analysis was carried out to determine the independent correlates of adherence to antiretroviral therapy. Variables with P value<=0.05 were interpreted as statistically significant.

Results: The mean age of the study population was 32.3 (SD 5.78) and majority were aged between 18 – 35 years (67.1%), had attained at least a secondary school education level (47.1%) and married (75.7%). The prevalence of adherence to antiretroviral therapy was 78.8% among the HIV infected mothers, with low adherence (47.1%), moderate adherence (21.4%) and high adherence at 31.4%. Prevalence of anxiety was 23.8%, depression (22.6%) and social support (45.7%). There was no statistically significant association between adherence and any of the psychosocial factors under study. However, there was a statistically significant association between level of education and adherence (aOR= 0.257, 95%CI: 0.068 – 0.982, P=0.047) with participants who attained college education level having higher odds of adherence compared to their counterparts in secondary level and below.

Conclusion: Adherence to antiretroviral therapy was sub-optimal and there was considerable level of comorbid psychosocial burden with anxiety, depression, and social support. Higher level of education was significantly associated with good adherence suggesting that adherence mechanisms should be intensified for mothers who have not attained tertiary education level. Integration of psychological and psychiatric services in the Prevention of Mother to Child Transmission Program is recommended. Further studies to underscore other potential barriers to antiretroviral therapy adherence such as side effects of antiretroviral medicine and socio-economic factors is recommendable.

CHAPTER ONE: INTRODUCTION

1.1 Background

Antiretroviral therapy has not only increased life expectancy among Human immunodeficiency virus (HIV) infected mothers attending antenatal clinics (ANC) but also drastically reduced the rate of mother to child transmission (MTCT) of HIV/AIDS (1). The risk of vertical transmission is as high as 25 - 30% in the absence of antiretroviral treatment (ART) (2). Antiretroviral (ARV) use has drastically decreased this risk to less than 1% in most developed countries (3). Although, the fore-mentioned drastic drop can only be realized through adherence to ART, the global adherence rates have been shown to vary between 35 to 93.5% (4). In sub–Saharan Africa, for instance, the rate is at 73.5% (5) while in Kenya, the rate ranges between 65 and 87% (6).

Studies have indicated that adherence to antiretroviral therapy is associated with improved treatment outcome (7). In expectant mothers, it also ensures reduced viral load prior to delivery and during breastfeeding, both of which reduce chances of vertical transmission (8). Reduced adherence is associated with development of resistance to the antiretroviral therapy and poor clinical outcomes (9).

Several factors have been documented to impact on adherence to ART among mothers attending ANCs. For instance, studies have documented that adherence to the ARVs remains a major challenge due to psychosocial factors such as denial, anxiety and depression regarding the diagnosis of HIV/AIDS (5). Depression and anxiety may negatively impact on ARV adherence with resultant decrease in CD4 counts, increase in the viral load and high chances of vertical transmission (10). Furthermore, the global prevalence of depression among seropositive ANC mothers ranges from 12 – 30% (11). In Africa the prevalence rate is at 23.4% (12), whilst in Kenya it is at 32.9% (13) with anxiety at 23.5% (14).

The ANC mothers are also faced with stigma and poor social support which further compound on the problems of anxiety and depression (15). The level of perceived social support can be stratified into high, middle and low (16). Studies have documented that the prevalence of perceived social support is at 22.1%, 47.2% and 30.7% for high, middle and low social support, respectively (16). Social and family support gives motivation, provides encouragement and reminders on taking the ARVs timely and diligently (17). Additionally, good social and family support improves ARV adherence

by 1.4 times (18). The impact of the aforementioned psychosocial factors (anxiety, depression and perceived social support) is further influenced by intervening variables which need adjustment if the above variables are to be studied. Smoking and the alcoholic status of the ANC mother are the confounders that must be adjusted for if the influence of the psychosocial factors in the study are to be underscored (4).

There is scant literature on the associated factors of adherence to ART among mothers attending ANCs in resource limited settings. The present study determined the level of adherence to ARV treatment among the seropositive ANC mothers as well as the psychosocial factors impacting on the adherence level. The psychosocial factors of interest in the study were anxiety, depression and perceived social support.

1.2 Problem statement

The prevalence rate of vertical transmission of HIV in Kenya is estimated at 11.5% while in Nairobi County, the rate is at 8.5% (19). This prevalence is high considering the widespread availability of safe and effective ARVs. In order to significantly lower the vertical transmission of HIV, early diagnosis and prompt start of ARV treatment with strict adherence is vital. In some countries in East Africa, adherence to ARV among ANC mothers is as high as 76.8% (20). In Kenya, the general adherence rates for ART among patients ranges between 65 and 87% (6). There are no documented studies on adherence rates of ART among mothers attending ANCs. Importantly, adherence level is affected by various psychosocial factors, majorly anxiety, depression and social support. Furthermore, the level of clinical depression among seropositive ANC mothers living in Nairobi County is estimated at 33.6% and approximately 24.3% of them are reported to be non-adherent to the ARV therapy (21). On the other hand, the prevalence of social support among seropositive ANC mothers living in Nairobi County is at 43.9% (22). Lack of family and social support plays a vital role in causing depression among the ANC mothers (23). As such, anxiety and depression are associated with decreased adherence, increased viral load and decreased CD4 counts (24). It has been established that poor maternal psychological health in pregnancy has a detrimental effect on the socio-emotional development of the unborn child (25) and should therefore be assessed and mitigated.

It has been proposed that addressing the aforementioned psychosocial factors is associated with improved adherence to ART (26) and subsequent reduction in vertical

transmission rate among mothers attending ANCs. This is because non-adherence is associated with sub-optimal drug plasma concentration, poor treatment outcome and increased resistance to ARVs (27). This is one of the strategies to upscale ARV uptake, which combined with the 'treat all' policy among ANC mothers in Kenya, has helped in reducing mother to child transmission (MTCT) from 26% to 11% between the years 2009 and 2018 (28).

1.3 Research questions

What was the level of adherence to antiretroviral treatment (ART) among mothers attending ANCs at Mbagathi and Kenyatta National Hospital?

What was the influence of anxiety and depression on ART adherence among mothers attending ANCs at Mbagathi and Kenyatta National Hospitals?

What was the impact of family and social support on ART adherence among mothers attending ANCs at Mbagathi and Kenyatta National Hospitals?

1.4 Hypothesis

1.4.1 Null hypothesis

There is no relationship between rates of adherence to ART and psychosocial factors among mothers attending ANCs at Mbagathi and Kenyatta National Hospitals.

1.4.2 Alternate hypothesis

There is a relationship between rates of adherence to ART and psychosocial factors among mothers attending ANCs at Mbagathi and Kenyatta National Hospitals.

1.5 Objectives of the study

1.5.1 Broad objective

To assess the impact of socio-demographic and psychosocial factors on adherence to ART among seropositive mothers attending ANCs at Mbagathi and Kenyatta National Hospitals.

1.5.2 Specific objectives

1. To determine level of adherence to ART among mothers attending ANCs at Mbagathi and Kenyatta National Hospitals.

- 2. To assess the influence of anxiety and depression on ART adherence among mothers attending ANCs at Mbagathi and Kenyatta National Hospitals.
- 3. To determine the impact of family and social support on ART adherence among mothers attending ANCs at Mbagathi and Kenyatta National Hospitals.

1.6 Justification of the study

Globally, around 1.8 million children live with HIV/AIDS with sub-Saharan Africa accounting for the majority. Approximately 90% of these cases occur through MTCT (29). Commencing ARV treatment for HIV infected expectant mothers is associated with improved maternal outcome and decreased vertical transmission of the disease when there is optimal adherence to therapy (30). However, the level of adherence is affected by various psychosocial factors which should be addressed. Among the psychosocial factors is the comorbid depression and anxiety that accompany the disease. Additionally, social support is an important aspect in managing depression and anxiety associated with the HIV/AIDS infection among mothers. Social support improves the treatment outcome, ensures adherence, promotes status disclosure, reduces isolation and stigma, promotes immune reconstitution, enhances disease coping strategies thus ultimately improving on the quality of life among ANC mothers (31). To ensure adequate adherence, reduced viral load, increased CD4 counts, improved treatment outcome and decreased vertical transmission, the aforementioned psychosocial factors need to be addressed. There are limited published studies to find out the impact of psychosocial factors on the level of adherence among the pregnant women in Kenya.

1.7 Significance of the study

The study established the association between degree of social support and level of anxiety and depression among the mothers attending ANCs in Nairobi. This is important because depression is the commonest psychiatric disorder affecting ANC mothers (32) and understanding the degree of its association with ART adherence level would improve HIV/AIDS management. Social support is an essential protective factor for the ANC mothers undergoing the emotional, physical and physiological changes of pregnancy as well as depression. Sufficient social support promotes psychological health in the ANC mothers (15). Conversely, low social support predisposes the ANC

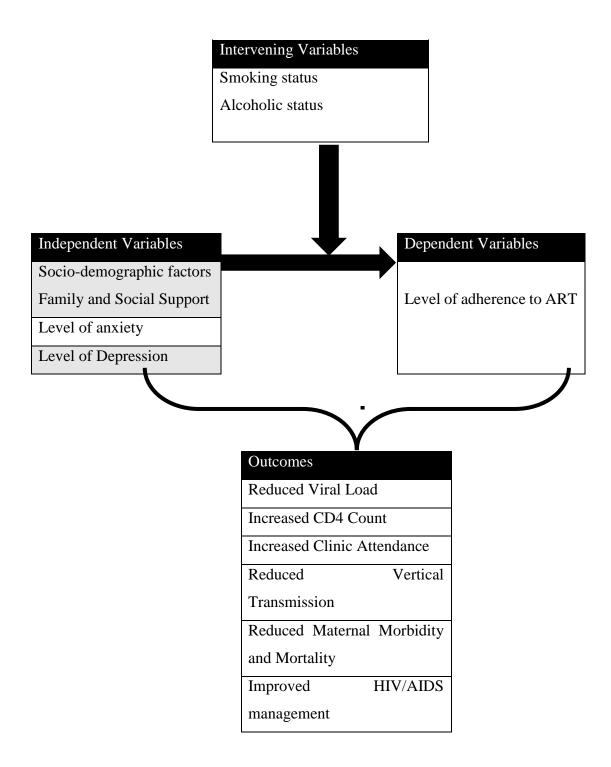
mother to anxiety and depression and probably poor adherence to ART. Assessing depression in the ANC seropositive mothers helps in highlighting the gravity of the condition and thus improves its management as well as management of HIV infection. Managing depression in seropositive ANC mothers is also likely to boost immunity. The increased immunity would help in boosting the CD4 counts and decreasing the viral load. Enhanced maternal health, increased CD4 counts, and diminished viral load are associated with improved pregnancy outcome.

1.8 Delimitations

The study was limited to ANC mothers on ARVs at Mbagathi and Kenyatta National Hospitals.

There are many psychosocial factors which could impact on adherence, but this study was only focusing on family and social support, anxiety and depression. The aforementioned are the psychosocial factors of prime importance in determining adherence.

1.9.1 Conceptual framework



1.9.2 Theoretical framework

The health belief model was used to promote adherence and address psychosocial barriers to the same. The patients were informed on how poor adherence would increase susceptibility of the unborn child to the HIV/AIDS infection as well as the severity of the disease and its detrimental effect on the baby considering the vulnerability and

poorly constituted immune system of the baby. The perceived benefit of good adherence for the mother and her partner as well as the unborn child was discussed. Cues to attaining and maintaining good adherence was highlighted like enrollment into groups for motivation and encouragement.

CHAPTER TWO: LITERATURE REVIEW

2.1 Burden of HIV/AIDS infection among pregnant women and babies

Globally, approximately 1.4 million HIV/AIDS seropositive mothers give birth to almost 330, 000 HIV/AIDs infected babies annually (33) and almost 95% of these infections occur in low-income countries, primarily sub-Saharan Africa (34). Other regions bearing increased disease burden include Latin America, central Asia, Eastern Europe and the Caribbean (35). In Eastern Africa, 26,000 incident cases of HIV infected babies were reported in 2018 and an estimated 10,000 of these cases were attributed to poor retention on ART care throughout gestation and breastfeeding period (28). Studies indicate that HIV/AIDS accounts for 6% mortality rate among children under five years in sub-Saharan Africa (36).

Young women under the age of 25 years account for approximately 30% of incident HIV/AIDS infection cases despite making a paltry 10% of the total population (37). Additionally, approximately 61% of HIV/AIDS cases in sub-Saharan Africa are attributed to women of childbearing age. In the region, structural drivers of the disease, for instance gender inequality, violence and poverty further elevate the rate (38). Pregnancy compounds the problem by increasing susceptibility to HIV infection by 2.8 folds (39).

Early diagnosis and effective management of maternal infection is paramount in reducing vertical transmission thus testing is a vital component of prevention of MTCT. For the HIV negative mothers, retesting is recommended at the last trimester, during delivery and/or post-partum. Despite the recommendation, HIV retesting during conception in sub-Saharan Africa ranges between 25 and 62% (40). Consequently, in the region, approximately 1.8 million children under the age of 15 years live with the disease, of which 90% is acquired through MTCT (29).

Without intervention, the risk of vertical transmission is as high as 30% (2). The high vertical transmission rate has been reduced to as low as 1.1% in developed countries. For instance, China reported a drastic drop from 34.8% in 2005 to 3.6% in 2020 (41). In the United States the figures dropped from 2000 to 200 as of 2010. In 2015, 86 cases of perinatal infection were reported in the USA (2). This reduction is made possible through diligent use of highly active antiretroviral therapy (HAART), formula feeding and infant prophylaxis (42).

The goal of reduction of MTCT was to put at least 95% of the seropositive ANC mothers on HAART. As a result of improved coverage and enhanced regimen, MTCT rate drastically dropped. The drop was more pronounced in southern and eastern Africa where the rate fell from 18% in 2010 to 6% in 2015 (43). However, challenges faced in reducing MTCT in resource limited settings include limited viral load monitoring and inadequate access to elective caesarian section (44).

2.2 Impact of HIV/AIDS on pregnancy and importance of using ARV in gestation

HIV/AIDS is associated with adverse pregnancy outcomes. Some of the known poor outcomes associated with the disease include stillbirths, miscarriages, increased infant mortality, low birth weight, intrauterine growth restriction and chorioamnionitis (45). The reduced immunity makes the disease adversely increase the frequency and lengthen the course of many infections in pregnancy. These include, human papilloma virus, genital herpes, syphilis, bacterial vaginosis, vulvovaginal candidiasis, cytomegalovirus, urinary tract infections, hepatitis B and C and bacterial pneumonia (35). Other concomitant diseases secondary to HIV infection include pneumocystis jerovecii pneumonia and tuberculosis. Additionally, HIV reduces fertility among women of childbearing age. The drop in fertility is proportional to the reduction in immunity among the mothers (46). The limited availability of specialized health care services in low-income countries, primarily the sub-Saharan Africa has made HIV a leading cause of maternal mortality and morbidity (35).

A systematic review and meta-analysis found that upon diagnosis, the mother experience initial shock, loneliness, hopelessness and low social support. Those who accidentally test positive without prior symptoms have relatively low acceptance rate (47). There is heightened psychological distress both from the pregnancy and concurrent HIV diagnosis (48). This takes toll on their social, physical and mental functioning. Having to deal with HIV diagnosis, pregnancy, possible vertical transmission, initiating lifelong ARV therapy, isolation and stigma, the moral obligation to disclose the HIV status predispose them to excessively distressing emotions. The psychosocial distress delays engagement in care and leads to poor self-management (49). The consequences of poor self-management and delayed engagement are very dire for both the mother and the unborn child (34). It causes increased viral load, reduced CD4 counts and hastened disease progression. This ultimately increases the MTCT rate (47). Prompt initiation and diligent use of ARVs

can keep the aforementioned problems at bay. However, the adherence is affected by several psychosocial factors which should be addressed for optimal management of the disease (50).

2.3 Adherence to ART among pregnant mothers

Antiretroviral treatment in pregnancy focuses on treatment of maternal HIV and lowering of perinatal transmission rate (51). It lowers perinatal transmission by reducing maternal antepartum viral load and prophylactic management of the newborn, both of which require optimal adherence to the treatment (51). Optimal adherence is defined as taking 95% of the prescribed ARVs on time (52). Suboptimal adherence includes discontinuations, treatment interruptions, late or missed doses, partial or subtherapeutic dosing (53).

The World Health Organization (WHO) has introduced several strategies to upscale adherence. The strategies can largely be classified into three. These are options A, B and B plus. In option A, pregnant mothers are advised to start triple ART as soon as diagnosis is made or as early as fourteen weeks of gestation and continue until a week postpartum or for life depending on the CD4 counts. In option B, the mothers are supposed to start ART as soon as HIV diagnosis is made or at the early 14 weeks of gestation and continue until delivery if not breastfeeding or until one week post breastfeeding or for life based on the maternal CD4 counts (54). The third approach, the option B plus was first implemented in 2011 in Malawi but is now implemented in many countries like Kenya, Tanzania, Uganda, Ethiopia just but to mention a few. The option recommends that all the seropositive ANC mothers be put on lifelong ARV treatment as soon as the diagnosis is made regardless of their CD4 counts (55). A meta-analysis to assess level of adherence to option B plus in African countries reported adherence rates as low as 31.9% in Malawi to rates as high as 95.97% in Uganda (54).

A systematic review and meta-analysis of high- middle- and low-income countries reported that only 73.5% of ANC seropositive mothers achieved optimal ARV treatment adherence. Demonstrated barriers to adherence included alcohol and drug use, depression and psychosocial issues. Moreover, mothers who were facing parenting stress and stressful live events were reported to have lower adherence rates with missed appointments and missed ART doses (56).

A study conducted in Nigeria reported an adherence rate of 61.0% citing fear of status disclosure as the main reason for non-adherence (57). Self-reported adherence to ARV therapy in South Africa was at 69% (58). There was a reported 20% drop out and/or discontinuation of therapy among HIV infected pregnant women (59). A positive correlation between the level of education and treatment compliance among the seropositive ANC mothers was reported (60).

Barriers to ART adherence include limited access to food, medication and transport due to financial constraints as well as side effects of the ARV drugs. Other barriers include lack of support from the spouse, stigma, and discrimination, cultural and religious factors (61). The above factors can be majorly classified as psycho or social factors. The psychosocial factors of interest in this study are anxiety, depression and perceived social support.

2.4 Anxiety among HIV infected pregnant women

Pregnancy is associated with profound changes in the body that can mistakenly be diagnosed as pathological though physiological in pregnancy sense (62). The changes can lead to stress and anxiety in some women (63). The prevalence of anxiety in pregnancy is estimated at 12% (64). HIV/AIDS further elevates the anxiety due to the lethality of the disease and the stigma associated with its diagnosis (14). Stressors causing anxiety among HIV positive ANC mothers include fear of confidentiality breach regarding their status, advanced disease stage, weakened physical condition, fear of infecting the unborn baby and concerns regarding the baby's future. Additionally, lack of social support, stigma, rejection and isolation further heighten the anxiety (65).

A study done in Tanzania reported an anxiety prevalence rate of 23.5%. Lifetime experience of violence, relationship status and HIV shame were positively associated with the anxiety levels. Single women had 3.6 times higher odds of developing anxiety compared to their married counterparts. Mothers with greater HIV shame had higher odds of developing anxiety. Mothers with history of lifetime violence were 2.3 times more prone to anxiety compared to those who did not experience violence (14). Mothers who concealed the positive status from their partners were faced with greater risk of stigma and discrimination and heightened anxiety thereof (66). A meta-analysis done in India identified depression and anxiety as major risk factors for poor adherence to

ART among the HIV infected populace. Anxiety increased odds of non-adherence to ART by 70% (67).

Anxiety in pregnancy is associated with poor pregnancy outcome, preterm labor, behavioral and cognitive problems in the newborn, increased cost of social and healthcare, delayed developmental milestones, loss of productivity, increased infant mortality and heightened need for special education (68).

2.5 Depression among HIV infected mothers attending ANC

Depression is defined by loss of interest, feeling of low self-esteem, restlessness, regrets, fatigue and poor concentration (31). It is the commonest psychiatric condition in pregnancy (69). It is triggered by stigma, stress, side effects of the ARV drugs and difficult life events (70). Low perceived social support and structural barriers to health care further aggravate the depression (71). Depression reduces quality of life, increases mortality rate and further worsens the disease burden (72). Maternal depression is positively associated with impaired socio-economic, behavioral, psychomotor and cognitive development of the child (73). Moreover, depression causes additional barrier to treatment. Studies have reported significant association between depression and poor adherence to ART, thus adversely influencing the desired clinical outcome (74). The prevalence of depression among ANC mothers is estimated at 23.4% (75). In the developed countries, the rate is estimated at 20% while in the developing countries, it is estimated at 25% (76). HIV diagnosis may further elevate the rate. A meta-analysis done to compare depression rate among HIV positive and HIV negative ANC mothers has reported a depression rate of 36% and 26%, respectively (12).

ANC mothers established that 52.5% of the participants had depressive symptomatology. Approximately 23% of the participants were reported to have suicidal ideations. There was an association between depression and poor illness perception with an adjusted odds ratio of 1.09 at 95% confidence interval (1.05, 1.14) (77). A study in Los Angeles reported an association between low CD4 count and antenatal depression where ANC mothers with CD4 counts of less than 200cells/mm³ were three times more prone to depression than those with CD4 counts above 500cells/mm³. A study conducted in Uganda reported depression prevalence rate of 39%. In Malawi the

prevalence was at 33.5% while south Africa reported a prevalence of 42.2 - 49.3% of depression among the mothers attending ANCs (73).

In Ethiopia, a 47.6% depression rate was reported with an overall adherence rate of 82% among HIV infected mothers attending ANCs. Seropositive ANC mothers with low income were twice more susceptible to depression with an adjusted odds ratio of 2.10 at 95% confidence interval (1.31 – 3.36). Advanced disease stage was also positively associated with depression. Depression negatively impacts on adherence causing failure in viral suppression among HIV infected ANC mothers (10). There was a statistically significant association between nonadherence to treatment and level of depression. Participants with depression were two times more likely to be non-adherent to treatment than their counterparts (5). Some longitudinal studies reported that decreased depression symptoms were concurrently associated with enhanced adherence to ART and therefore improved clinical outcome among the seropositive ANC mothers (78).

2.6 Perceived social support among mothers attending ANC

Social support is defined as system of material or spiritual support from all societal aspects including spouse, parents, friends and relatives (15). Social and familial support is deemed to have a vital role in maternal health and wellbeing in pregnancy (79). The need is more pronounced for HIV/AIDS patients because they are normally confronted with depressing social issues such as abandonment, criticism, rejection and stigma (80). This is further aggravated by the special health needs of HIV/AIDs patient, unknown disease status of the fetus, the unique needs of the infant to be born such as administration of prophylactic treatment and constant surveillance for the first couple of years (3).

The aforementioned psychosocial stressors have direct consequences on the social, physical and mental health of the affected patients and their families (81). Increased social support is associated with improved physical and mental health (82). Additionally, increased social support is associated with improved quality of life and increased CD4 counts (83). A study to establish association between social and emotional support and psychiatric symptoms revealed that mothers with low social support were seven times more likely to present with physical symptoms of mental disorders (84).

Social support acts as a buffer from depression and other mental health problems (85). Low social support predisposes pregnant mothers to substance abuse, mental illnesses such as depression and adverse pregnancy outcomes (86). Depression is associated with suboptimal adherence to ARV treatment and subsequent increase in viral load (10). Increased viral load cause increased chances of vertical transmission (87).

A meta-analysis on HIV infected adults on ART in sub-Saharan Africa reported a positive association between non-adherence and perceived stigma while status disclosure and higher levels of social and familial support were associated with improved adherence (88). A study done in Brazil reported that emotional support for people living with HIV/AIDS improved adherence by 7.9% (89). Consequently, Interventions aiming to promote adherence to ART among the ANC mothers should focus on enhancing peer support among the infected mothers, promoting relationship with their families and spouses and strengthening collaborative provider-patient relationships (90).

2.7 Gaps in literature

Studies have been done to determine influence of depression on adherence to ART among the general population infected with HIV/AIDS. Most of the studies done on adherence to ART among patients suffering from HIV/AIDS focus on the entire infected population. Relatively few studies have underscored the relationship between anxiety and adherence to ART among the HIV/AIDS infected population. Influence of perceived social support on ART adherence has received the least attention. There are very few studies that have comprehensively established the concurrent influence of the psychosocial factors on adherence to ART among HIV/AIDS patients. HIV infection in pregnancy being a special condition has its own challenges and unique features which must be studied with the peculiarity it deserves. However, very few studies have been done on this special population, more so on their determinants of adherence to ART. The limited published studies on the HIV-seropositive ANC mothers focus on magnitude of depression. There are very few studies to underscore the influence of anxiety and social support on adherence to ART among the ANC mothers. The study aimed at determining the influence of anxiety, depression and social support on adherence to ART among the ANC mothers in Nairobi County, Kenya.

CHAPTER THREE: METHODOLOGY

3.1 Perspective of research methodology

This chapter was focused on the materials and methods that were used in the study. It contains the study design, the selected study area, the participants enrolled and criteria that were used in doing the same. The chapter ends with the logistic and ethical considerations that were observed in the study.

3.2 Research design

The proposed study design was a descriptive cross-sectional design. The design is inexpensive, less time consuming and more convenient given the allocated short research period of 480 hours. The research was carried out between April and July 2023.

3.3 Study site and study area

The study was conducted in Nairobi County, Kenya. It was a hospital-based study at selected public referral hospitals in Nairobi County. The selected hospitals were Kenyatta National Hospital and Mbagathi County Hospital. Kenyatta National Hospital is the largest teaching and referral hospital in Kenya. It is situated in the capital city, Nairobi and serves as the teaching hospital for the University of Nairobi (U.o.N) and Kenya Medical Training College (KMTC) health science students. The hospital has 1800 bed capacity with over 6000 staff members. It has 24 theatres, 50 wards and 22 outpatient clinics. Mbagathi County Hospital is a level 5 hospital in Nairobi, Kenya and 1.7 km away from KNH. The study was carried out at the ANCs of the said hospitals. At the time of the study, there were around 70 HIV infected mothers attending the ANCs of the selected hospitals. Kenyatta National Hospital had 36 HIV infected ANC mothers while Mbagathi County Hospital had 34. Antenatal clinic is a specialized clinic that provides special services to pregnant mothers. Being major public referral hospitals, patient inflow is high. This eased attainment of the required sample size.

3.4 Target population and study population

3.4.1 Target population

ANC mothers with HIV/AIDS infection who are on ARVs were targeted. This included all adult mothers in the reproductive age bracket (>18 years). All pregnant mothers were included regardless of the trimester provided they have been on ART for at least

a month. Considering status acceptance, it takes about a month for the patient to stabilize and adopt to the treatment. Besides some of the adherence questions enquire the adherence behavior in the final two weeks hence the choice of one month.

3.4.2 Study population

HIV/AIDS infected mothers on ART attending ANCs at Kenyatta National Hospital and Mbagathi County Hospital.

3.5 Eligibility criteria

3.5.1 Inclusion criteria

- i) Pregnant mothers with confirmed diagnosis of HIV/AIDS who were on ART.
- ii) The inclusion was limited to mothers attending their ANCs at Kenyatta National Hospital and Mbagathi County Hospital.
- iii) The mother must have been on antiretroviral therapy for at least a month.
- iv) Adult mothers in the reproductive age brackets (>18 years) were included in the study.
- v) All the three trimesters of pregnancy were considered.
- vi) Only mothers who gave informed voluntary consent were enrolled to the study.

3.5.2 Exclusion criteria

- i) Pregnant mothers with confirmed diagnosis of HIV/AIDS but who were not on ART.
- ii) Newly diagnosed mothers or mothers who were on ART for less than a month.
- iii) Pregnant mothers aged less than 18 years were excluded

3.6 Sample size estimation

The population of HIV infected ANC mothers attending clinic at Kenyatta National Hospital was 36 while that at Mbagathi, had 34.

Therefore the total of HIV infected ANC mothers attending clinics in the 2 hospitals was 70.

Considering the target population<100, the entire population (70 patients) was sampled.

The study therefore used universal sampling method.

3.7 Sampling method

The study sites-Kenyatta National Hospital and Mbagathi County Hospital were purposively targeted. Eligible mothers attending ANC at KNH and Mbagathi County Hospital were categorically targeted.

Considering the fact that the total target population in the 2 hospitals was less than 100, Participants were sampled based on universal sampling technique. Eligible participants were invited to participate as they come for their clinic appointments. A sample of 36 Participants from KNH and 34 participants were recruited from Mbagathi County Hospital based on the total respective target population in the 2 hospitals.

Recruitment of participants occurred between 0800 hours to 1300 hours every day excluding the weekends. This continued until the desired sample size was achieved. The sampling frame was from all the described HIV positive ANC mothers from the two selected hospitals.

3.8 Participant recruitment strategy and consenting process

Antenatal clinic records were used to identify potential participants. The records helped in determining the visit dates of potential participants. The participants were informed about the study in the waiting bay as they wait for their CCC services. Based on universal sampling technique, the participants were recruited as they came for their clinic appointment. Assistance in recruitment were sort from the ANC staff. The recruitment exercise was undertaken soon after the patient cleared with CCC. Interested participants were recommended to pass through the researcher and be taken through the eligibility criteria by the principal researcher and the trained research assistant to ensure that they qualify to be included in the study. The participants were then issued with consent form and taken through the consent process. Any question or clarification thereof was addressed. Upon satisfying the inclusion criteria and giving voluntary informed consent, the participant was enrolled into the study. This was done in seclusion in a separate room.

3.9 Research instruments and data collection

Structured interviewer administered questionnaire which was tested and standardized before the main study was used as the formal tool for data collection. The questionnaire only composed of closed ended questions. The socio-demographics, anxiety, depression, perceived social support and adherence level of each participant was determined. Anxiety and depression levels were assessed by the Generalized Anxiety Disorder- 7 (GAD-7) and the Patient Health Questionnaire-9 (PHQ-9) tools respectively (64). Perceived social support and adherence levels were assessed by the Multidimensional Scale of Perceived Social Support (MSPSS) (31) and the Morisky tools respectively. The aforementioned tools have been validated, are widely accepted and used globally. The license for using the morisky tool was obtained by contacting the author.

3.9.1 The Generalized Anxiety Disorder (GAD-7)

The questionnaire was administered to the patient by either the principal investigator or the research assistant. The tool contains 7 questions assessing the level of anxiety. The response for each question was rated 0-3. The total score was summed up. A score of 0-4 was classified as minimal anxiety. A score 5-9 as mild, 10-14 as moderate and 15-21 as severe anxiety.

3.9.2 The Patient Health Questionnaire-9 (PHQ-9)

The tool contains 9 questions for assessing depression level based on the Diagnostic and Statistical Manual 5^{th} edition (DSM-V). There were 4 possible responses for each question with allocated score of 0-3. Once completed, the score was summed up. Scores of <5, 5, 10, 15, 20 represent cut points for nonminimal, mild, moderate, moderately severe and severe depression, respectively.

3.9.3 The Multidimensional Scale for Perceived Social Support

The tool had 12 questions for assessing level of perceived social support from friends, family and a significant other. The responses were rated between 1-7. Once completed, summation of the score was done. The mean score was calculated by dividing the total score by the 12 items. A score of 1 to 2.9 was graded as low. A score of 3-5 was rated as moderate while a score of 5.1-7 was regarded as high level of social support.

3.9.4 The Morisky tool

The adherence measurement tool was administered by the principal researcher or the trained research assistant. The tool comprised of 8 items. The first 7 questions were graded 0 or 1 depending on a 'No' or 'Yes' response given. The last question was scaled between 0-4. The total score was summated. A score of 8, 6-7, <6 was regarded as high, medium and low adherence, respectively.

3.10 Pilot study (pre-testing)

A pilot study was carried out to pre-test the questionnaire before commencement of the main study. A sample of 10 patients randomly selected from KNH was used. Any irregularity, ambiguity or shortfall in the data collection process was addressed before the actual study. This was to ensure reliability and validity of the result. The pilot sample was not included in the study sample.

3.11 Validity

The case definition, exclusion and inclusion criteria were determined prior to the commencement of the study. It was ensured that the eligibility criteria are directly related to the study questions.

The tools that were used in assessing anxiety, depression, social support and adherence were all validated tools.

Face validity was further performed. This involved thorough consultation and expert's review of the questionnaire by the supervisors so as to ensure that the questionnaire is valid and suitable enough to measure the concept under study.

Content validity: accuracy, clarity and comprehensiveness of the questionnaire were rated by the principal researcher under the guidance of the supervisor(s). This was to ensure soundness, accuracy and replicability of the data collection tool.

3.12 Reliability

Reliability was determined through test-retest method. Testing was done using a sample of 10 participants not included in the study. The same group were retested (subjected to the same questionnaire) in a span of 2 weeks. The two responses were compared to assess if there is close agreement in the responses now that the variables measured remained good. Cronbach coefficient of 0.7 was targeted. However, the closer the coefficient gets to 1, the better.

3.13 Study variables

Independent variables: Socio-demographics such as employment status, level of education, marital status of the HIV positive ANC mother(s).

Depression, anxiety and social support among HIV positive ANC mothers who are on ARVs were also independent variables.

Dependent variables: Adherence to ART among HIV positive ANC mothers who are on ARVs.

3.14 Data management

The research assistant submitted the filled questionnaire to the principal researcher at the close of business each day. The submitted filled questionnaires were kept under lock and key and were only accessed by the principal investigator. They were then coded before recording started to ensure privacy. The coded questionnaires were then entered and stored into a data system by either the principal researcher or the trained research assistant. The data was verified again by the principal investigator to ensure correct data entry and proper coding. It was then entered into IBM SPSS version 23 and cleaned. The verification and cleaning helped in removing erroneous entries. Analysis was done using IBM Statistical Package for Social Sciences (SPSS) Chicago Illinois version 23. Summary data analysis was done with continuous variables such as age summarized using mean and standard deviation while categorical variables such as employment status, level of education summarized by calculating proportions. Prevalence and severity of anxiety, depression and perceived social support was computed and presented as percentages with 95% confidence interval. Inferential data analysis was then done with association between adherence and the various psychosocial factors determined by use of chi squared test or Fischer's exact test of association. The statistical association was tested at 5% level of significance. P value equal to or less than 0.05 was interpreted as significant. Ordinal logistic regression analysis was carried out. Result was presented in figures and tables where appropriate.

3.15 Logistic and ethical considerations

Approval to undertake the study was sought and obtained from KNH/U.o.N Ethics and Review Committee (KNH-ERC). Permission to conduct the study was further sought from National Council of Science and Technology (NACOSTI) as well as Nairobi County department of health. Voluntary informed consent from the HIV infected ANC mothers. The participants were at liberty to withdraw from the study without any repercussion whatsoever. The questionnaires were coded to ensure confidentiality. The data collected was only accessed by the researcher and was under lock and key. The information obtained was purposely meant for this study and was not to be shared with any other party. The information was kept for a maximum of five-year period after completion of the study. This is to cater for the need of any clarification, verification or

further analysis. Upon completion of the five-year period, the coded questionnaire would be destroyed through shredding. Covid19 protocol was observed in the entire study process by consistent maintenance of face mask.

3.16 Risk

As far as risk is concerned, the risk involved was minimal since the study was just observational with not much engagement of the patient.

3.17 Benefits of the study

The knowledge from the study would improve adherence and better enhance management of HIV/AIDS in pregnancy. Patients diagnosed with comorbid anxiety and/or depression were referred to a mental health facility or mental health expert (psychiatrist) of their choice for further evaluation and management. The data generated from the study was shared through publication. A copy of the research paper was also shared with KNH and the UoN library. Dissemination of the study results was strictly governed by KNH/UoN policies.

CHAPTER FOUR: RESULTS

4.0 Introduction

The chapter discusses the general study population and their characteristics, the level of adherence, anxiety and depression among mothers attending ANCs at Mbagathi and Kenyatta National Hospitals. It explores the level of family and social support accorded to the seropositive mothers. The relationship between levels of adherence and each of the psychosocial factor (anxiety, depression, social support) among the seropositive ANC mothers is also illustrated. A total of seventy participants were recruited into the study, with 36 from KNH and 34 from Mbagathi County Hospital. Table 4.1 shows the sociodemographic and clinical characteristics of the respondents.

Table 4.1: Socio-demographic characteristic of the participants

		Frequency	Percentage
Variable	Category	(N=70)	(%)
Age	18-35	47	67.1
	36-50	23	32.9
Mean (SD)		32.33(5.775)	
Trimester	1st	12	17.1
	2nd	27	38.6
	3rd	31	44.3
Religion	Christian	66	94.3
	Muslim	4	5.7
	primary	9	12.9
Level of education	secondary	33	47.1
	Tertiary	28	40.0
Marital status	Married	53	75.7
	Not married	17	24.3
F 1	Employed	45	64.3
Employment	Not	25	35.7
status	employed		
History of alcohol	No	63	90.0
consumption	Yes	7	10.0
History of smoking	No	70	100.0
	Yes	1	1.4
History of anxiety diagnosis	No	69	98.6
History of anxiety treatment	No	70	100.0
History of depression	Yes	4	5.7
diagnosis	No	66	94.3
History of depression	No	70	100.0
treatment			

The mean age of the study population was 32.3 (SD 5.78) with a range of 18-50 years. Majority were aged between 18-35 years at 67.1%, followed by 36-50 years (32.9%). The participants were mainly Christians (94.3%). Most participants had attained at least a secondary school education level at 47.1%, were employed (64.3%) and married at 75.7%. None of the participants had a history of smoking but 10% had a history of alcohol consumption. Only 1.4% had an anxiety diagnosis history while 5.7% had a history of depression diagnosis (Table 4.1).

Psychosocial factors among the study population

The levels of anxiety, depression and social support among the study participants are displayed in table 4.2.

Table 4.2: Prevalence of anxiety, depression, social support among the participants (N=70).

Variable	Category	Frequency (N=70)	Percentage (%)
	Minimal	37	52.9
	Mild	24	34.3
Anxiety	Moderate	3	4.3
	Severe	6	8.6
	Minimal	30	42.9
	Mild	23	32.9
Danasaisa	Moderate	11	15.7
Depression	Moderately	5	7.1
	severe		
	Severe	1	1.4
	Low	33	47.1
Social support	Moderate	32	45.7
	High	5	7.1

The overall prevalence of each of the psychosocial factor was calculated by dividing the mean by the highest possible score as per the tool used in determining (measuring) the factor under study. The prevalence of anxiety was 23.8% with a mean anxiety score of 5.0 (SD=4.8). The anxiety was divided into 4 levels with the prevalence rates being: minimal anxiety (52.9%), mild anxiety (34.3%), moderate anxiety (4.3%) and severe anxiety at 8.6%. The study recorded 22.6% prevalence of depression with mean depression score of 6.1 (SD= 5.8). Depression was divided into 5 levels. The prevalence of the types of depression were minimal (42.9%), mild (32.9%), moderate (15.7%), moderately severe (7.1%) and severe at 1.4%. The prevalence of social support was found to be 45.7% with a mean social support score of 3.2 (SD=1.31). Social support was categorized into 3 levels: low social support (47.1%), moderate social support (45.7%) and high social support at 7.1% (Table 4.2).

Adherence to ART among the study patients

Figure 4.1 shows the adherence to ART among the ANC mothers studied.

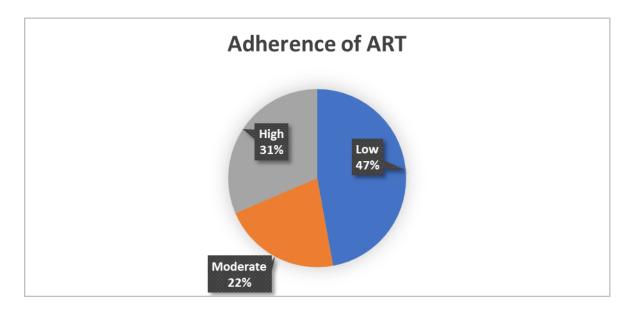


Figure 4.1 ART adherence

The prevalence of ART adherence was 78.8% with mean ART adherence score of 6.3 (SD= 1.65) among the HIV infected ANC mothers. The ART adherence was divided into 3: low adherence at 47.1%, moderate adherence at 21.4% and high adherence at 31.4% (figure 4.1).

Factors associated with adherence to ART among the study patients.

In order to find the association between variable factors and adherence, the levels of adherence were categorized into two. Adherence levels <8 (both low and medium)

was categorized as low. This is because high (optimal) adherence is defined as taking 95% of the prescribed ARV on time which roughly equates to a score of 8.

Table 4.3 Association between socio-demographic factors and adherence to ART

Sociodemographics	Category	ART adherer	nce (N=70)	OR (95%CI)	P-value
2	Low(n=48) High (n=22)				
Age	18-35 years	33(68.75%)	14(63.64%)	0.795(0.275,2.30)	0.795
Age	36-50 years	15(31.25%)	8(36.36%)	Ref	
	1 st	9(18.75%)	3(13.64%)	Ref	
Trimester	2 nd	21(43.75%)	6(27.27%)	1.167(0.238,5.726)	0.849
	3 rd	18(37.50%)	13(59.09%)	0.462(0.104,2.045)	0.309
Religion	Christian	44(91.67%)	22(100.00%)	0.220(0.011,4.264)	0.317
Kengion	Muslim	4(8.33%)	0(0.00%)	Ref	
	Primary	5(10.41%)	4(18.18%)	Ref	
Education level	Secondary	20(41.67%)	13(59.09%)	1.231(0.228,5.454)	0.785
	Tertiary	23(47.92%)	5(22.73%)	3.680(0.719,18.824)	0.118
Marital status	Married	36(75.00%)	17(77.27%)	0.882 (0.268, 2.907)	0.837
Wartar status	Not married	12(25.00%)	5(22.73%)	Ref	
Employment status	Employed	33(68.75%)	12(54.55%)	1.833(0.650,5.175)	0.252
Employment status	Not employed	15(31.25%)	10(45.45%)	Ref	
	Yes	6(12.50%)	1(4.55%)	Ref	I.
History of alcohol consumption	No	42(87.50%)	21(95.45%)	0.333(0.038,2.951)	0.324
History of anxiety	Yes	1(2.08%)	0(0.00%)	Ref	
diagnosis	No	47(97.92%)	22(100.00%)	0.681(0.580,0.800)	0.686
History of	Yes	3(6.25%)	1(4.55%)	Ref	<u>I</u>
depression diagnosis	No	45(93.75%)	21(95.45%)	0.714(0.070,7.281)	0.776

As shown in table 4.4, there was no statistically significant findings between the clinical characteristic of the patients and adherence. However, lower age (18-35) was associated with lower odds of adherence with a reported Odds ratio (OR) of 0.8. Christians had lower odds of adherence to ART (OR 0.22, CI (0.011-4.264)) compared to their muslim counterparts though this was not statistically significant. Participants with tertiary education were almost four times more likely to be adherent to the ART therapy than those with primary level of education. Marital status did not significantly affect the odds of adherence to ART. In comparison to the unemployed, getting employed almost doubled the odds of ART adherence (Table 4.3).

Association between adherence to ART and psychosocial factors

Table 4.4 shows the association between adherence to ART and each of the psychosocial factor under study.

Table 4.4 Association between adherence to ART and psychosocial factors

37 ' 11			ART adherence (N=70)	D 1	
Variable	Category	Low(n=48)	High (n=22)	P-value	
	Minimal	25 (52.1%)	12 (54.6%)		
A	Mild	15 (31.2%)	9 (40.9%)	0.264	
Anxiety	Moderate	2 (4.2%)	1 (4.5%)	0.364	
	Severe	6 (12.5%)	0 (0.0%)		
	Minimal	20 (41.7%)	10 (45.5%)		
	Mild	14 (29.2%)	9 (40.9)		
Danraggian	Moderate	9 (18.7%)	2 (9.1%)	0.673	
Depression	Moderately	4 (8.3%)	1 (4.5%)	0.073	
	severe				
	Severe	1 (2.1%)	0 (0.0%)		
	Low	23 (47.9%)	10 (45.4%)		
Social support	Moderate	22 (45.8%)	10 (45.5%)	0.953	
	High	3 (6.3%)	2 (9.1%)		

There was no statistically significant association between anxiety, depression, social support and adherence to ART among the HIV infected ANC mothers (Table 4.4).

Association of social support with anxiety and depression

Social support may affect the level of anxiety and depression which may in turn have an influence on adherence to ART. The association of social support with anxiety and depression was therefore determined as show in table 4.5.

Table 4.5: Association of social support with anxiety and depression

		Social	support (N=70	0)	
		Low	Moderate	High	P-value
Variable	Category	(n=33)	(n=30)	(n=7)	
	Minimal	15	17	5	
	willima	(45.5%)	(56.7%)	(71.4%)	
	Mild	14	9	1	
Amriotry	MIII	(42.4%)	(30.0%)	(14.3%)	
Anxiety	Moderate	0	2	1	
	Moderate	(0%)	(6.7%)	(14.3%)	0.307
	Severe	4	2	0	
		(12.1%)	(6.7%)	(0%)	
	Minimal	14	13	3	
		(42.4%)	(43.3%)	(42.9%)	
	Mild	11	8	4	
		(33.3%)	(26.7%)	(57.1%)	
D	Madanaka	5	6	0	
Depression	Moderate	(15.2%)	(20.0%)	(0%)	
	Moderately	2	3	0	
	severe	(6.1%)	(10.0%)	(0%)	0.748
	G	1	0	0	
	Severe	(3.0%)	(0%)	(0%)	

There was no statistically significant association between social support and anxiety as well as social support and depression (Table 4.5).

Association between anxiety and depression

Anxiety and depression are related psychological factors (one may cause or influence the level and severity of the other). Their association was therefore determined as shown in Table 4.6.

Table 4.6: Association between anxiety and depression

Depression (N-70)							
Variable	Category	Minimal (n=30)	Mild (n=23)	Moderate(n=11)	Moderately severe (n=5)	Severe(n=1)	P-value
	Minimal	20 (66.7%)	11 (47.8%)	4 (36.4%)	2 (40.0%)	0 (0%)	
	Mild	9 (30.0%)	8 (34.8%)	6 (54.5%)	1 (20.0%)	0 (0%)	
Anxiety	Moderate	1 (3.3%)	2 (8.7%)	0 (0%)	0 (0%)	0 (0%)	0.0174
	Severe	0 (0%)	2 (8.7%)	1 (9.1%)	2 (40.0%)	1 (100%)	

There was a statistically significant association between anxiety and depression (P= 0.017) (Table 4.6)

Multivariate regression analysis

In order to estimate independent factors associated with adherence to ART among the study participants, multivariate regression analysis was done using adherence as outcome variable and participants socio-demographic and psychosocial factors as predictors.

Table 4.7: Independent predictors of adherence to ART among seropositive pregnant mothers

		Bivariate analy	sis		Multivariate analysis			
Variable	Category	Crude OR (95%CI)	P-value	Beta	Adjusted OR (95%CI)	p-value		
Constant				42.425		0.999		
Age	18-35 years	0.795(0.275,2.300)	0.179	0.047	1.049(0.287, 3.836)	0.943		
	36- 50 years	Ref	1		1			
Trimester	First and Second trimester	0.415(0.148,1.165)	0.091	0.826	2.285(0.691,7.559)	0.176		
	Third trimester	Ref			•			
Religion	Christian	-	0.301	19.323	-	0.999		
	Muslim	Ref			•			
Level of	Secondary and below	3.128(0.994, 9.846)	0.046	-1.357	0.257(0.068,0.982)	0.047		
education	Tertiary level	Ref			•			
Marital	Married	1.133(0.344,3.733)	0.837	-0.296	0.744(0.172,3.219)	0.771		
status	Not married	Ref	1	I				
Employment	Employed	0.545(0.193,1.540)	0.250	0.617	1.853(0.555,6.187)	0.316		
status	Not employed	Ref						
History of	Yes	Ref						
alcohol consumption	No	3.000(0.339,26.561)	0.420	-0.782	0.458(0.030,7.018)	0.575		
History of	Yes	Ref	•		1			
anxiety diagnosis	No	0.681(0.580,0.800)	1.000	-17.505	0.000(0.000, ∞)	1.000		
History of	Yes	Ref	•	•		•		
depression diagnosis	No	1.400(0.137, 14.270)	1.000	-0.161	0.852(0.050,14.452)	0.991		
Anxiety	Mild	4.200(0.492,35.873)	0.255	-1.548	0.213(0.019,2.377)	0.209		
Allalety	Severe	Ref	•	1	•	1		
Depression	Mild	2.608(0.664,10.237)	1	-0.499	0.607(0.116,3.189)	0.555		
Depression	Severe	Ref						
Social	High	1.104(0.401,3.038)	0.848	-0.110	0.896(0.249, 3.222)	0.867		
support	Low	Ref	_1	ı	1	1		

Mothers in their first and second trimester were 2.3 more likely to adhere to ART than those in the first trimester (aOR= 2.285, 95%CI =0.691 - 7.559, P =0.176). Participants with tertiary level of education were more likely to adhere than those with primary and secondary level of education and the association was statistically significant at (aOR = 0.277, 95%CI=0.068 - 0.982, P=0.047). Compared to the unemployed, getting employed increased odds of adherence by 1.8 times (aOR=1.853, 95%CI=0.555 - 6.187, P = 0.316). Non-alcoholism reduced odds of adherence to ART (aOR=0.458, 95%CI=0.030 - 7.018, P=0.575) (Table 4.7).

CHAPTER FIVE: DISCUSSION

5.1 Introduction

The chapter interrogates the findings of the study and compares or contrast them with available literature. Plausible explanation is given for deviation from the published literature where possible.

5.2 Discussion

The aim of the study was to underscore the burden of psycho-social factors (anxiety, depression and family-social support) and their influence on ART adherence among HIV infected ANC mothers attending clinics at KNH and Mbagathi County Hospital

Regarding ART adherence, high adherence was at 31.4%, medium adherence (21.4%), low adherence (47.1%), with a general adherence prevalence of 78.8% among the seropositive mothers. The adherence rate is in close range with the 61.0% rate reported in Nigeria (57), 73.5% in Ethiopia (5), 69% adherence rate in urban South Africa and rural Uganda (58), 76.8% rate in central Uganda (20) and 65 – 87% adherence rate in Kenya (6). However, relatively lower and higher figures have been reported elsewhere. Adherence rate as low as 31.9% has been reported in Malawi and rates as high as 95.97% in Uganda (54). The conflicting findings in the latter studies could be caused by the difference in the study design (systemic review and meta-analysis against the cross-sectional design employed by the present study). The study, however, did not establish any statistical association between adherence and the psychosocial factors explored.

The study did not establish a statistically significant association between social support and adherence. The lack of association was also shown by a study in Kwazulu-Natal, South Africa (88). However, this contradicts with the findings by a systemic review and meta-analysis which reported significant association with P value of .01 (18), a study in South Africa (71) and one in southern Brazil (89). Adequate awareness and previous counselling services may have come in handy in boosting the morale and acting in place of social support, hence obscuring the association.

Anxiety levels were categorized into 4 using the GAD-7 scale for anxiety determination. The present study demonstrated prevalence rates of minimal anxiety (52.9%), mild anxiety (34.3%), moderate anxiety (4.3%) and severe anxiety at 8.6%.

However, the general anxiety prevalence was 23.8% (low anxiety). A similar low anxiety prevalence of 23.5% was reported in Kilimanjaro region, Tanzania (14).

The overall prevalence of depression was 22.6%. This low level is in tandem with a study conducted in Zimbabwe to determine depression among HIV positive pregnant women using the Edinburgh Postnatal Depression Scale (EPDS) which cited depression rates of 12 – 30% as per previous regional studies and systemic reviews. However, the study itself reported a higher prevalence of antenatal depression (39.4%) among the HIV infected ANC mothers (11). Additionally, a systemic review and meta-analysis on prevalence of perinatal depression among HIV positive women cited antenatal depression rate of 23.4% among the seropositive mothers. However, the study itself reported antenatal depression rate of 36% among the HIV positive mothers compared to 26% rate in their negative counterparts (12). The difference in the depression rates reported could like be due to the higher study power associated with systemic review and meta-analysis.

In contrast to the present study, higher levels of antenatal depression among HIV infected mothers have been reported elsewhere in the world. For instance, a higher prevalence rate of 35.0% has been reported in Kibera south, Nairobi in an effort to determine the association between depression using EPDS and non- adherence to ART among pregnant women living with HIV (21). A study in India determining the prevalence of depression among seropositive ANC mothers reported depressive symptomology of 52.5% among the participants with 23.0% having suicidal ideations (77). The Indian study used a bigger population from 8 centers across 4 states in India and considered both pregnant and post-partum women hence the difference in the findings.

The social support level was categorized into 3 using the Multidimensional Scale of Perceived Social Support. The overall social support prevalence was 45.7% which mirrored a study done in Kenya, at KNH on burden of HIV related stigma (22). However, the study contrasts with the study done at public hospitals in Gamo zone, southern Ethiopia which reports 30.7%, 47.2% and 22.1% for low, moderate and high family-social support respectively (16). The difference in the latter study is possibly attributable to the larger sample size of 423 against 70 in our present study.

Concerning the effects of sociodemographic factors on adherence, employment almost doubled the odds of adherence to ART unlike in the study done in Eastern cape, South Africa where employment and work-related demands were illustrated as obstacles against adherence to ART (4). Low level of education reduced adherence to ART as evident in participants with secondary and lower level of education (OR 0.257, 95%CI 0.068 – 0.982, P 0.047). This is in concurrence with a study in Uganda (33), in Greece (60) and Nigeria (52) that proved that low or lack of formal education acted as hindering factor to retention in care and adherence to therapy. Therefore, ART adherence mechanisms should be intensified among mothers who have not attained tertiary education level.

There was no statistically significant association between anxiety and adherence in the study. This is in contradiction with a scoping review which revealed that anxiety and other mental health disorders such as depression, isolation and suicidal ideations have a detrimental effect on retention in care and adherence to ART (17). The study finding also contrast with systemic review and meta-analysis which associates non-adherence to ART with psychological stressors such as anxiety, depression and substance abuse (26). The contradiction is attributable to the bigger sample size (high study power) of 5095 participants from 43 randomized controlled trials by the systemic review and meta-analysis study.

The study showed no statistically significant association between depression and adherence to ART among the HIV infected ANC mothers (P=0.672). This is in contradiction with a study in Kibera south health center, Nairobi (21) on association between depression and non-adherence to ART among pregnant women living with HIV and one in South Africa which showed association (71). The difference could possibly be due to difference in the study methodology as for instance, the study in South Africa limited their participants only to mothers who completed a third trimester interview.

There was no association between social support and anxiety. This is in contrast with a systemic review and meta-analysis which revealed that social support in the antenatal period had an important influence on women's feeling of stress and anxiety and that the family is a major source of stress and can as well be a support source for women (63). The difference is attributable to the study design where our present study used a cross-

sectional design against a systemic review (bigger sample size and relatively high study power).

The study revealed no association between social support and depression. This is in contrast with the findings by a study in Southern Ethiopia which reported social support such as good husband support as a protective factor against maternal depression and one in South Africa which associated elevated depression symptomology with low social support (71). Additionally, a study in India reported a significant inverse relation between social support and depression (83). The contrasting findings could be attributed to the difference in the inclusion criteria. For instance, the Indian study recruited only pregnant women in their third trimester.

There was a statistically significant association between anxiety and depression in the study (P=0.017). This is in concurrence with the study in Kilimanjaro region, Tanzania which reported a sizeable prevalence of comorbid anxiety and depression (18.1%) among HIV infected expectant mothers (14). Similarly, a study in Kwazulu Natal, South Africa (24) reported a strong association between anxiety and depression with a p<0.01 and one in Bangalore which revealed anxiety in pregnancy as a positive predictor of prenatal depression (32). The study findings are in contrast with the findings by a study done in Kibera slums, Nairobi, Kenya which revealed no association between anxiety and depression among HIV infected mothers (25).

5.3 Limitation of the study

The participants were recruited from main referral hospitals in the city and the findings may not be replicated in a rural set up. The study relied on self-report of adherence and the associated psychosocial factors. This was not ascertained by objective diagnostic review; patients may have over or under reported the factors under study. Being a cross-sectional study, causal inferences were not determined. Therefore, longitudinal study design may provide additional insights in the causal relationships.

5.4 Mitigation of the study limitations

Using universal sampling technique, all the seropositive mothers enrolled in the PMTC program of the 2 hospitals were considered. This would likely include mothers from rural set-ups (visitors or newly migrated) hence capturing the possible findings in a rural set-up. To limit the subjective reporting of the psychosocial factors by the patients,

the caregiving nurses (patients are comfortable and can confide with their care providers) were engaged in the data collection process.

5.5 Conclusion

The level of ART adherence among the seropositive ANC mothers was found to be sub-optimal (78.8%) with considerable level of psychosocial comorbidity. There was no significant association between adherence and any of the psychosocial factor under study. However, high level of education was associated with better adherence to ART, and this was statistically significant at the 95% CI (aOR= 0.257, 95%CI: 0.068 - 0.982, P=0.047).

5.6 Recommendations

5.6.1 Recommendations for practice and policy

- There was poor adherence to ART among ANC mothers with low education attainment. Therefore, ART adherence mechanisms should be intensified among mothers who have not attained tertiary education level.
- ii. There is considerable level of undiagnosed and untreated anxiety and depression among the seropositive mothers. This calls for continued counselling, psychosocial education and multi-disciplinary team management including psychiatrist and/or psychologist review and treatment.
- iii. The level of family social support accorded to the mothers is low. Efforts should be made to create awareness, reduce stigma and promote acceptance if adequate social support is to be realized.

5.6.2 Recommendations for further studies

- Prospective studies with larger sample size and encompassing more hospitals (sites) may give more reliable and conclusive evidence of association between adherence and psychosocial factors.
- ii. The present study has revealed that the psychosocial factors explored do not hinder adherence to ART. However, other obstacles to the same may exist. Further studies to underscore other barriers to ART adherence including side effects of ARV medicine, socio-economic factors are recommendable.

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Appendix i: Consent form

Title of the study: Adherence to antiretroviral therapy and associated psychosocial factors among mothers attending antenatal clinics at selected public referral hospitals in Nairobi.

Introduction

My name is Abdihakim M Osman, a postgraduate student in the department of pharmacology, clinical pharmacy and pharmacy practice at the University of Nairobi. The purpose of this consent form is to provide you with all the necessary information to enable you make informed choice whether to participate in this study. This process is called informed consent. Once you have understood the purpose of the study and agreed to be part of it, you will be requested to sign on this form.

Aim of the study

The research intends to study adherence to antiretroviral therapy and associated psychosocial factors among mothers attending expectant mothers' clinics. The study will also establish the relationship between each of the selected psychosocial factors and adherence to antiretroviral therapy.

Procedure to be followed in the study.

Your decision to be part of this study is voluntary but based on informed consent. Should you accept to participate, we will ask you some questions from a questionnaire. The interview will take approximately 30 minutes and will be conducted in private room to allow privacy and comfort. The interview shall be conducted by a trained interviewer to assist you in areas that you may not be conversant with.

Benefits of participating

You will benefit from the study by receiving a referral to a psychologist and/or psychiatrist should you be diagnosed with anxiety and/or depression thus start early therapy to avert further complications that may come with a diagnosis of depression and/or anxiety. The information obtained in the study will help in appreciating the magnitude and influence of psychosocial issues on adherence. Addressing the psychosocial issues will help in enhancing adherence to treatment and consequent improvement in HIV/AIDS management.

Risks of participating

There is no harm involved in participating in this study. That said, any study has

potential to introduce psychological, social, emotional, and physical risks.

Compensation

There is no monetary or non-monetary compensation for participating in this study.

Confidentiality

All the responses obtained as well as your results shall remain confidential. We will use

a code number to identify you in a password protected computer database and will keep

all your paper records in a locked file cabinet. Any publication arising from this study

will not identify you in person.

Rights to withdrawal

You may decline to take part in this study or drop out at will and at any time during the

study. This will not in any way lead to loss of benefits or denial of treatment at the

facility.

Participation

Participation in this study is voluntary and at any given time you are allowed to

withdraw or refuse to participate without any victimization on your part.

Questions regarding the study

If you have any question or concerns about participating in this study, kindly contact

me on this phone number 0724395840.

For more information about your rights as a research participant, you may contact the

secretary or chairperson Kenyatta National Hospital University of Nairobi Ethics and

Research Committee or the research supervisors:

Telephone: 2726300

Ext: 44102

Email: uonknh_erc@uonbi.ac.ke

Dr Nyamu, telephone: 0722 403 671

Email: dgnyamu@gmail.com

49

Prof Amugune, telephone 0722 802 074

Email: beatrice.amugune@uonbi.ac.ke

I have read this consent form or had the information read out to me in a way I understood. I have had the opportunity to ask questions about it and any question I have asked has been answered to my satisfaction. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I understand that all efforts will be made to ensure that my personal information is kept confidential. I consent voluntarily to participate in this research study.

Participant name

Participant signature/Thumb stamp

Investigator's statement

I, the undersigned has fully explained the relevant details including implication of this research study to the participant named above.

Investigators signature......

Date22/11/2023

Kiambatisho cha kwanza: Fomu ya habari kwa wanaoshiriki na idhini

Kichwa cha utafiti: Ufuasi wa madawa za kurefusha maisha na sababu zinazohusiana za kisaikolojia miongoni mwa akina mama wa kliniki ya wajawazito katika hospitali za rufaa za umma zilizochaguliwa mtaani Nairobi

Utangulizi

Majina yangu ni Abdihakim M Osman, mimi ni mwanafunzi wa kuhitimu katika idara ya madawa katika chuo kikuu cha Nairobi. Madhumuni ya fomu hii ya idhini ni kukupa habari zote muhimu kukuwezesha kufanya uchaguzi sahihi kuwa mshiriki katika utafiti huu. Utaratibu huu unaitwa idhini iliyo na habari. Pindi tu utakapoelewa madhumuni ya utafiti na ukubali kuwa sehemu ya masomo, nitakuomba utie Saini kwenye fomu hii.

Lengo la utafiti

Madhumuni ya utafiti huu ni kutathmini ufuasi wa tiba ya kurefusha maisha na sababu zinazohusiana za kisaikolojia miongoni mwa akina mama wa kliniki ya wajawazito. Utafiti huu pia utathamini uhusiano ulioko baina ya kila moja ya sababu iliyochaguliwa ya kisaikolojia na ufuasi wa tiba ya kurefusha maisha.

Utaratibu wa kufuatiwa katika utafiti

Uamizi wako wa kushiriki katika utafiti huu ni wa hiari kabisa na ikiwa utakubali kushiriki tutakuuliza maswali kadhaa kutoka kwa dodoso. Mahojiano yatachukua takriban dakika 30 yataendeshwa katika chumba cha kibinafsi ilikuruhusu faragha na faraja. Mahojiano yataendeshwa na mhoji aliyefunzwa ilikukusaidia katika maeneo ambayo huwezi kuwa na mazungumzo nayo.

Faida ya kushiriki

Unaweza kufaidika kwa utafiti huu kwa kupokea rejelea kwa mwanasaikolojia au daktari wa akili endapo utapatikana na wasiwasi au unyogovu hivyo kuanza tiba mapema ilikuzuia matatizo zaidi ambayo inaweza kuja na ugonjwa wa wasiwasi au unyogovu. Habari itakayopatikana katika utafiti itasaidia kuthamini ukubwa na ushawishi wa masuala za kisaikolojia juu ya ufuasi wa dawa za kurefusha maisha. Kushughulikia maswala za kisaikolojia itasaidia katika kuimarisha uzingatiaji wa matibabu hivyo basi kuchangia kwa uboreshaji wa udhabiti wa ukimwi.

Hatari ya kushiriki

Hakuna madhara yanayohusika katiki kushiriki katika utafiti huu. Utafiti wowote una

uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihisia na kimwili.

Fidia

Hakuna fidia ya kifedha au isiyo ya kifedha kwa kushiriki katika utafiti huu.

Usiri

Majibu yote yatakayopatikana pamoja na matokeo yako yatabaki siri. Tutatumia

nambari ili kukutambua kwenye darasani ya kompyuta itakayohifadhiwa na neno siri

na tutachukua rekodi zote za karatasi na kuweka kwa kabati ya faili iliyofungwa.

Kichapisho chochote kinachotokana na utafiti huu haitakutambulisha wewe

mwenyewe.

Haki ya uondoaji

Unaweza kushuka kushiriki katika utafiti huu au kuwacha kwa mapenzi wakati

wowote. Hii haitasababisha kupoteza faida au kukataa matibabu katika kituo hicho

Kushiriki

Kushiriki katika utafiti huu ni kikamilifu kwa hiari na wakati wowote unaruhusiwa

kufuta au kukataa kushiriki bila unyanyasaji wowote kwa sehemu yako.

Maswali kuhusu utafiti

Ikiwa una maswali yoyote au wasiwasi juu ya kushiriki katika utafiti huu, tafadhali

wasiliana nami kwa nambari hii ya simu 0724395840.

Kwa habari zaidi juu ya haki zako kama mshiriki wa utafiti unaweza wasiliana na katibu

au mwenye kiti kamati ya mapitio ya maadili hospitali ya kitaifa ya Kenyatta-Chuo

kikuu cha Nairobi au wasimamizi wa mradi.

Nambari ya simu: 2726300 Mpana: 44102

Barua pepe: uonknh_erc@uonbi.ac.ke

Dr Nyamu, simu: 0722 403 671

Barua pepe: dgnyamu@gmail.com

52

Prof Amugune, simu: 0722 802 074

Barua pepe: beatrice.amugune@uonbi.ac.ke

Nimesoma fomu hii ya idhini au nilisomewa kwa namna nilivyoelewa. Nimekuwa na fursa ya kuuliza maswali na swali lolote nililouliza limejibiwa kwa kuridhika kwangu. Hatari na faida zimeelezwa kwangu. Ninaelewa kuwa ushiriki wangu katika utafiti huu ni hiari na ninaweza kuchagua kujiondoa wakati wowote. Ninaelewa kwamba jitihada zote zitafanywa ili kuhakikisha kuwa maelezo yangu binafsi yanawekwa siri.

Ninakubali kwa hiari kushiriki katika utafiti huu.

Jina la Mshiriki	•••••
Sahihi au gumba ya mshiriki	
Tarehe	

Kauli ya mpelelezi

Mimi niliyetia sahihi chini nimeeleza kikamilifu maelezo muhimu ikiwa pamoja na matekeo ya utafiti kwa mshiriki aliyetajwa hapo juu.

Saini ya mpelelezi

Tarehe ...22/11/2023

Appendix ii: Questionnaire

1.	Patient identifier:	
2.	Age in years	
3.	Trimester	
1)	1 st trimester	()
2)	2 nd trimester	()
3)	3 rd trimester	()
4.	Religion	
	1) Christian	()
	2) Muslim	()
	3) Others (specify)	()
5.	Level of education	
	1) Primary	()
	2) Secondary	()
	3) Tertiary	()
6.	Marital status	
	0) Single	()
	1) Married	()
	2) Divorced	()
	3) Widowed	()
	4) Separated	()
7.	Employment status	
	0) Not Employed	()
	1) Employed	()
8.	History of alcohol consumption	
	0) No	()
	1) Yes	()
9.	History of smoking	
	0) No	()
	1) Yes	()
10.	Have you ever been diagnosed with anxi	ety?
	0) No	()

1) Yes	()
11. If yes to the above question, wer	re you put on treatment?
0) No	()
1) Yes	()
12. Have you ever been diagnosed w	vith depression?
0) No	()
1) Yes	()
13. If yes to the above question, wer	e you put on treatment?
0) No	()
1) Yes	()
Determination of anxiety among the I	HIV infected ANC mothers
14. Over the last 2 weeks, how or	ften have you been bothered by any of the
following problems?	
Feeling anxious, nervous or on edg	ge?
0) Not at all	()
1) Several days	()
2) More than half the days	()
3) Nearly every day	()
15. Not being able to stop or control	worrying?
0) Not at all	()
1) Several days	()
2) More than half the days	()
3) Nearly every day	()
16. Worrying too much about different	ent things?
0) Not at all	()
1) Several days	()
2) More than half the days	()
3) Nearly every day	()
17. Trouble relaxing?	
0) Not at all	()
1) Several days	()
2) More than half the days	

3) Nearly every day	()
18. Being so restless that it is hard	to sit still
0) Not at all	()
1) Several days	()
2) More than half the days	()
3) Nearly every day	()
19. Becoming easily annoyed or in	ritable?
0) Not at all	()
1) Several days	()
2) More than half the days	()
3) Nearly every day	()
20. Feeling afraid as if something a	awful might happen?
0) Not at all	()
1) Several days	()
2) More than half the days	()
3) Nearly every day	()
Determination of depression among	the HIV infected ANC mothers
21. Little interest or pleasure in do	ing things
0) Not all	()
1) Several days	()
2) More than half the days	()
3) Nearly every day	()
22. Feeling down, depressed or hop	peless
0) Not all	()
1) Several days	()
2) More than half the days	()
3) Nearly every day	()
23. Trouble falling asleep, staying	asleep or sleeping too much
0) Not all	()
1) Several days	()
2) More than half the days	()
3) Nearly every day	()
24. Feeling tired or having little en	ergy?

0) Not at all	()	
1) Several days	()	
2) More than half the days	()	
3) Nearly every day	()	
25. Poor appetite or overeating?		
0) Not at all	()	
1) Several days	()	
2) More than half the days	()	
3) Nearly every day	()	
26. Feeling bad about yourself or that	you are a failure or have let yourself	or your
family down?		
0) Not at all	()	
1) Several days	()	
2) More than half the days	()	
3) Nearly every day	()	
27. Trouble concentrating on things,	such as reading the newspaper or w	atching
television		
0) Not at all	()	
1) Several days	()	
2) More than half the days	()	
3) Nearly every day	()	
28. Moving or speaking so slowly th	nat other people could have noticed.	Or, the
opposite-being so fidgety or restle	less that you have been moving arou	nd a lot
more than usual		
0) Not at all	()	
1) Several days	()	
2) More than half the days	()	
3) Nearly every day	()	
29. Thoughts that you would be better	r off dead or of hurting yourself in sor	me way
0) Not at all	()	
1) Several days	()	
2) More than half the days	()	
3) Nearly every day	()	

Determination of perceived social support among the HIV infected ANC mothers

Key							
1. Very Strongly disagree 2. Strongly disagree 3.mildly disagree 4. Neutral							
5.midly agree 6. Strongly agree 7. Very strongly agree							
30. There is special person who							
is around me when am in need							
1() 2() 3() 4() 5() 6() 7()							
31. There is a special person with whom I can share joys and sorrows							
1() 2() 3() 4() 5() 6() 7()							
32. My family really tries to help me							
1() 2() 3() 4() 5() 6() 7()							
33. I get the emotional help and support I need from my family							
1() 2() 3() 4() 5() 6() 7()							
34. I have a special person who is a real source of comfort to me							
1() 2() 3() 4() 5() 6() 7()							
35. My friends really try to help me							
1() 2() 3() 4() 5() 6() 7()							
36. I can count on my friends when things go wrong							
1() 2() 3() 4() 5() 6() 7()							
37. I can talk about my problems with my family							
1() 2() 3() 4() 5() 6() 7()							
38. I have friends with whom I can share my joys and sorrows							
1() 2() 3() 4() 5() 6() 7()							

39. There is a special person in my life who cares about my feeling

1()	2() 3() 4() 5() 6() 7()
40. M	My family is willing to help me make deci	sions
1()	2() 3() 4() 5() 6(() 7()
41. I c	I can talk about my problems with my frie	nds
1()) 2() 3() 4() 5() 6	() 7()
De	Determination of adherence to ART am	ong the HIV infected ANC mothers
42	42. Do you sometimes forget to take your	medicine?
	0) No) () 1) Yes	
43	43. People sometimes forget their medic	` '
		here any days when you did not take your
	medicine	ioro uniy duyo whon you did not unio your
	0) No () 1) Yes	
44	44. Have you ever cut back or stopped tal	
77	doctor because you felt worse when yo	
	0) No () 1) Yes (
15		
43	45. When you travel or leave home, do yo medicine?	u sometimes forget to bring along your
		`
1.0	0) No () 1) Yes (
46	46. Did you take all your medicines yester	
	0) No () 1) Yes (
47	47. When you feel like your symptoms ar	e under control, do you sometimes stop
	taking your medicines?	
	0) No () 1) Yes ()	
48	48. Do you ever feel hassled about sticking	g to your treatment plan?
	0) No () 1) Yes ()	
49	49. How often do you have difficulty reme	mbering to take all your medicine?
	0) Never	
	1) Once in a while	
	2) Sometimes	
	3) All the time	



UNIVERSITY OF NAIROBI FACULTY OF HEALTH SCIENCES P O BOX 19675 Code 00202 Telegrams: varsity Tel: (254-920) 2726300 Est 44355

Ref: KNH-ERC/A/73

Abdihakim Mohamed Osman Reg. No. U56/38337/2020 Dept. of Pharmacy Faculty of Health Sciences University of Nairobi

Dear Abdihakim.

KNH-UON ERC

Email: uonknh_arc@uenbl.ac.ke
Website: http://www.arc.uonbl.ac.ke
Facebook: https://www.facebook.com/uonknh.arc
Twitter: @UONKNH ENC https://www.arc.uon/UONKNH ENC



KENYATTA NATIONAL HOSPITAL P O BOX 20723 Code 00202 Tel: 725309-9 Fax: 725272 Telegrams: NEOSUP, Nairobi

16th February, 2023



RESEARCH PROPOSAL ADHERENCE TO ANTIRETROVIRAL THERAPY AND ASSOCIATED PSYCHOSOCIAL FACTORS AMONG MOTHERS ATTENDING ANTENATAL CLINICS AT MBAGATHI AND KENYATTA NATIONAL HOSPITALS IN NAIROBI (P856/11/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is P856/11/2022. The approval period is 16th February 2023 – 15th February 2024.

This approval is subject to compliance with the following requirements:

- Only approved documents including (informed consents, study instruments, MTA) will be used.
- All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
- Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
- v. Clearance for export of biological specimens must be obtained from relevant institutions.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
- Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE SECRETARY, KNH-UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Assistant Director, Health Information Dept., KNH
The Chairperson, KNH- UoN ERC
The Chair, Dept. of Pharmacy, UoN
Supervisors: Dr. David Nyamu, Dept. of Pharmacy, UoN
Dr. Beatrice Amugune, Dept. of Pharmacy, UoN



Tel.: 2726300/2726450/2726550

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Email: knhadmin@knh.or.ke

OFFICE OF HEAD OF DEPARTMENT, OBSTETRICS & GYNAECOLOGY

KNH/HOD-OBS&GYN/07/VOL.111/

Date: 1" March, 2023

Abdihakim Mohamed Osman Reg. No.U56/38337/2020 Dept. Of Pharmacy Faculty of Health Sciences University of Nairobi

Dear Dr. Nangila,

RE: RESEARCH PROPOSAL: "ADHERENCE TO ANTIRETROVIRAL THERAPY AND ASSOCIATED PSYCHOSOCIAL FACTORS AMONG MOTHERS ATTENDING ANTENATAL CLINICS AT MBAGATHI AND KENYATTA NATIOANAL HOSPITAL - (P856/11/2022)

This is to inform you that the department has given you permission to conduct the above study which has been approved by ERC.

Liaise with SACN, Clinic 18, Ward 1D, GFA, GFD, 1D and Health Information (HRIO) to facilitate your study.

You will be expected to disseminate your results to the department upon completion of your study,

Dr. Maureen Owiti

HOD-OBSTETRICS & GYNAECOLOGY

Cc

SACN

HOD-Health Information

Clinic 18 - 1/C

Ward GFA - I/C

Ward GFB - I/C

Ward ID -1/C

Vision: A World Class Petient-Centered Specialized Heapital raifed

Certified



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7, 100 17





Ref No. 311952

Date of Issue: 26/April/2023

RESEARCH LICENSE



This is to Certify that Mr.. Abdihakim Mohamed Osman of University of Nairobi, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Nairobi on the topic: Adherence to anti-retroviral therapy and associated psychosocial factors among mothers attending antenatal clinics at Mbagathi and Kenyutta national hospitals for the period ending: 26/April/2024.

License No: NACOSTI/P/23/24868

311952

Applicant Identification Number

Walterson

Director General
NATIONAL COMMISSION FOR
SCIENCE, TECHNOLOGY &
INNOVATION

Verification QR Code



NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

See overleaf for conditions

THE SCIENCE, TECHNOLOGY AND INNOVATION ACT, 2013 (Rev. 2014).

Legal Notice No. 108: The Science, Technology and Innovation (Research Licensing) Regulations, 2014

The National Commission for Science, Technology and Innovation, hencefor referred to as the Commission, was the established under the Science, Technology and Innovation Act 2013 (Revised 2014) herein after referred to as the Act. The objective of the Commission shall be to regulate and assure quality in the science, technology and innovation sector and advise the Government in matters related thereto.

CONDITIONS OF THE RESEARCH LICENSE

- 1. The License is granted subject to provisions of the Constitution of Kerrya, the Science, Technology and Innovation Act, and other relevant laws, policies and regulations. Accordingly, the licenses shall adhere to such procedures, standards, code of ethics and guidelines as may be prescribed by regulations made under the Act, or prescribed by provisions of International treaties of which Kernya is a signatory to
- 2. The research and its related activities as well as outcomes shall be beneficial to the country and shall not in any way;
 - i. Endanger national security
 - ii. Adversely affect the lives of Kenyans
 - iii. Be in contravention of Kenya's international obligations including Biological Weapons Convention (BWC), Comprehensive Nuclear-Test-Ban Truzty Organization (CTBTO), Chemical, Biological, Radiological and Nuclear (CBRN).
 - iv. Result in exploitation of imellectual property rights of communities in Kenya
 - v. Adversely affect the environment
 - vi. Adversely affect the rights of communities
 - vii. Endanger public safety and national cohesion
 - viii. Plagiarize someone else's work
- 3. The Licrose is valid for the proposed research, location and specified period.
- 4. The license any rights therrunder are non-transferable
- 5. The Commission reserves the right to cancel the research at any time during the research period if in the opinion of the Commission the escurch is not implemented in conformity with the provisions of the Act or any other written law.
- 6. The Licensee shall inform the relevant County Director of Education, County Commissioner and County Governor before ommencement of the research.
- 7. Excevation, filming, movement, and collection of specimens are subject to further necessary clearance from relevant Government Agencies.
- 8. The License does not give authority to transfer research materials.
- 9. The Commission may monitor and evaluate the licensed research project for the purpose of assessing and evaluating compliance with the conditions of the License.
- 10. The Licensee shall submit one hard copy, and upload a soft copy of their final report (thesis) onto a platform designated by the Commission within one year of completion of the research.

 11. The Commission reserves the right to modify the conditions of the License including cancellation without prior notice.
- 12. Research, findings and information regarding research systems shall be stored or disseminated, utilized or applied in such a manner as may be prescribed by the Commission from time to time.
- 13. The Licensee shall disclose to the Commission, the relevant Institutional Scientific and Ethical Review Committee, and the relevant national agencies any inventions and discoveries that are of National strategic importance.
- 14. The Commission shall have powers to acquire from any person the right in, or to, any scientific innovation, invention or patent of strategic importance to the country.
- 13. Refevent Institutional Scientific and Ethical Review Committee shall monitor and evaluate the research periodically, and make a report of its findings to the Commission for necessary action.

National Commission for Science; Technology and Innovation(NACOSTI). Off Waiyaki Way, Upper Kabete P. O. Box 30623 - 00100 Nairobi, KENYA Telephone: 020 4007000, 0713788787, 0735404245 E-mail: dg@nucosti.go.ke Website: www.nacosti.go.ke



HEALTH, WELLNESS AND NUTRITION

Office of the County Chief Officer – Medical Services

REF: NCCG/DHS/REC/365

DATE: 19th May 2023

MR. ABDIHAKIM MOHAMED OSMAN JKUAT NAIROBI.

Dear Mr. Abdihakim,

RE: RESEARCH AUTHORIZATION

This is to inform you that the Nairobi City County – County Health Services Research Ethics Committee (REC) reviewed the documents on the study titled "Adherence to anti-retroviral therapy and associated psychosocial factors among mothers attending antenatal clinics at Mbagathi and Kenyatta national hospitals."

I am pleased to inform you that you have been authorized to carry out the study at Mbagathi Hospital in Nairobi County. The researcher will be required to adhere to the ethical code of conduct for health research in accordance with the Science Technology and Innovation Act, 2013 and the approval procedure and protocol for research for Nairobi.

On completion of the study, you will submit one hard copy and one copy in PDF of the research findings to the REC. In addition, you will disseminate recommendations of the research at a virtual meeting organized by the REC. By copy of this letter, the Medical Superintendent - Mbagathi hospital to accord you the necessary assistance to carry out this research study.

Yours sincerely,

DR. IRENE MUCHOKI

CHIEF OFFICER MEDICAL SERVICES &

Ag. CHIEF OFFICER NUTRITION, WELLNESS & SCHOOL FEEDING PROGRAM

Cc: Chief Officers – Public Health and Health Facilities Medical Superintendent - Mbagathi hospital

NAIROBI CITY COUNTY

Tel: 2724712, 2725791, 0721 311 808 mbagathihesp@gmail.com



Mbagathi Hospital
P.O. Bex 20725-00202 Nairob

HEALTH, WELLNESS AND NUTRITION SERVICES

REF: MDH/RS/VOL.3/11/250

22™ JUNE, 2023

ABDIHAKIM OSMAN UON NAIROBI.

Dear, Dr.Osman

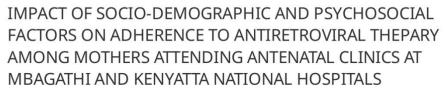
RE: RESEARCH AUTHORIZATION.

This is in reference to your application for authority to carry out a research, on 'Study adherence to antiretroviral therapy and associated psychosocial factors among antenatal clinic mothers at Mbagathi County Hospital.'

I am pleased to inform you that your request to undertake research in the hospital has been granted.

On completion of the research, you are expected to submit one hard copy and one soft copy of the research report/ thesis to this office.

Dr. Nicolas Tinega Medical Superintendent Mbagathi hospital 0 TO JON 7073



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