PREVALENCE AND FACTORS ASSOCIATED WITH HERBAL MEDICINE USE AMONG PEOPLE LIVING WITH HIV ON HIGHLY ACTIVE ANTIRETROVIRAL THERAPY IN SELECTED HOSPITALS IN NAIROBI CITY COUNTY, KENYA

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Prevalence and factors associated with herbal medicine use among people living with HIV on Highly Active Antiretroviral Therapy in selected hospitals in Nairobi City County, Kenya

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DECLARATION

This thesis is my original work and has not been presented for degree in any other university.

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

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DEDICATION

This work is dedicated to my family, my lovely children Tabitha Faith and Mary Hope, my wife Magdalene, my mum Veronicah Wanja, my sister Caroline and friends whom without their support this work wouldn't have been possible. This work is also dedicated to all HIV positive patients whose health I seek to improve. Above all, to the Lord God almighty who provided me with strength to accomplish this work.

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ABBREVIATIONS AND ACRONYMS

3TC	Lamivudine
ABC	Abacavir
ADR	Adverse drug reaction
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral drugs
AZT	Zidovudine
CAM	Complementary and alternative medicine
CCC	Comprehensive care center
DTG	Dolugetravir
EFV	Efavirenz
HAART	Highly active antiretroviral therapy
HIV	Human immunodeficiency virus
LPV	Lopinavir
LPV/r	Lopinavir/ritonavir
NVP	Nevirapine
PCP	Pneumocystis pneumonia
PEP	Post-exposure prophylaxis
PLWH	Persons Living with HIV

PMTCT	Prevention of mother-to-child transmission of HIV
PrEP	Pre-exposure prophylaxis
RAL	Raltegravir
THM	Traditional herbal medicine
WHO	World Health Organization

ABSTRACT

Traditional remedies have been used for many years in Africa to treat various ailments before the introduction of conventional medicines into the continent. Concurrent use of traditional herbal medicines with highly active antiretroviral therapy (HAART) is widespread among HIV infected patients. Studies done in different parts of the world show conflicting health outcomes among HIV positive patients using HAART and herbal medicine concurrently. Some reporting better health outcomes while others report increased adverse drug reactions. The extent of THM use is not known in most settings in sub-Saharan Africa Kenya included. This study aimed to determine the prevalence and factors associated with traditional herbal medicines use among HIV infected patients on HAART attending two comprehensive care centers in Nairobi County. A descriptive cross-sectional study was conducted at Kenyatta National Teaching and Referral Hospital and Mbagathi County Hospital. From the two centers a total of 370 participants were selected via systematic sampling. Data was collected using an interviewer-administered semi-structured questionnaire seeking information on herbal medicine use, socio-demographic and economic factors associated with herbal medicine use and the association between herbal medicine use and occurrence of adverse drug reactions. Chi square test was computed for categorical variables to test for association between herbal medicine use and occurrence of adverse drug reactions. All variables observed to be significant at 5% were subjected to logistic regression analysis. The study established that the prevalence of herbal medicine use among PLWH taking HAART was 15.5%. There were 59.7% participants who had good /fair adherence to HAART while 40.3% had poor adherence. The longer the duration between HIV diagnosis and HAART start, the more likely a HIV positive patient was to use herbal medicine ($P< 0.05$). Patients who had poor adherence were more likely to use herbal medicine. ($P<0.05$). The use of herbal medicine with HAART increased the odds of side effects ($P< 0.05$). There was a significant difference in proportion of those with side effects by duration in years between HIV diagnosis and HAART start, $P<0.05$. Patients who had poor adherence to HAART had significantly higher proportion of side effects as compared to those who had good/fair adherence, 104 (45.7%) and 45 (32.1%) respectively, $p <0.05$. Out of the patients who had used herbal medicine, 67.3% had never disclosed to the doctor or any health care worker at the CCC about their herbal medicine use. The routes of administration of herbal products by PLWH on HAART were oral 100%, topical 7%, inhalation at 7%, rectal 2% and vaginal 0%. The reasons for preferring herbal medicine is that it is easily accessible (97.8%), more acceptable (97.3%) and also because herbal medicine is cheap (92.9%). The sources of herbal medicine were the herbalist (92.6%), garden (87.1%), friends (80.8%), and pharmacy (50%). Herbal medicine use led to decreased adherence to HAART. After starting HAART, 62% of the patients reported to have experienced side effects. Use of herbal drugs together with HAART increases chances of patients experiencing adverse drug reactions. Further investigations ought to be done to establish the safety, efficacy and drug interactions between herbal drugs commonly used by HIV positive patients and antiretroviral agents used for HIV/AIDS treatment.

CHAPTER ONE

INTRODUCTION

1.1 Background of the study

Traditional remedies have been used for many years in Africa to treat various ailments before the introduction of conventional medicines into the continent (Romero-Daza, 2002). The term "traditional medicine" refers to ways of protecting and restoring health that existed before the arrival of modern medicine (Domfeh, 2007). Thus, in all countries of the world there exists traditional knowledge related to the health of humans and animals. The importance of traditional medicine (TM) as a source of primary healthcare was first officially recognized by the World Health Organization (WHO) in the Primary Health Care Declaration of Alma Ata (1978) and has been globally addressed by the Traditional Medicine Program of the WHO.

Herbal medicine is defined as "herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredients parts of plants, or plant materials, or combinations thereof"—is used to treat a multitude of ailments throughout the world (WHO, 2002). Other general terms that are often used interchangeably with herbal medicine include traditional Medicine, complementary and alternative medicine (CAM) and integrated medicine. Complementary medicine is any form of treatment used in conjunction with standard conventional treatment while alternative treatment is any treatment used in place of the standard conventional treatment (WHO, 2008).

The World Health Organization (WHO) estimates that 4 billion people use herbal medicine for their primary health care or in conjunction with conventional medicine (WHO, 2008). But about 80% of this population is found in the developing countries. The wide spread use of traditional medicine (TM) among both rural and urban population could be attributed to cultural acceptability, physical accessibility and economic affordability, as well as efficacy against certain types of diseases, as compared to modern medicine (Mukherjee, 2002). On the other hand, complementary/alternative

medicine (CAM) is being increasingly used in the developed countries with prevalence as high as 70%–80% of the population in developed countries having been using CAMs for decades (WHO, 2008). The most popular therapies used include herbal therapy, chiropractic, relaxation techniques, vitamin therapy as well as massage therapy. People seem to be motivated to use CAM largely because they have misgivings about pharmaco-therapy in particular and the conventional system in general. Other considerations include minimization of the risks of adverse effects of synthetic drugs and also on account of the increasing cost of personal health maintenance (Eisenberg et al. 1998; Hoareau and Da Silva, 1999). World Health Organization estimates state that 50% of Canadians and 75% of people in France have tried CAM, which often includes herbal remedies. In Japan, 85% of doctors prescribe not only modern medicine but also the traditional herbal medicine (called Kampo), which is covered by health insurance (Aschwanden, 2001).

Herbal medicine has been found to be among the most popular therapies in complementary/alternative medicine, representing a market value of about US$ 43 billion a year. In the United States alone, over 1500 herbal medicines are sold annually for a total of nearly US$ 5 billion and now constitute the fastest growing sector of the US pharmaceutical market. It is estimated that Europe, annually imports about 400,000 tons of medicinal plants with an average market value of US$ 1 billion from Africa and Asia. China with exports of over 120,000 tons per annum and India with some 32,000 tons per annum dominate the international market (Aschwanden, 2001).

In Kenya, patients would opt for traditional herbal medicine because the traditional herbal medicine practitioners are more accessible than the trained doctors. A large number of the rural poor, in particular, turn to traditional medical practitioners for certain conditions, when access to allopathic health workers is restricted (Lambert *et al*., 2011).

Herbal medicines have been used in Kenya by various communities to treat both livestock and human ailments. In Mwingi district of Kenya herbal medicine is used for various animal ailments; a concoction of boiled bark and roots of *Sclerocarya birrea* is

topically applied for tick control while sap expressed from *Juniperus procera* is applied on fresh wounds of all livestock (Grace N.N *et al*., 2010).

In Samburu district of Kenya various herbal substances are used to treat various aliments; a hot decoction made from grinding the flowers of *Cordia sinensis* locally known as lkweite is used for treatment of malaria, fevers and eye infections and a hot decoction made from the stem, bark and leaves of *Warbugia ugandensis* are used to treat helminthiasis, heart water, ectoparasites black quarter, emetic and trypanosomiasis (Nanyingi et al., 2008).

1.1.1 Burden of HIV disease

The emergence of human immunodeficiency virus (HIV) infection in Africa in mid 1980s presented a new health challenge to the continent. According to UNAIDS it is estimated that in 2019, 38.0 million people were living with HIV in the world of which 19.2 million were women aged 15 years and above. There were 1.7 million new HIV infections globally in 2019 and 690,000 AIDS related deaths. It is approximated that in 2019 there were 4,500 new HIV infections per day of which 59% were in Eastern and Southern Africa (UNAIDS, 2020). In Eastern and Southern Africa, 20.7 million adults and children are currently living with HIV/AIDS, and this is more than 50% of the global burden of the disease (UNAIDS, 2020). About 72% of the people living with HIV in Eastern and Southern were receiving HAART in 2019 (UNAIDS, 2020). These estimates demonstrate the extent to which the problems HIV/AIDS continue to cause in African countries, Kenya being included.

According to the Kenya Population-based HIV Impact Assessment (KENPHIA) 2018, 1.3 million adults aged 15-64 years were living with HIV. The national HIV prevalence was 4.9 %. About 1 million person living with HIV are using HAART. There are regional variation of adults living with HIV/AIDS (15-64 years). The five counties with the highest burden of HIV infections in Kenya are Homa Bay 19.6%, Kisumu 17.5%, Siaya 15.3%, Migori 13.0% and Busia with a HIV prevalence of 9.9%. The HIV prevalence in women, 6.6%, was twice as high compared to men at 3.1%. Approximately 79.5 % of persons living with HIV knew their HIV status with 96% of

those who knew their HIV status taking HAART. Among the people living with HIV taking HAART, 90.6% had achieved viral suppression (NASCOP,2020). Approximately 1,136,000 persons living with HIV in Kenya were on antiretroviral therapy by December 2017 (NASCOP, 2018).

1.2 Statement of the problem

The standard anti-retroviral drugs (ARVs) used for the treatment of HIV/AIDS have significant side effects resulting in lack of adherence and the emergence of multidrug resistant viral strains. The side effects experienced by HIV patients lead them to distrust of conventional therapy and are likely to turn to complementary and alternative medicine (Hsiao *et al*., 2003). Negative attitude towards the effectiveness of HAART and greater desire for medical information by HIV infected patients makes them more likely to use complementary and alternative medicines which have the potential to cause adverse effects (Lee *et al*., 2006). Patients would opt for traditional herbal medicine because the traditional herbal medicine practitioners are more accessible than the trained doctors but also a large number of the rural poor, in particular, turn to traditional medical practitioners for certain conditions, when access to allopathic health workers is limited. Also since there is no cure for HIV, patients look at herbal remedies as an expected hope for cure. Some of the herbal substances used have been reported to interact with conventional drugs reducing their effectiveness or leading to side effects (Peltzer *et al*., 2008). There is limited documented information on herbal medicine use by persons living with HIV using HAART in Kenya. There is need for carrying out studies focusing on the uptake of herbal medicine among HIV infected patients receiving antiretroviral drugs in order to establish the magnitude, health effects and the associated factors.

1.3 Justification

Studies done in different parts of the world show conflicting health effects on HIV positive patients using HAART and herbal medicine concurrently with some reporting better health outcomes while others report increased risk of adverse drug reactions (Hasan *et al*., 2010, Mudzviti *et al*., 2012). The HIV prevalence in kenya is 4.9%

translating to about 1.3 million adults aged 15-64 years living with HIV. Approximately one million persons living with HIV in kenya use HAART (NASCOP, 2018). Nairobi City County has a population of approximately 4,337,080 persons (KNBS, 2019) with a HIV prevalence of 3.8% and over 125,000 persons living with HIV using HAART (NASCOP, 2018). Mbagathi County Hospital records 1465 adult males and 2396 adult females giving a total of 3861 patients HAART. Kenyatta national hospital records 3177 adult females and 1873 adult males giving a total of 5050 patients on HAART. The total number of patients in the two sites was 8911 according to the ARV Dispensing Tool databases in the two Comprehensive Care Centre (CCC) Pharmacies. The situation of persons living with HIV and use HAART and herbal medicine concurrently in Kenya remains unknown. It is therefore important to establish the health effects, prevalence and factors associated with herbal medicine use among persons living with HIV and use HAART. The results of the study will provide background information that will be useful for coming up with policies and strategies that can be incorporated to efficiently and effectively respond to use of herbal medicine among persons living with HIV and use HAART.

1.4 Research questions

1. What is the prevalence of herbal medicine use among HIV positive patients on HAART?
2. What are the socio-demographic and socio-economic factors associated with herbal medicine use among HIV positive patients taking HAART?
3. What is the level of knowledge, attitudes and practices associated with herbal medicine use among HIV positive patients taking HAART?
4. What is the association between herbal medicine use and the occurrence of adverse drug reactions among HIV positive patients on HAART?

1.5 Hypotheses

1.5.1 Null hypotheses

1. There is no association between socio-demographic and socio-economic factors and herbal medicine use among HIV positive patients taking HAART
2. There is no association between duration from HIV diagnosis to HAART start and herbal medicine use
3. The is no association between herbal medicine use and adherence to HAART among HIV positive patients on HAART
4. There is no association between herbal medicine use and the occurrence of adverse drug reactions among HIV positive patients on HAART
5. There is no association between adherence to HAART and occurrence of adverse drug reactions among HIV positive patients on HAART

1.6 Objectives

1.6.1 Broad objective

Prevalence and factors associated with herbal medicine use among HIV positive patients on highly active antiretroviral therapy in selected hospitals in Nairobi City County, Kenya

1.6.2 Specific objectives

1. To determine the prevalence of herbal medicine use among HIV positive patients on highly active antiretroviral therapy.
2. To determine the socio-demographic and socio-economic factors associated with herbal medicine use among HIV positive patients taking HAART.
3. To determine the level of knowledge, attitude and practices associated with herbal medicine use among HIV positive patients taking HAART.
4. To determine the association between herbal medicine use and occurrence of adverse drug reactions among HIV positive patients taking HAART.

CHAPTER TWO

LITERATURE REVIEW

2.1 Human Immunodeficiency Virus (HIV)

Human Immunodeficiency Virus infects cells of the human immune system and destroys or impairs their function by destroying the CD4 cells, T cells and macrophages which are key components of the cellular immune system (Maddon *et al.,* 1986). Infection with this virus results in the progressive deterioration of the immune system, leading to immune deficiency. A deficient immune system is not able to fight off infections and this makes the HIV infected people susceptible to a wide range of infections (opportunistic infections) which are rare in people with a competent immune system and eventually death (Bonnet *et al*., 2005).

HIV is spread through different routes where the most significant rout is via sexual contact with an HIV infected partner. Most people infected with HIV do not know that they have become infected, because they do not feel sick immediately after infection. Some people at the time of Seroconversion (the development of antibodies to HIV and usually takes place between 1 and 6 weeks after HIV infection has happened) develop fever, rash, joint pains and enlarged lymph nodes (UNAIDS, 2008).

2.2 Acquired Immune Deficiency Syndrome

Acquired immunodeficiency syndrome is based on signs, symptoms, infections, and cancers associated with the deficiency of the immune system associated with HIV infection. There are various stages of HIV infection;

Clinical stage 1 - asymptomatic or generalized swelling of the lymph nodes

Clinical stage 2 - includes minor weight loss, minor mucocutaneous manifestations, and recurrent upper respiratory tract infections

Clinical stage 3 - includes unexplained chronic diarrhea, unexplained persistent fever, oral candidiasis or leukoplakia, severe bacterial infections, pulmonary tuberculosis, and

acute necrotizing inflammation in the mouth. Some persons with clinical stage 3 have AIDS.

Clinical stage 4 - includes 22 opportunistic infections or cancers related to HIV.

All persons with clinical stage 4 have AIDS (WHO, 2005).

2.3 Standard HIV treatment

2.3.1 Co-trimoxazole prophylaxis

According to the 2018 edition of the 'Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya', all HIV-positive patients should be given lifelong Co-trimoxazole prophylaxis unless contraindicated.

Benefits of co-trimoxazole prophylaxis include

1. Co-trimoxazole prophylaxis has many benefits to the HIV positive patients including; Protection against diarrheas, pneumocystis carini pneumonia, toxoplasmosis, sepsis, common bacterial infections and malaria.
2. In pregnancy co-trimoxazole prophylaxis should be initiated irrespective of the gestation period and continued for life. Women on Co-trimozaxole therapy do not require sulfadoxine-pyrimethamine preventive therapy for malaria (NASCOP, 2018).

2.3.2 Use of HAART

All patients who test positive for HIV should be started on HAART soonest possible even on the same day after testing positive for HIV. Initiating HAART on the same day following HIV positive test results has additional benefits in HIV prevention for pregnant and breastfeeding women, partners in a discordant relationship, and is also associated with improved retention, viral suppression, and survival.

The first-line regimen for children from birth up to four weeks is AZT + 3TC + NVP while from 4 weeks up to 3 years is ABC + 3TC + LPV/r. Children aged 4 weeks up to 3

years and are unable to tolerate LPV/r can have it substituted with RAL. The first line regimen for persons aged 3 years up to 14 years is ABC + 3TC + EFV while for those aged 15 years and above is TDF + 3TC + DTG or TDF + 3TC + EFV. The HAART regimen could be changed in case of adverse drug reactions or treatment failure (NASCOP, 2018).

2.3.3 Prevention of mother-to-child transmission of HIV (PMTCT)

Pregnant Women should be tested for HIV as part of routine antenatal care and those who test positive for HIV initiated on HAART ideally, on same day as HIV diagnosis. The preferred first line for pregnant and breastfeeding mothers is TDF/3TC/EFV. HIV exposed infants should be initiated on AZT+NVP for 6 weeks and then NVP continued throughout the breastfeeding period until 6 weeks after complete cessation of breastfeeding (NASCOP, 2018).

2.3.4 Post-exposure prophylaxis (PEP)

This is the use of HAART to reduce the likelihood of HIV infection after potential exposure to HIV. Potential exposure to HIV include accidental exposure to HIV through healthcare work, unprotected sex or sexual assault among adults and children. Healthcare workers are at increased risk of exposure to HIV through contact with contaminated blood and other body fluids containing HIV through needle stick injuries and injuries by other sharp objects or through non-intact skin and mucous membranes. PEP should be offered as soon as possible and not exceeding 72 hours after exposure to HIV and continued for 28 days. The recommended HAART regimen for PEP in Kenya for persons 15 years old and above (or more than 35 kg body weight) is TDF + 3TC + DTG (or TDF + 3TC + ATV/r for women and adolescent girls of childbearing potential). The recommended HAART regimen for PEP in Kenya for children 0-14 years and less than 35 kg body weight is ABC + 3TC + LPV/r (NASCOP, 2018).

2.3.5 Pre-exposure prophylaxis (PrEP)

Pre-exposure prophylaxis is the use of antiretroviral medication to prevent HIV infection by an uninfected person at substantial risk of acquiring HIV infection. The recommended HAART regimen for use as PrEP is TDF 300 mg and Emtricitabine 200 mg once daily given as a fixed dose combination. Alternatively, TDF 300 mg once daily or TDF 300 mg/ 3TC 300 mg may be used (NASCOP, 2018).

2.4 Adverse drug reactions associated with antiretroviral drugs

Antiretroviral drugs are not 100% safe but also do have negative health effects (adverse drug interactions). An adverse drug reaction can simply be defined as an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product. Some adverse drug reactions associated with antiretroviral therapy are shown in the table below (South Africa department of health, 2007).

These life prolonging HAART have several significant side effects and the management of these side effects remains a major challenge especially in the developing countries and this has also contributed to the use of complementary and alternative medicines (UNAIDS, 2008). In Canada, majority of the patients who reported HAART related side effects especially neuropathy, also used complementary or alternative medicine (Agnoletto *et al*., 2006).

Table 2.1: Adverse drug reactions associated with antiretroviral drugs

ARV Agent	Adverse Drug Reaction	High Risk Situations/Comments
Nucleoside reverse transcriptase inhibitors (NRTIs)		
ABC	ABC hypersensitivity reaction	Do not re-challenge
AZT	Anaemia, neutropenia	Risk factors: CD4 count < 200 cells/mm^3; BMI < 18.5 (or body weight < 50 kg); anaemia at baseline; concurrent use of other drugs with similar ADR (cotrimoxazole, gancyclovir, ribavirin)
	Lactic acidosis	Risk factors: Pregnancy; obesity
	Lipoatrophy	Risk factors: Low CD4 count
TDF	Renal dysfunction	Risk factors: Underlying renal disease; age > 40 years; BMI < 18.5 (or body weight < 50 kg); diabetes; hypertension; concomitant PI use ornephrotoxic drug
Non-nucleoside reverse transcriptase inhibitors (NNRTIs)		
All NNRTIs	Rash/hypersensitivity (NVP>>EFV>ETR)	Risk factors: for NVP hypersensitivity, women with CD4 count > 250 cells/mm^3, men with CD4 count > 400 cells/mm^3
EFV	CNS side-effects	Risk factors: Pre-existing psychiatric disorder
	Gynaecomastia	Switch from EFV to an alternative, and consult if gynecomastia does not improve
NVP	Hepatotoxicity	Risk factors: HBV or HCV co-infection; concomitant use of hepatotoxic drugs; women with CD4 count > 250 cells/ mm^3; men with CD4 count> 400 cells/mm^3
Protease inhibitors (PIs)		

All PIs boosted with RTV	GI intolerance (LPV/r>DRV/r>ATV/r)	
	Dyslipidaemia (LPV/r>DRV/r>ATV/r)	Risk factors: Obesity; sedentary lifestyle; diet high in saturated fats and cholesterol
ATV/r	Hyperbilirubinemia	This only requires drug substitution if cosmetic effect of jaundice is likely to interfere with patient adherence
DRV/r	Rash/hypersensitivity	Risk factors: sulfa allergy
Integrase strand transfer inhibitors (INSTIs)		
DTG	Insomnia	Give in the morning; if no improvement then try giving with low fat meal or on empty stomach
All INSTIs	Rash/hypersensitivity	

Patients starting HAART should be educated on above potential adverse drug reactions. Adverse drug reactions can have a significant impact on patient adherence to HAART and must be identified early and managed aggressively (NASCOP 2018)

2.5 Herbal medicine use by people living with HIV

In Europe, approximately 60% of HIV/AIDS patients use CAM while 42.9 % use more than two types (Agnoletto *et al.*, 2006). In the Asia-Pacific region, it was found that 56% of Australians with HIV/AIDS use CAM (Visser *et al*., 2000). About 95 % of Thais with HIV/AIDS use CAM (Wiwanitkit., 2003). A study conducted in Malaysia on patients with HIV/AIDS reported that traditional herbal medicine is the second most popular form of CAM used after vitamins and supplements and the reasons for use included reduction of body heat (14.8%) and improved health (12.9%). Interestingly, 40% of the participants felt that CAM had improved their health, and none of them felt that his/her health condition had deteriorated after CAM use. (Hasan *et al.*, 2010).

In Africa many HIV patients use traditional herbal medicine for primary health care or management of side effects (Babb *et al*, 2007). Traditional beliefs, inconsistent access or unavailability of antiretroviral drugs has led to increase in the use of herbal remedies

among HIV-infected individuals in Africa (Maponga *et al*., 2007). In South Africa about 75% of HIV-infected patients take some remedies from complementary or African traditional medicine (Malangu, 2008). In Zimbabwe, 54% of the HIV infected patients that took part in the study were taking antiretroviral drugs together with one or more traditional herbal remedies (Bepe *et al*., 2010). **A** study by Bepe reported that, HIV positive patients using HAART and herbal medicines in Zimbabwe were at a higher risk of ADRs than those who used HAART only (Bepe et al., 2010). Patients who used HAART and indigenous herb, Musakavakadzi, were 75 percent less likely to develop ADRs compared to patients who did not use the herb while those who used *Peltoforum africanum* were 50% less likely to develop adverse drug reactions when compared to patients who did not use the herb (Mudzviti *et al*., 2012). In Uganda 33.7% of HIV infected people on highly active antiretroviral therapy (HAART) use herbal medicine (Namuddu *et al*., 2011). A study in western Uganda established that 38% of HIV positive patients used traditional medicines for the treatment of HIV and for symptoms associated with HIV. The patients also used HAART at the same time for the management of HIV infection (Klassen *et al*., 2007).

In South Africa 4 % of those with infected with HIV refused to take antiretroviral and opted for CAM exclusively to treat the infection (Peltzer *et al*, 2008). Similarly, 1.7 % of the participants from Boston used CAM exclusively to treat the infection (Fairfield *et al*, 1998). About 64% of respondents in Uganda reported using CAM after they were diagnosed with HIV, and 32.8% of them were taking CAM together with antiretroviral drugs (Klassen *et al*., 2007). According to a study done in Uganda the prevalence of traditional herbal medicine (THM) use was 33.7%, (95% CI: 33.38-34.02). The use of THM was higher among women (36.4%) compared to men (27.3%). Reasons stated for THM use were to reduce constant fever (67.4%), treat cough (65.2%) among others. The study reported that 69.6% of the herbs were obtained from registered herbalist while 5.2% were obtained from pharmacies. Single individuals were also more likely to use THM compared to the married individuals ($P<0.01$). The participants who were $\geq$ 39 years were less likely to use THM than those who were $\leq$ 38 years, ($P<0.01$). Participants who reported side effects from HAART were two times more likely to use

THM compared to those who did not. Individuals who had been on HAART for < 4 years were more likely to use herbs than those who were on HAART for ≥ 4 years, ($P<0.05$). Patients who could not tell if herbs actually improved health were more than three times more likely to use THM compared to those who could tell it improves on the health of an individual (Namuddu *et al*., 2011).

The use of CAM is less common in patients who adhere to HAART and more common in patients who experience side-effects of HAART (Agnoletto *et al*, 2006). However, HIV infected people do not like disclosing to the health care professionals about their CAM use (Peltzer *et al*, 2008). Some people do feel that CAM does improve their quality of life (Duggan *et al*, 2001).

HIV patients on HAART may not inform medical practitioners about their herbal medicine use as they believe it is not important and taking herbal medicine together with prescribed drugs is harmless especially if for different problems or fear of being treated differently by the healthcare providers (Vickers et al., 2006). Even though there is a general feeling that herbal medicines are safe, a review of toxicity and quality control issues of herbal medicines in Kenya reveal the existence of contamination of herbal medicines with heavy metals, undocumented pharmaceuticals, misidentified plants, pesticides, excessive levels of microorganisms or their toxins and other noxious organic materials as well as high bacteria content that poses serious health risks (Maina *et al*., 2013). Adverse events arising from consumption of herbal medicines may also be due to over dosage, misuse of herbal medicines by either healthcare providers or consumers and use of herbal medicines concomitantly with other medicines. Analysis of adverse events related to the use of herbal medicines is more complicated than in the case of conventional pharmaceuticals (WHO Programme on Traditional Medicine, 2005).

2.6 Drug interactions between herbal medicine and conventional antiretroviral drugs

There is no ultimate cure for HIV and this has led to people trying different things in an attempt to get cured. Some of the herbal drugs have been reported to cause adverse effects and there have been reports of drug interactions with antiretroviral drugs (Izzo,

2005). These herbal substances could induce enzymes involved in the metabolism of antiretroviral drugs resulting in low plasma concentrations of the drugs or alternatively inhibit the enzymes resulting to higher plasma concentrations of the drugs which would exacerbate their toxicity (Lee *et al*., 2006). Herbal medicines do present various health challenges. The multiplicity of these medicines leads not only to potentially severe side effects, but also to clinically significant interactions between ARVs and other medicines. Use of HAART concurrently with traditional herbal medicine may lead to drug interactions undermining the effectiveness of antiretroviral drugs (Lee *et al*., 2006).

Garlic supplementation decreases the plasma concentrations of saquinavir (Piscitelli *et al*.,2002). When garlic supplements were administered to study volunteers receiving saquinavir, the saquinavir mean area under curve decreased by 51% and this is significant. Milk thistle reduces the plasma concentrations of indinavir (Piscitelli *et al*.,2002). When milk thistle was administered concomitantly with indinavir, the AUC reduced by 9%. Though this reduction should not interefere with indinavir therapy in HIV positive patients, it is an indication of possible drug interactions. St. Johns wort reduces the plasma concentrations of indinavir. When administered concomitantly with indinavir, st. Johns wort was shown to reduce the area under curve of indinavir by 57%. This significant drop poses a risk of development of drug resistance or treatment failure (Piscitelli *et al*.,2000). High doses of vitamin C decrease the plasma concentration of indinavir (Slain *et al*., 2012). After 7 days of administration of high doses of vitamin C (100mg), the mean steady state indinavir maximum plasma concentration was decreased by 20 % and the mean area under curve reduced by 14 %. Some herbal medicines do not interact with certain antiretroviral agents and can be safely co-administered. There are no drug interactions between goldenseal root and indinavir (Sandhu *et al*., 2003).

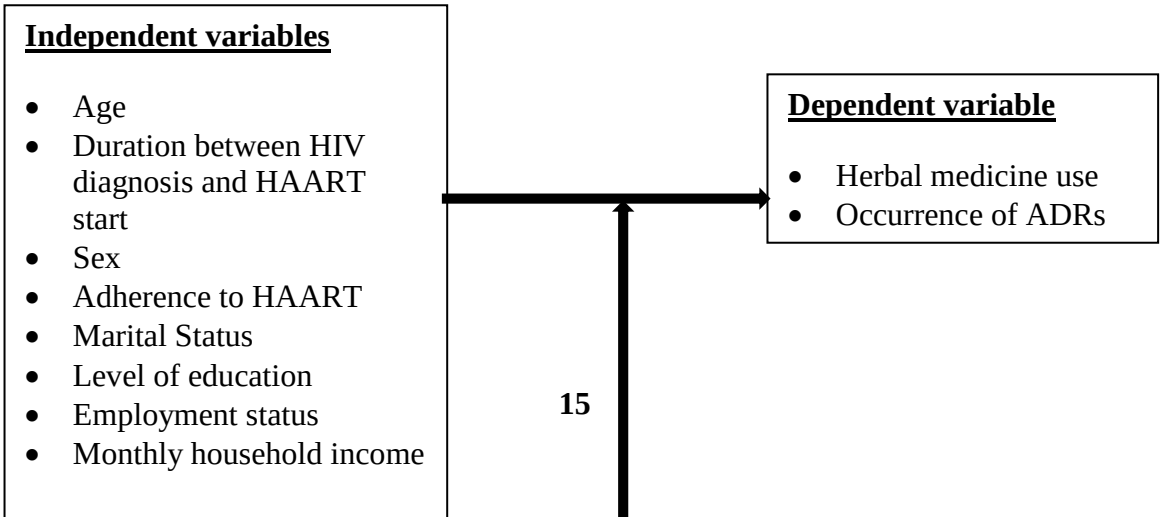

Figure 1.1: Conceptual frame work

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study area

The study was conducted at Kenyatta National Hospital (KNH) CCC and Mbagathi County Hospital CCC both in Nairobi County. These two facilities had the highest patient volumes in Nairobi County. Mbagathi County hospital has a history of being an infectious disease hospital and had the structurers for Tuberculosis and HIV care and management established early in Nairobi. Patients with TB and HIV infection within Nairobi County would be referred to Mbagathi County hospital for treatment. Kenyatta National Hospital is a teaching and referral hospital and all complicated medical cases are usually referred to KNH for further care and management. These two facilities offer diversity of patients within Nairobi County.

Mbagathi County Hospital is located approximately 4 kilometers from the city center. It has a bed capacity of 200 and offers a variety of services including Antiretroviral Therapy, Curative In-patient Services, Family Planning, HIV Counseling and Testing, Immunization and many others. The facility is easily accessible from the city center and is well known as it was the district referral center giving it a wide catchment area. It has a history of being an infectious disease hospital hence it popularity among Nairobi residents. It serves close to 4000 HIV positive patients taking HAART making it an ideal center for the study.

Kenyatta National Hospital has 50 wards, 22 out-patient clinics, 24 theatres and Accident & Emergency Department. It has a total bed capacity of 1800 out of which 209 beds are for the Private Wing. It is accessible to the majority of the population in the county due to its strategic geographical location and the health capacity of the facility. It is the national referral hospital and all the complicated medical conditions that cannot be managed in other hospitals are usually referred to KNH. The facility serves over 5000 HIV positive patients taking HAART.

3.2 Study design

The research adopted a facility based descriptive cross-sectional study which recruited HIV positive patients on HAART aged 18 years and above attending Kenyatta National Teaching and Referral Hospital CCC and Mbagathi County Hospital CCC. A semi-structured questionnaire was administered to patients who met the selection criteria. Participants received information on the study including the time required for questionnaire completion and assured anonymity of their responses.

3.3 Study population

The study population comprised of HIV positive patients receiving HAART and attending the Kenyatta National Teaching and Referral Hospital and Mbagathi County Hospital CCCs.

3.4 Inclusion criteria

The subjects eligible for the study were those that were;

- Above 18 years
- Able to respond to study questions
- Willing to participate in the study
- Nairobi residents.

3.5 Exclusion criteria

The subjects not eligible for the study were those that were;

- Unable to answer questions
- Those who declined to give informed consent.

3.6 Sample size determination

The appropriate sample size for a population-based survey was determined by three factors:

i. The estimated prevalence of herbal medicine use among HIV positive patients on HAART.
ii. The desired level of confidence which was 95%.
iii. The acceptable margin of error.

For a survey design based on a simple random sample, the sample size required was calculated according to the Cochran (Cochran., 1977) formula as follows;

$$n = (Z^2pq) / d^2$$

Where:

n = The desired sample size (if the target population is greater than 10,000)

z = The standard normal deviate at the required confidence level, whereby in this study the degree of confidence was 95%. Therefore, at 95% confidence level, the standard normal deviate is 1.96.

P = The proportion in the target population estimated to be taking HAART and herbal medication concurrently. Since there were no available estimates of the HIV infected patients taking HAART and herbal medication concurrently, then 50 % was used as recommended by fisher *et al* (1985). Therefore, in this study p was 0.05.

q = 1-p.

d = The level of statistical significance test which in my study was 0.05.

Therefore, the sample size was;

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

$$= 384.16 = 385 \text{ persons.}$$

In this study the target population was 8911 which was less than the minimum reference population of 10,000 for the validity of the estimated sample size. In this case finite population correction (fpc), was adjusted using the following formula;

$$nf = \frac{n}{1+n/N}.$$

Where

nf = the desired sample size (when the population is less than 10,000)

n =desired sample size (when the population is more than 10,000.

N= minimum reference population in the target study community.

Therefore, the sample size of this study was

$$nf = \frac{385}{1 + (385/8911)}$$

=369.055 =370 participants.

3.7 Sampling frame

The number of study participants selected from each facility was weighted to the number of HIV positive patients taking HAART registered at each facility. (Table 3.1).

Table 3.1: Sampling frame

Facility	Number of Registered HIV positive patients taking HAART	Number of study participants selected from each facility
Mbagathi	3861	160
Kenyatta	5050	210

3.8 Sampling procedure

Systematic sampling procedure was used. The number of participants chosen from each facility was weighted to the number of patients that usually received treatment at each facility.

A sampling factor (n^{th} factor) was determined by dividing the sampling frame by the desired sample size. That is;

$$\frac{\text{Total number of patients}}{\text{Required sample size}}$$

$$\frac{8911}{370} = 24.084$$

Every 24^{th} subject who met the inclusion criterion was recruited into the study. If the 24^{th} subject did not meet the inclusion criteria, the next subject would be selected. The first patient was selected randomly by picking a number at random from 1 to 24, say k. The patients were chosen at the CCC waiting area as they waited to be seen by the clinician. The interviewer would approach the patient, greet the patient and introduce him/herself. The interviewer then explained to the patient his intention to have them participate in the study. Informed consent was obtained from those patients who agreed to participate in the study. Patients who were HIV positive and on HAART were identified by requesting them to show their CCC clinic registration cards that bore their identity and the HAART regimen they were taking.

The first patient to be selected would be the k^{th}, the second k+24, 3^{rd} 2k+24 etc. until all the study participants were selected.

The research team continued recruiting the study subjects until they got enough sample size for the study. Before interviewing any respondent, the research assistants would

introduce themselves to the participants and explain to the subjects the purpose of the study, any foreseen risks, guarantee of anonymity, confidentiality, benefits and compensation or lack of them. Informed consent to conduct the interview was sought from every respondent before the interview.

3.9 Data collection

Primary data was obtained using an interviewer administered semi structured questionnaire. The questionnaire was prepared in both English and Swahili languages. The questionnaire was administered to the participants and the responses written on each questionnaire. It took approximately 20 minutes to complete the questionnaire.

The type of data collected included demographic characteristics of the participants; age, sex, religion, highest level of education attained, marital status, drug related factors including adherence to HAART, duration on HAART, and side effects; individual factors including familiarity with herbs, beliefs in the usefulness of THM, why they started using THM, what herb was taken and how. Medication adherence was assessed using the validated Morisky medication adherence scale in outpatient setting (Morisky *et al*., 2008).

3.10 Pretesting of the data collection tools

Pre-testing of the data collection tools was done at Kayole II Sub county hospital, Nairobi County. Kayole II sub county hospital and Mbagathi County hospital are both level 4 hospitals within Nairobi County. The patients seen at Kayole II sub county hospital are from the middle to lower socioeconomic profile within Nairobi County similar patients served at Mbagathi County Hospital and were therefore expected to have similar characteristics. The calculated sample size was 370 study participants and 10% of the sample size (37 participants) was involved in the pre-test. Any problems in wording, content of questions, lack of clarity of instructions or ambiguous questions from the questionnaire were adjusted to ensure clarity of the questions. The pre-test was also used to estimate the duration it would take one person to fill a questionnaire.

3.11 Data management and analysis

All study participants received a unique participant identification number that was recorded on the questionnaire. Data was checked for accuracy and completeness and was stored in flash disks, compact disks and a laptop for back up before and after analysis. Questionnaires were kept under lock and key while electronically stored data was password protected. The data was keyed in Microsoft Excel and then exported to STATA version 15.1 for analysis. Dependent variables include prevalence of herbal medicine use and occurrence of ADRs. Chi square test was computed for categorical variables to test for association between predictor and outcome. All variables observed to be significant were subjected to multivariate regression analysis to test for interaction. Level of significance was determined at 5% (p-value < 0.05).

3.12 Ethical consideration

Ethical approval was obtained from Kenya Medical Research Institute (KEMRI) Ethics Review Committee and Kenyatta National Hospital (KNH)/ University of Nairobi (UON) Ethics Review Committee. Approval to conduct research granted by the medical superintendent Mbagathi County Hospital. Prior to the study, sensitization meetings with the health authorities in charge of the heath facility were held.

The objectives of the study were explained and permission sought to carry out the study at the health facilities. Data collection emphasized on issues of confidentiality and privacy by restricted access to the information collected and coding of questionnaires. After voluntary informed consent had been obtained from the patient, only those patients, who met the study requirements, verbally consented and voluntarily signed the consent forms were enrolled into the study.

Each participant was informed about their right to decline or withdraw any time from participating in the study without feeling constrained. Respondents were informed that the information would not be made available to persons outside the study team. Respondents were further assured that no person-identifiers would be used for

publication. The interviews were conducted in identified private rooms to ensure that no information leaked.

CHAPTER FOUR

RESULTS

4.1 Socio-demographic and socio-economic characteristics of patients on HAART

A total of 370 participants were recruited into the study. There were 136 (36.8%) males and 234 (63.2%) females. A total of 8 (2.2%) participants were below 25 years, 41 (11.3%) were 25-29 years while 31 (8.6%) participants were aged over 55years. The married participants were 208 (61.5%), single 78 (23%) while 52 (15.3%) were either divorced or separated. A total of 125 (33.9%) participants had acquired tertiary education, 163 (44.2%) had secondary school, while 11 (3%) had no education. With regard to employment status 113 (32%) participants were in private business, 170 (48%) were employed and 70 (19.8%) were unemployed. There were 7(2.4%) participants who had a monthly household income less than Ksh5000, 29 (10%) earned between ksh5000-ksh9999, while 65 (22.4%) had a monthly income above ksh50000. (Table 4.1)

Table 4.1: Socio-demographic and economic characteristics of patients on HAART

Variable		Frequency	percentage
Sex	Male	136	36.76
	Female	234	63.24
Age Category in Years	Below 25	8	2.21
	25-29	41	11.33
	30-34	52	14.36
	35-39	48	13.26
	40-44	72	19.89
	45-49	69	19.06
	50-54	41	11.33
	55 and above	31	8.56
Marital Status	Single	78	23.08
	Married	208	61.54
	Divorced or Separated	52	15.39
Level of education	No formal education	11	2.98
	Primary school	70	18.97
	Secondary school	163	44.17
	Tertiary education	125	33.88
Employment status	Unemployed	70	19.83
	Employed	170	48.16
	Private business	113	32.01
Monthly household income (Ksh)	Below 9999	36	12.41
	10000-19999	71	24.48
	20000-29999	70	24.14
	30000-39999	28	9.66
	40000-49999	20	6.90
	Above 50000	65	22.41

4.2 Characteristics of patients on HAART

There were 54 (14.8%) participants who were started HAART within 3 years of HIV diagnosis, 71 (19.4%) were started HAART between 3-5 years, 110 (30%) between 6-8 years, and 131 (35.8%) were started HAART more than 9 years after HIV diagnosis. There were 221 (59.7%) participants who achieved good /fair adherence while 149 (40.3%) had poor adherence. After starting HAART, 228 (62%) participants reported to have experienced side effects while 140 (38%) didn't experience any side effects. (Table 4.2).

Table 4.2: Adherence, side effects and HAART start characteristics of patients on HAART

Variable		Frequency	Percentage
Duration in years between HIV diagnosis and HAART start	Less than 3 years	54	14.75
	3-5	71	19.40
	6-8	110	30.05
	More than 9 years	131	35.79
Adherence	Good/ Fair	221	59.73
	Poor	149	40.27
Side effects after HAART start	Experienced side effects	228	61.96
	Didn't experience side effects	140	38.04

4.3 Prevalence of herbal medicine use among HIV positive patients on HAART

The Prevalence of herbal medicine use among HIV positive patients on highly active antiretroviral therapy was 15.5%. (Table 4.3).

Table 4.3: Prevalence of herbal medicine use among HIV positive patients on HAART

Herbal & HAART use	Frequency	Percent
No	305	84.49
Yes	56	15.51

Before being diagnosed HIV positive, 46.2% of the patients were using herbal medicine for treatment of ailments while 13.8% used herbal medicine between the time they were diagnosed HIV positive and the time they were started on HAART.

4.4 Socio-demographic, socio-economic factors and herbal medicine use among HIV positive patients taking HAART.

The study established that a higher proportion of HIV positive women on HAART (17%) used herbal medicine as compared to men (12.9%) though this was not statistically significant. (Table 4.4).

Table 4.4: Socio-demographic, socio-economic factors and herbal medicine use among HIV positive patients on HAART

Variable		Herbal Use						Test Stat, P- value
		No		Yes		Total		
		Freq	%	Freq	%	Freq	%	
Sex (n=361)	Male	115	37.7	17	30.4	132	36.6	Pearson chi2(1)= 1.1013, Pr= 0.294
	Female	190	62.3	39	69.6	229	63.4	
Age (n=355)	<35	87	29	12	21.8	99	27.9	Pearson chi2(2) = 1.1921, Pr = 0.551
	35-44	99	33	20	36.4	119	33.5	
	45+	114	38	23	41.8	137	38.6	
Marital Status (n=331)	Not Married	107	38.1	20	40	127	38.4	Pearson chi2(1) = 0.0663, Pr = 0.797
	Married	174	61.9	30	60	204	61.6	
Education (n=360)	Primary and lower	68	22.4	10	17.9	78	21.7	Pearson chi2(2) = 0.7427, Pr = 0.690
	Secondary	136	44.7	25	44.6	161	44.7	
	Tertiary	100	32.9	21	37.5	121	33.6	
Employment (n=344)	Unemployed	57	19.7	12	22.2	69	20.1	Pearson chi2(2) = 0.2006, Pr = 0.905
	Employed	142	49	26	48.1	168	48.8	
	Private Business	91	31.4	16	29.6	107	31.1	
Income (n=282)	<20000	90	37.3	16	39	106	37.6	Pearson chi2(2) = 0.8298, Pr = 0.660
	20000-39999	76	31.5	15	36.6	91	32.3	
	40000 and above	75	31.1	10	24.4	85	30.1	

4.5 Characteristics of patients on HAART and herbal medicine use

The study established that there was a statistically significant association between herbal medicine use and duration in years between HIV diagnosis and HAART start ($P< 0.05$). A statistically significant association between adherence and herbal medicine use ($P<0.05$) was also observed. Side effects after HAART start was associated with herbal medicine use ($P<0.05$). (Table 4.5).

Table 4.5: Adherence, side effects, HAART start factors and herbal medicine use among HIV positive patients on HAART

Variable		Herbal Use						Test Stat, P-value
		No		Yes		Total		
		Freq	%	Freq	%	Freq	%	
Duration in years between HIV diagnosis and HAART (n= 357)	Less than 3years	48	15.9	4	7.3	52	14.6	Pearson chi2(3) = 9.0929, Pr = 0.028
	3-5	58	19.2	12	21.8	70	19.6	
	6-8	97	32.1	11	20	108	30.3	
	More than 9 years	99	32.8	28	50.9	127	35.6	
Adherence (n=361)	Good / Fair	191	62.7	24	42.9	215	59.5	Pearson chi2(2) = 7.6742, Pr = 0.006
	Poor	114	37.4	32	57.1	146	40.4	
Side effects after HAART start (n=360)	No	125	41.1	11	19.6	136	37.8	Pearson chi2(1) = 9.2783, Pr = 0.002
	Yes	179	58.9	45	80.4	224	62.2	

4.6 Multivariate analysis of factors associated with herbal medicine use among HIV positive patients taking HAART

The factors that were independently associated with herbal medicine use were a more than 9 years' duration between HIV diagnosis and HAART start (P< 0.05), poor adherence to HAART (P< 0.05), and side effects after HAART start (P< 0.05). Patients who were started HAART more than 9 years' after HIV diagnosis were 4.6 times more likely to use herbal medicine as compared to those who were started HAART within 3 years of HIV diagnosis (OR 4.6, P< 0.05). Patients who had poor adherence to HAART had higher odds of using herbal medicine (OR 2.84, P< 0.05). Patients who had experienced side effects after HAART start were three times more likely to have used herbal medicine (OR 3.4, P< 0.05). (Table 4.6).

Table 4.6: Multivariate model for factors associated with herbal medicine use among HIV positive patients taking HAART

Variable		OR	95% CI	P-value
Duration in years between HIV diagnosis and HAART start	Less than 3 years	Ref		
	3-5 years	2.692	0.761-9.561	0.087
	6-8 years	1.673	0.445 -5.608	0.392
	More than 9 years	4.631	1.283-12.045	0.009
Adherence	Good/ Fair	Ref		
	Poor	2.84	1.55 - 7.81	0.027
Side effects after HAART start	Didn't experience side effects	Ref		
	Experienced side effects	3.402	2.015-4.165	0.031

4.7 Socio-demographic, socio-economic factors and occurrence of adverse drug reaction among HIV positive patients taking HAART.

The study established that a higher proportion of females 90 (64.3%) had a side effect after HAART start as compared to males 144 (63.2%), without statistical significance, p= 0.827. There was no significant difference in proportion with side effects by marital status, p > 0.05. Similarly, there was no difference in proportion with side effects by education level and income level, p >0.05. There was a higher proportion of those employed with side effects, 114 (52.5%) vs. 56 (41.8%) but without any statistical significance p> 0.05. (Table 4.7).

Table 4.7: Socio-demographic, socio-economic factors and occurrence of adverse drug reactions among HIV positive patients on HAART

	Side Effects	No (n=140)		Yes (n=228)		Total (n=368)		Test statistic, P value
		Freq	%	Freq	%	Freq	%	
Sex (n=368)	Male	50	35.7	84	36.8	134	36.4	Pearson chi2(1) = 0.0477, Pr = 0.827
	Female	90	64.3	144	63.2	234	63.6	
Age (n=360)	<35	32	23.2	69	31.1	101	28.1	Pearson chi2(2) = 2.8606, Pr = 0.239
	35-44	51	37	69	31.1	120	33.3	
	45+	55	39.9	84	37.8	139	38.6	
Marital status (n=337)	Not Married	51	39.2	79	38.2	130	35.6	Pearson chi2(2) = 0.0383 Pr = 0.845
	Married	79	60.8	128	61.8	207	61.4	
Education Level (n=366)	Primary or lower	37	26.6	44	19.4	81	22.1	Pearson chi2(2) = 3.1731, Pr = 0.205
	Secondary	61	43.9	101	44.5	162	44.3	
	Tertiary	41	29.5	82	36.1	123	33.6	
Employment Status (n=351)	Unemployed	30	22.4	40	18.4	70	19.9	Pearson chi2(2) = 3.8313, Pr = 0.147
	Employed	56	41.8	114	52.5	170	48.4	
	Private business	48	35.8	63	29	111	31.6	
Income level (n=288)	<20000	39	36.1	67	37.2	106	36.8	Pearson chi2(2) = 3.1766, Pr = 0.204
	20000-39999	31	28.7	66	36.7	97	33.7	
	40000 and above	38	35.2	47	26.1	85	29.5	

4.8 Characteristics of patients on HAART and occurrence of adverse drug reactions

There was a significant difference in proportion of those with side effects by duration in years between HIV diagnosis and HAART start, p <0.01. Patients who had poor adherence had significantly higher proportion of side effects as compared to those who had good/fair adherence, 104 (45.6) vs. 45 (32.1%), p <0.05. (Table 4.8).

Table 4.8: Adherence, HAART start factors and occurrence of adverse drug reactions among HIV positive patients on HAART

	Side Effects	**No (n=140)**		**Yes (n=228)**		**Total (n=368)**		**Test statistic, P value**
		Freq	**%**	**Freq**	**%**	**Freq**	**%**	
Duration in years between HIV diagnosis and HAART (n=364)	<3 (n=54)	11	8	43	18.9	54	14.8	Pearson chi2(3) = 12.2605, Pr = 0.007
	3-5 (n=69)	21	15.3	48	21.1	69	19	
	6-8 (n=110)	46	33.6	64	28.2	110	30.2	
	>9 (n=131)	59	43.1	72	31.7	131	36	
Adherence (n=368)	Good/Fair (n=219)	95	67.9	124	54.4	219	59.5	Pearson chi2(1) = 6.5327, Pr = 0.011
	Poor (n=149)	45	32.1	104	45.6	149	40.5	

4.9 Logistic regression of socio-demographic, economic factors, HAART start and occurrence of adverse drug reaction among HIV positive patients taking HAART.

On univariable analysis, females had slightly lowered odds of having a side effect OR= 0.95, 95% CI (0.62-1.48), p= 0.827 without statistical significance.

Those started HAART 6-8 years after HIV diagnosis, OR= 0.36, 95% CI (0.17-0.76), and those started more than 9 years OR= 0.31, 95% CI (0.15-0.66) had statistically significant lower odds of side effects compared to those started HAART less than 3 years after diagnosis, p=0.008 and p=0.002 respectively. Those with poor adherence compared to those with good or fair adherence, had statistically significant higher odds of side effects, OR= 1.77 95% CI (1.14-2.75).

Multivariable model included all the variables. On multivariable analysis, patients started HAART 6-8 years after HIV diagnosis, OR= 0.35 95% CI (0.13-0.91), and more than 9 years OR= 0.27, 95% CI (0.1-0.73) had statistically significant lower odds of side effects compared to those started HAART less than 3 years, p=0.032 and p=0.009 respectively. Patients with poor adherence compared to those with good or fair adherence, had statistically significant higher odds of side effects, OR= 2.38 95% CI (1.33-4.27), p=0.004. (Table 4.9).

Table 4.9: Multivariate model for factors associated with adverse drug reactions among patients on HAART

	Side Effects (Yes vs. No)	Univariable OR	P value	Multivariable OR	P value
Sex	Male	Ref		Ref	
	Female	0.95 (0.62-1.48)	0.827	1.28 (0.72-2.3)	0.403
Age Category	<35	Ref		Ref	
	35-44	0.63 (0.36-1.09)	0.099	1.06 (0.49-2.31)	0.883
	45+	0.71 (0.41-1.22)	0.210	1.19 (0.54-2.6)	0.668
Marital status	Not Married	Ref		Ref	
	Married	1.05 (0.67-1.64)	0.845	1.17 (0.54-2.17)	0.639
Education	Primary or lower	Ref		Ref	
Level	Secondary	1.39 (0.81-2.39)	0.230	1.38 (0.62-3.05)	0.428
	Tertiary	1.68 (0.95-2.99)	0.077	2.43 (0.94-6.25)	0.0663
Employment Status	Unemployed	Ref		Ref	
	Employed	1.53 (0.86-2.7)	0.147	2.26 (0.24-21.6)	0.480
	Private business	0.98 (0.54-1.8)	0.959	1.73 (0.18-16.7)	0.635
Income level	<20000	Ref		Ref	
	20000-39999	1.24 (0.69-2.22)	0.469	1.32 (0.63-2.75)	0.463
	40000 and above	0.72 (0.4-1.29)	0.268	0.57 (0.26-1.26)	0.164
Duration in	<3	Ref		Ref	
years	3-5	0.59 (0.25-1.35)	0.209	0.63 (0.22-1.83)	0.399
between	6-8	0.36 (0.17-0.76)	0.008	0.35 (0.13-0.91)	0.032
	>9	0.31 (0.15-0.66)	0.002	0.27 (0.1-0.73)	0.009
Adherence	Good/Fair	Ref		Ref	
	Poor	1.77 (1.14-2.75)	0.011	2.38 (1.33-4.27)	0.004

4.10 Side effects experienced by HIV positive patients on HAART

After HAART start, 62% of the patients experienced side effects. The side effects experienced were nausea and vomiting 47 (20.6%), drowsiness 42 (18.4%), dizziness 31 (13.6%), hallucinations and joint pains 39 (17.1%), skin rashes 13 (5.7%), weight loss 17 (7.5%) and night mares 15 (6.6%) and other side effects 24 (10.5%). (Figure 4.1)

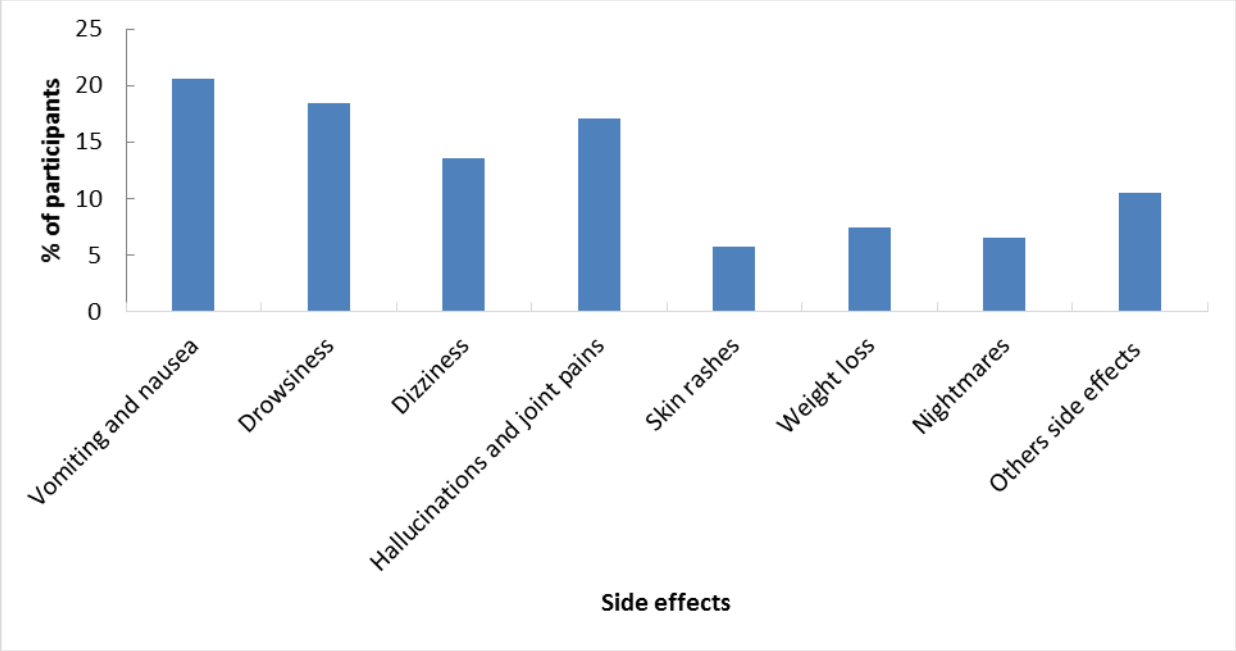

Figure 4.1: Side effects experienced by participants After HAART start

4.11 The level of knowledge of HIV positive patients taking HAART.

4.11.1 Benefits of HAART known by HIV positive patients on HAART

The benefits of using HAART were known by 359 (98.4%) participants with 6 (1.6%) not knowing any benefit of taking HAART. The benefits known to study participants included to suppress viral load, improve or prolong life and to boost immunity. (Figure 4.2).

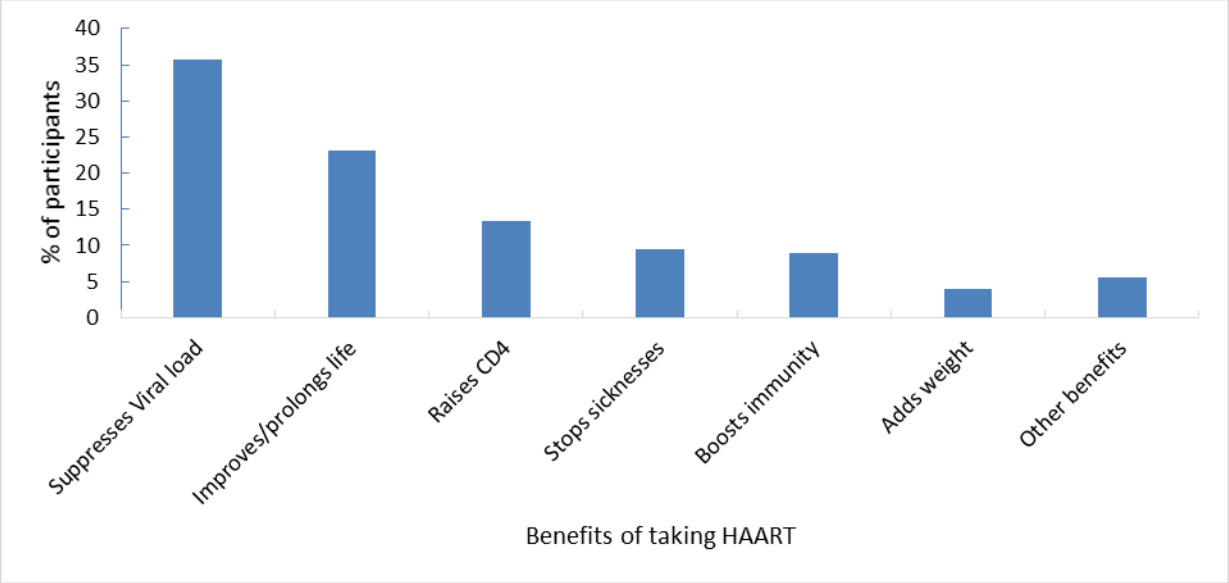

Figure 4.2: Benefits of using HAART known by HIV positive patients taking HAART

4.11.2 Knowledge on herbal products used for HIV treatment

The study established that 30% of the study participants had knowledge of at least one herbal medicine used for treatment of HIV. The herbal products known by the participants for treatment of HIV included aloevera, makini products, caspower,changaa,herbs from maasai ,medicine found in loliondo, Dr.murungi products, forever living products, GNLD products, tianshi products, healthy you products, imbindi, bhangi, mokombero, muratina, dawa ya virusi, kanova,indian product, kupona, marijuana, micro2 cycle, reishi coffee, ginseng coffee, zaminacal capsules, cordyceps coffee, arthroxta, muringa herbs, mwarubaini, ochuonga, singeteti, stinging nettle and herbs whose names were not known to the participants.

Participants learnt of these herbal products by themselves (2), from friends (56), from relatives (29), from the media (59), from other HIV patients (3) and from agents of companies trading in herbal medicine (2).

4.12 The attitudes associated with herbal medicine use among persons living with HIV taking HAART

The study established that 59.7 % of the patients on HAART strongly agreed that herbal medicine is more effective in treatment of illnesses as compared to conventional medicines while 55.8% strongly agreed that it was okay for persons on HAART to take herbal medicine. (Table 4.10)

Table 4.10 The attitude of HIV positive patients taking HAART.

Question	Strongly disagree Freq(%)	Disagree Freq(%)	Neutral Freq(%)	Agree Freq(%)	Strongly agree Freq(%)	Mean (Stanndard Deviation)
Herbal medicine is more effective in treatment of illnesses as compared to conventional medicines	13 (3.5)	16 (4.3)	67 (18.1)	53 (14.3)	221 (59.7)	3.2 (1.1)
Herbal medicines are entirely safe since they are natural.	18 (4.9)	30 (8.1)	92 (24.9)	65 (17.6)	165 (44.6)	2.9 (1.2)
It is okay for persons on HAART to take herbal medicine.	5 (1.4)	10 (2.7)	67 (18.2)	81 (22)	206 (55.8)	3.3 (0.9)
Herbal medicine can cure all diseases affecting mankind.	5 (1.4)	8 (2.2)	114 (31)	72 (19.6)	169 (45.9)	3.1 (1)
All the information in the media about herbal medicine is true	2 (0.5)	6 (1.6)	132 (36)	80 (21.8)	147 (40.1)	3 (0.9)
Use of HAART and herbal medicine concurrently could lead to occurrence of adverse drug reactions.	240 (65)	34 (9.2)	66 (17.9)	6 (1.6)	23 (6.2)	0.8 (1.3)
It is not important to disclose herbal medicine use to the doctor?	158 (42.8)	1 (0.3)	48 (13)	20 (5.4)	142 (38.5)	2 (1.8)

The study established that 92.5% of the participants would not advise a person living with HIV/AIDS to take herbal medicine while 7.5% would. The reasons as to why participants would advise a person living with HIV to take herbal medicine is because the herbal medicine is cheap, has less side effects, herbal medicine boosts immunity, it treats opportunistic infections, herbal medicine is like food, it cures other diseases and also because herbal medicine has been in use for many years to treat various ailments.

4.12.1 Reasons for preferring herbal medicine

The reasons for preferring herbal medicine among patients who had reported to have ever used herbal medicine is that it is easily accessible (97.79%), more acceptable (97.26%) and also because herbal medicine is cheap (92.86%). Other reasons for preferring herbal drugs included need for faster healing, peer pressure, coercion by care givers, and desperation from the burden HAART drugs.

After herbal medicine use, 44.2% of HIV positive patients on HAART felt that their health improved. The study established that 16.1% of HIV positive patients who used HAART and herbal medicine concurrently had ever stopped taking HAART to take herbal medicine. In case one got sick, 96.3% of the HIV positive patients who used herbal drugs and HAART concurrently would consider modern medicine as the first choice for treatment while 3.7% would consider traditional medicine as the first choice for treatment

4.13 The practices of HIV positive patients taking HAART

4.13.1 Duration and types of herbal medicines used by HIV positive patients on HAART

HIV positive patients on HAART used herbal drugs for periods ranging from one day to 156 days while others used herbal drugs on and off. The types of herbal medicine used by HIV positive patients on HAART included Loliondo 20 (35.7%), aloevera 12 (21.4%), marijuana 9 (16%) while 15 (26.8%) users did not know the names of herbal medicines they used. (Figure 4.3)

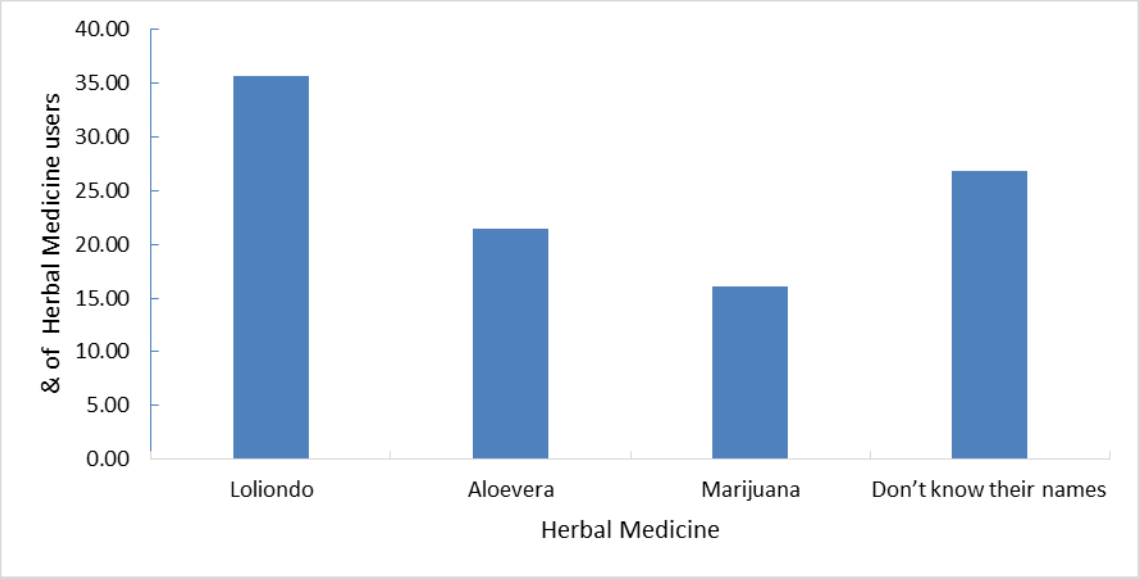

Figure 4.3: Types of herbal medicines used by HIV positive patients on HAART

4.13.2 Routes of administration of herbal products used by HIV positive patients on HAART

The routes of administration of herbal products by HIV positive patients on HAART were oral 100%, topical 7%, inhalation at 7%, rectal 2% and vaginal 0%. (Figure 4.4).

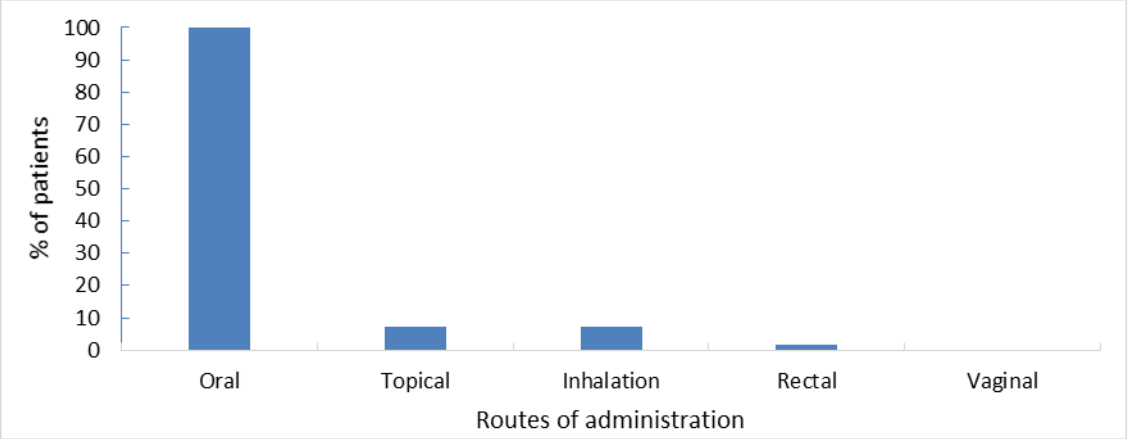

Figure 4.4: Routes of administration of herbal products used by HIV positive patients on HAART

4.13.3 Sources of education programs on herbal medicine for HIV treatment

About 69.8% of the study participants had ever heard of an education program on herbal medicine for HIV treatment. The sources of education programs on herbal medicine for HIV treatment were TV (79%), radio (72.4%), newspaper (35.7%), magazine (25.5%), books (23.8%), internet (38%), market place (87.8%), religious gathering (20.3%). (Figure 4.5).

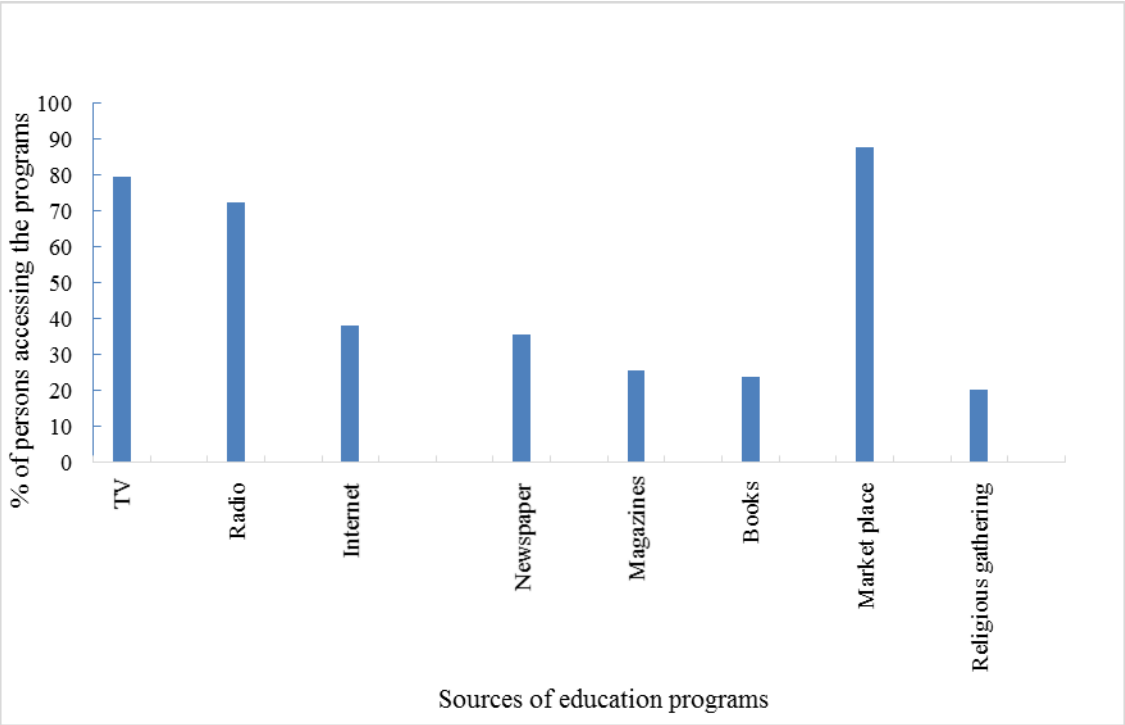

Figure 4.5: Sources of education programs on herbal medicine for HIV treatment

4.13.4 Money spent per month on herbal medicine by HIV positive patients on HAART

The study established that 45% of the participants who use herbal medicine spent less than Ksh1,000/= per month on herbal medicines while 15% spent over Ksh5,000 per month on herbal medicine. (Figure 4.6).

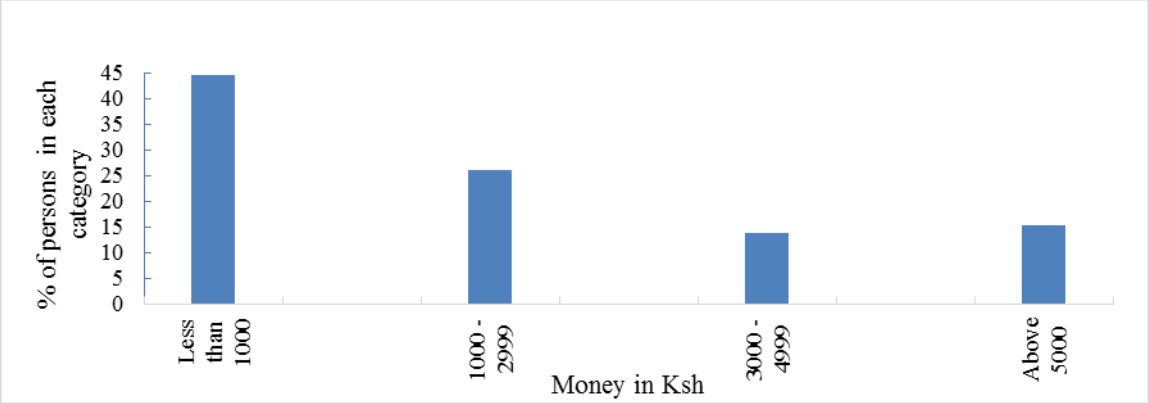

Figure 4.6: Money spent per month on herbal medicine

4.13.5 Introduction to herbal medicine

About 10.7% (6) of the HIV positive patients on HAART who used herbal medicine initiated themselves into herbal medicine use, 7.1% (4) were initiated by healthcare professionals, 25% (14) by herbalists, 35.7% (20) by a family member, 51.8% (29) by friends while 10.7% (6) were initiated into herbal medicine use by other patients. (Figure 4.7)

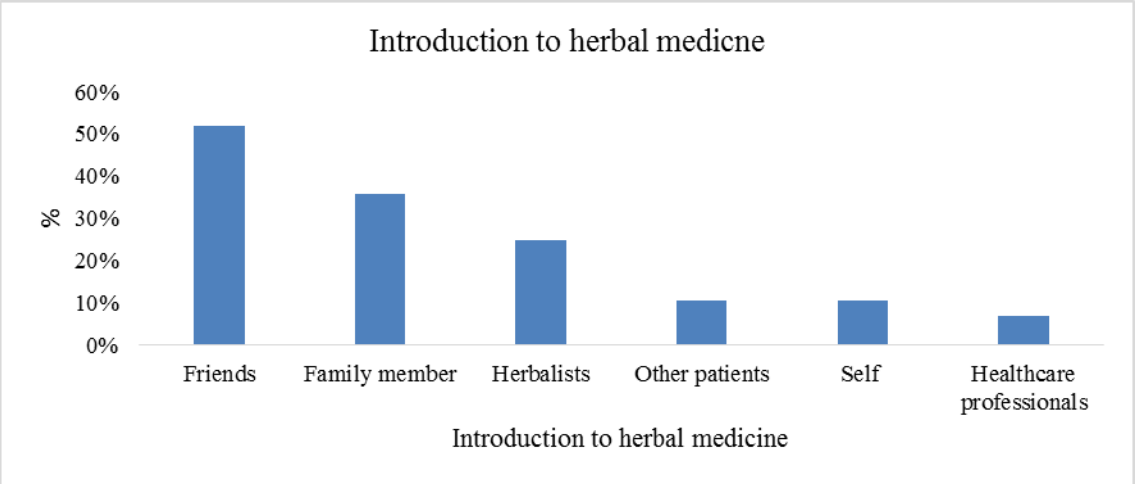

Figure 4.7: Introduction to herbal medicine

4.13.6 Sources of herbal medicine

The sources of herbal medicine were the herbalist (92.59%), garden (87.1%), friends (80.77%), and pharmacy (50.00%). (Figure 4.8).

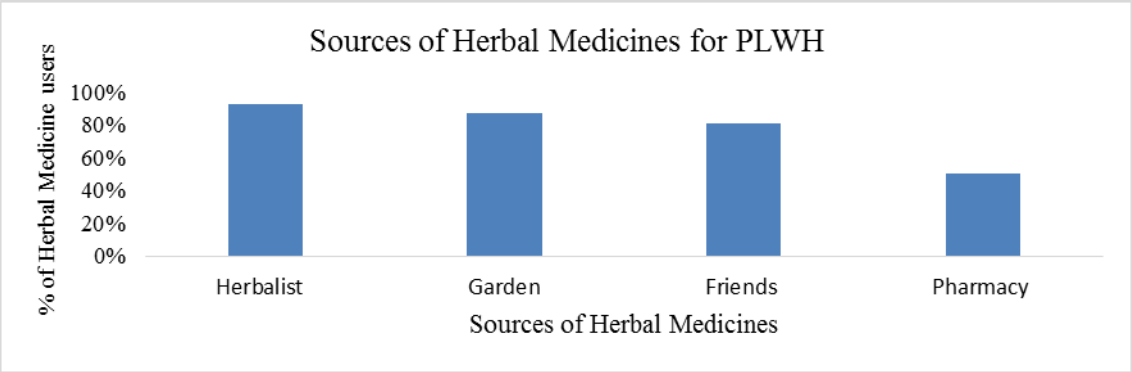

Figure 4.8: Sources of Herbal Medicines

4.13.7 Disclosure of herbal medicine use

With regard to disclosure of herbal medicine use to health care workers, 67.3% of the participants who used herbal medicine concurrently with HAART had never disclosed their herbal medicine use to any clinician at the comprehensive care Centre. The reasons for non-disclosure included the fear of being treated harshly by healthcare workers, the patient never considered it important to disclose, the healthcare workers never inquired while some started using herbs before HAART start hence continued. The motivation for those who disclosed herbal medicine use to healthcare workers included deterioration of the patient health, high viral load results, healthcare worker discussing herbal medicine use with the patients while others disclosed as they sought more information on herbal medicine use. (Figure 4.9)

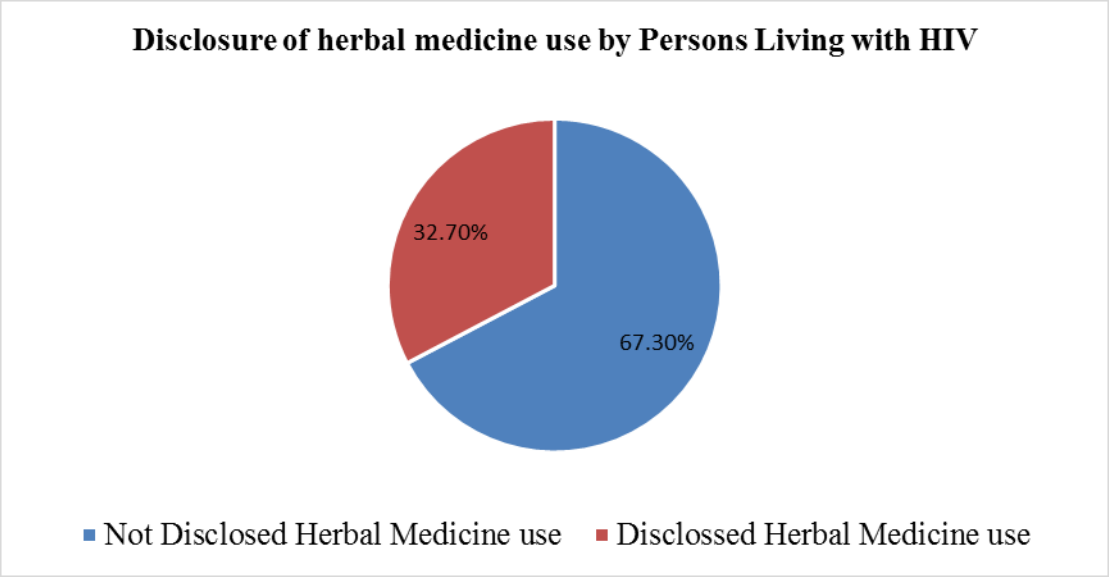

Figure 4.9: Disclosure of Herbal Medicine use

CHAPTER FIVE

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussion

5.1.1 Prevalence of herbal medicine use among HIV positive patients on HAART

The study established that 15.5% of the study participants used herbal medicine together with HAART. These finding concur to those of Babb *et al* (2007) that in Africa many HIV patients use traditional herbal medicine for primary health care or management of side effects. The prevalence of herbal medicine use among HIV positive patients on antiretroviral therapy in this study was lower than in Uganda (33.7%) as reported by Namuddu *et al* (2011). A study by Bepe *et al* (2010) established that 54% of the patients were taking antiretroviral drugs together with one or more traditional herbal remedies. The lower prevalence observed in this study could be attributed to patient education by health care providers that discourage HIV positive patients from taking herbal remedies while on HAART hence the patients may not have revealed the real extent of herbal medicine use as noted by Peltzer *et al (*2008).

This study established that herbal medicine use declined from 46.2% before being diagnosed HIV positive to15.5% after patients were started on HAART. These findings are consistent with those of Klassen *et al* (2007) who reported that the use of herbal medicines declined from approximately 90% prior to HIV diagnosis to 53% in patients with HIV-related symptoms on ARVs. Peltzer *et al* (2010) also observed in a cohort of South African HIV Positive patients, that herbal medicine use for HIV treatment prior to initiation of antiretroviral drugs declined from 36.6% prior to antiretroviral initiation to 8.0% after being on antiretroviral drugs for 6 months. This decline observed in the current study could be attributed to patient education by healthcare providers not to use herbal medicine. Some patients might also have been reluctant to disclose their herbal medicine use hence the decrease in prevalence.

5.1.2 Socio-demographic, economic factors and herbal medicine use among HIV positive patients taking HAART.

In this study, a higher proportion of HIV positive women on highly active antiretroviral therapy used herbal medicine though this was not statistically significant. A study by Gore-Felton *et al* (2003) established that women were four times more likely to use alternative therapies than men. Furler *et al* (2003) observed that Complementary and alternative medicine use in Canadian patients with HIV was extremely common, with higher use among women. The study findings are also consistent with the findings of Agnoletto *et al* (2006) that showed CAM use was more common among females than males with an odds ratio of 1.6; 95% confidence interval. The lower prevalence of herbal medicine use observed in males in this study could be attributed to the traditional beliefs in masculinity that men should be strong, self-reliant and not openly show emotions. These traditional beliefs in the society could have hindered men from discussing their health issues with herbalists or openly seeking alternative forms of treatment for their health challenges.

The study established that the prevalence of herbal medicine use among HIV positive patients on HAART who had attained tertiary education (17.4%) was higher than for those who had attained secondary school education (15.5%) and those who had primary school education (12.8%), but this was not statistically significant ($P>0.05$). These results compare well with what was reported by Bica *et al* (2003) that users of ingested complementary therapies were more likely to be at least high school educated. The reasons for this observation could be attributed to the fact that there is no current cure for HIV so patients might seek alternative remedies and look at herbal medicine as an expected hope to get cure for the disease. The observation could also be due to better access by the more educated to internet and other electronic media platforms where information on herbal products is available.

In this study, there was no statistically significant association between employment status and herbal medicine use ($P>0.05$). This is unlike what was observed by Otang *et*

al (2011) who reported that the proportion of unemployed HIV/AIDS patients who used herbs for symptom management was significantly higher than that of the employed. The reasons for the differing outcomes between the studies could be attributed to the difference in the study settings and characteristics of the patients between the two studies. The lack of statistically significant association between herbal medicine use and employment status in this study could be attributed to easy availability and accessibility of herbal drugs by both employed, unemployed and those in private business. Similarly, the cost of obtaining herbal medicines used by HIV positive patients could be within the affordability of patients in either employment status.

5.1.3 Patient characteristics and herbal medicine use

The study established that herbal medicine use led to decreased adherence to HAART (P-value <0.01). These findings are consistent with the findings of Peltzer *et al* (2010) that the use of herbal treatments was associated with ARV non-adherence. The findings of this study are also consistent with those of Namuddu *et al* (2011) who observed that Participants with HAART adherence levels > 95% were less likely to use traditional herbal medicine.

The findings of the present study could be due to patient education not to use herbal drugs with HAART hence the patient might skip HAART when they intend to take herbal medicines. The multiplicity and adverse effects of antiretroviral drugs could have made patients opt for herbal medicines hence decrease in adherence.

5.1.4 The association between herbal medicine use and occurrence of adverse drug reactions among HIV positive patients taking HAART.

This study established that patients who used herbal medicine with HAART were more likely to experience adverse drug reactions, p-value < 0.01. Bepe *et al* (2010) observed that abdominal pain (odds ratio = 3.0, p-value < 0.01) and rash (odds ratio = 2.5, p-value

< 0.02) are the adverse events significantly associated with herbal drug use during antiretroviral therapy. The findings of this study are unlike what was observed by Mudzviti *et al* (2012) who reported that Patients who used the indigenous herbs Musakavakadzi and Peltoforum africanum were less likely to develop adverse drug reactions compared to patients who did not use the herbs.

This observation could be attributed to the difference in the type of herbs found in different parts of the African continent. The genetic predisposition of patients across the continent could also have caused the difference in susceptibility to adverse drug reactions.

5.1.5 Factors associated with occurrence of adverse drug reactions among HIV positive patients on HAART.

This study established that patients with poor adherence had statistically significant higher odds of side effects compared to those with good or fair adherence, $p<0.05$. These findings compare well with those of Rajesh *et al* (2012) who observed the occurrence of ADRs due to antiretroviral therapy was significantly associated and significantly predicted with the percentage of adherence being less than 80% ($P < 0.001$).

This observation could be attributed to the fact that antiretroviral drugs have the potential to cause adverse drug reactions that can be severe enough to make some patients stop taking them as prescribed hence poor adherence. Patients who use herbal forms of treatment are also likely to have poor adherence and experience adverse drug reactions due to drug interaction between herbal medicines and antiretroviral drugs

5.1.6 Side effects experienced by HIV positive patients on HAART

In this study 62% of the patients experienced side effects since they started using ARVs. These findings compare well with the findings of Tadesse *et al* (2014) that 89.8% of the study participants experienced at least one adverse drug reaction. A study by Masenyetse *et al* (2015) established that 37% of the patients on Highly Active Antiretroviral Therapy experienced adverse drug reactions. The findings of this study correspond with those of

Mudzviti *et al* (2012) who observed that 70.4% of the patients experienced at least one ADR during ART treatment.

This observation is attributed to the various changes that antiretroviral drugs cause in the body hence adverse drug reactions.

5.1.7 Types of herbal medicine used by HIV positive patients on HAART

The types of herbal medicine used by HIV positive patients on HAART included Loliondo 20 (35.7%), aloe Vera 12 (21.4%), marijuana 9 (16%) while 15 (26.8%) users did not know the names of herbal medicines they used. A study by Hasan *et al*., (2010) reported that among the types of Complementary and alternative medicine used by Malaysian patients with HIV/AIDS, 33.8% of the patients used herbal products. The study findings are consistent with those of Klassen *et al* (2007) who reported that some patients didn't know the specific names of the traditional herbal medicines they used.

The choice of herbal medicine could be attributed to availability, geographical accessibility and traditional believes. Patients could have failed to know the type of herbal products they use since the herbal products are not tested, for some, contents undisclosed and their use not monitored due to weak regulatory framework. Herbal medicines going by the same name could actually be different product formulations based on the source hence confusing patients as observed by Maina *et al* (2013).

5.1.8 Sources of education programs on herbal medicine for HIV treatment

The study established that the sources of education programs on herbal medicine for HIV treatment were TV (79%), radio (72.4%), newspaper (35.7%), magazine (25.5%), books (23.8%), internet (38%), market place (87.8%), religious gathering (20.3%). These findings are consistent with those of Hasan *et al*., (2010) where patients reported using complementary and alternative medicine upon the influence of family members and some of them were also seeking information from the mass media after being infected with HIV/AIDS. These observations could be attributed to increased access to mass media i.e. television, radio, mobile phones and newspapers. Kenya has over 12

million persons with access to a television and over 26 million persons with access to a radio (KNBS, 2009). The information on mass media on herbal medicines is also not regulated and though may increase consumer awareness, it could have given herbal medicines undue credibility.

5.1.9 Reasons for preferring herbal medicine

The study established reasons for preferring herbal medicine is that it is easily accessible (97.79%), more acceptable (97.26%) and also because herbal medicine is cheap (92.86%). These findings are consistent with the findings of Lambert *et al* (2011) that in Kenya, patients would opt for traditional herbal medicine because the traditional herbal medicine practitioners are more accessible than the trained doctors but also a large number of the rural poor, in particular, turn to traditional medical practitioners for certain conditions, when access to allopathic health workers is restricted. Klassen *et al* (2007) observed that the reasons for use of traditional herbal medicine were availability/abundance of THM, treatment effectiveness of THM, proximity of the herbs to the patient, familiarity with THM and affordability. In Africa, herbal medicine has been in use for many years before the introduction of conventional medicine into the continent (Romero-Daza, 2002). The long period of herbal medicine use in the continent could have contributed to the observed access and acceptability.

5.1.10 Sources of herbal medicine

The study established that the largest source of herbal medicine for the patients was from herbalist (92.6%) and the smallest source was from the pharmacy (50%). These findings are in line with the findings of Namuddu *et al* (2011) that reported herbs were obtained from registered herbalist and very few were obtained from pharmacies. This observation could be attributed to herbalists consulting with the patients, diagnosing and dispensing herbal drugs within a single contact with the patient unlike in conventional medicine where doctors consult, prescribe and send patients to pharmacies for drugs. Pharmacists also might have limited knowledge on herbal remedies (Abu Taha et al., 2013) hence may not effectively dispense or trade in herbal medicines.

This study established that 44.2% of the patients who used herbal medicine felt that their health improved. These findings are consistent with the finding of Hasan et al (2010) who observed that in Malaysia, 40% of HIV positive CAM users felt that CAM improved their health status and none of them felt that their health had deteriorated due to CAM use. The study findings are consistent with those of Otang *et al* (2011) who reported that 32.5% patients disclosed that herbal medicine had a significant and great contribution towards the management of their signs/symptoms of opportunistic fungal infections.

This observation could be attributed to patients feeling that herbal remedies are natural and harmless. Also since there is no cure for HIV, patients look at herbal remedies as an expected hope for cure and subsequent use could have created a sense of improvement.

The study established that 16.1% of HIV positive patients on HAART who used herbal medicine had ever stopped taking HAART to take herbal medicine. This is more than what was reported by Fairfield et al (1998) who reported that 1.7% of the patients decided to take CAM only and not HAART for management of HIV infection. Despite HAART being free in the country, patients could have opted to stop HAART and use herbal medicines due to frustrations from long-term use of HAART and lack of immediate relief. Some patients could also have stopped HAART to experiment herbal remedies.

This study established that 67.3% of the patients who used herbal medicine had never disclosed to the doctor or any health care worker at the CCC about their herbal medicine use. These findings are consistent with those of Peltzer *et al* (2008) who reported that HIV infected people don't like disclosing to the health care professionals about their CAM use. A study by Hasan *et al* (2010) reported that despite the side-effects experienced by the study participants, about 68% and 84% of them did not disclose their complementary and alternative medicine use to doctors and pharmacists, respectively. Underlying reasons for nondisclosure were unnecessary to disclose, and that health care professionals never asked regarding complementary and alternative medicine use.

Patients might have been reluctant to disclose their herbal medicine use to healthcare workers at the CCC due to fear of discrimination since healthcare workers discourage HIV positive patients from using herbal medicines as noted by Peltzer *et al (*2008).

5.2 Conclusions

1. Among people living with HIV using Highly Active Antiretroviral Therapy, 15.5% also use herbal medicines.
2. Herbal medicine use reduces adherence to HAART whereas 16.1% of HIV positive patients on HAART who also use herbal medicine actually stop taking HAART to take herbal medicine.
3. With regard to disclosure, 67.3% of HIV positive patients who use both HAART and herbal medicines do not disclose their herbal medicine use to the health care workers at the CCC clinic.
4. The main reasons why patients opt for herbal medicine is because herbal medicine is easily accessible, more acceptable and cheap.
5. Use of herbal drugs together with HAART increases chances of patients experiencing adverse drug reactions
6. The null hypotheses are hereby rejected.

5.3 Recommendations

1. People living with HIV using HAART also use herbal medicines and therefore further investigations ought to be done to establish the safety, efficacy and drug interactions between herbal drugs commonly used by HIV positive patients and antiretroviral agents used for HIV/AIDS treatment

2. Herbal medicine use reduces adherence to HAART and therefore adherence being the greatest patient-enabled predictor of treatment success should be reinforced at every clinic visit.

3. HIV positive patients who use both HAART and herbal medicines do not disclose their herbal medicine use to the health care workers at the CCC clinic

and therefore the healthcare workers should routinely screen patients for herbal medicine use at every clinic visit.

4. Concomitant use of herbal drugs with HAART has the potential to cause ADRs and therefore patients should be screened thoroughly for ADRs to ensure early identification and management.

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APPENDICES

Appendix I: Consent form

Research topic: Prevalence and factors associated with herbal medicine use among HIV positive patients on HAART in selected hospitals in Nairobi County

Principal investigator: Aaron Murithi Mungiria

Institutional affiliation: Msc Public Health Student at Jomo Kenyatta University of Agriculture and Technology.

Introduction

Greetings. My name is…….. I am conducting a research in partial fulfillment for the award of a Master of Science degree in public health of Jomo Kenyatta University of agriculture and technology. The research is about the proportion of HIV positive patients on Highly Active Antiretroviral Therapy (HAART) that use herbal medicine and the circumstances, facts and influence that contribute to the use of herbal medicine by HIV positive patients on HAART in selected hospitals in Nairobi County. There are many studies done on herbal medicine use for various human and animal ailments but only scanty information is available on the proportion of HIV positive patients on Highly Active Antiretroviral Therapy (HAART) that use herbal medicine and the circumstances, facts and influence that contribute to the use of herbal medicine by HIV positive patients on HAART. The study will be conducted in both Mbagathi County Hospital and KNH and 370 participants aged 18 years and above, Nairobi residents, HIV positive and taking HAART will take part in the study.

Purpose of the study

The study aims at establishing proportion of HIV positive patients on Highly Active Antiretroviral Therapy (HAART) that use herbal medicine and the circumstances, facts and influence that contribute to the use of herbal medicine by HIV positive patients on HAART.

Study procedures

The interviewer will ask you a set of questions as contained in the questionnaire. You will be interviewed only once in the course of the study.

Risks of study participants

The study poses no physical risks to you. Some study questions may be private to you, but you reserve the right not to answer any questions you may find uncomfortable.

Research benefits

You will not receive any direct personal benefits for participating in the study, but however the results of this study will provide background information useful for coming up with policies and strategies that can be incorporated to efficiently and effectively respond to use of herbal medicine among patients receiving HAART. This will go a long way to ensure better health for people living with HIV and taking HAART.

Study costs

Apart from the time spent, there are no monetary costs that you will incur and therefore there will be no monetary compensation.

Privacy and Confidentiality

Privacy will be guaranteed when getting information from you. Your information will be treated confidentially. Your names shall not appear on the interview questionnaire and instead codes will be used. Also your names shall not be used in any reports resulting from the study

Contacts

In case of any questions or clarifications, you can use the following contacts.

Principal investigator: Aaron Murithi Mungiria 0721683982

Supervisor: Mr. Lawrence Muthami 0721235136

KEMRI Ethics Review Committee P.O BOX 54840-00200 NAIROBI, Telephone 0202722542, 0722205901, 0733400003, Email address ERCAdmin@kemri.org

I …… do agree to take part in this study as explained to me above. I have fully understood what the study entails and my role as a participant. I also understand that I can withdraw from the study any time in case I feel uncomfortable to continue.

Participants' Signature ……...Date ……..

(Figure print  not able to sign)

Name of independent witness……..……Signature…….date……

Name of interviewer……..……Signature…….date……

Appendix II: Questionnaire

Research topic: "Prevalence and factors associated with herbal medicine use among HIV positive patients on highly active antiretroviral therapy in selected hospitals in Nairobi County". Questionnaire number……..

Date administered …….

Hospital……..……....

Interviewer's names ……..

Tick (✓) in the appropriate box, unless otherwise indicated

Section A: Bio data

1. Gender of respondent 1. Male [ ] 2.Female [ ]
2. Date of Birth …….
3. Current Marital status
   1. Single ☐
   2. Married ☐
   3. Divorced ☐
   4. Separated ☐
   5. Others

      (specify)……..
4. Religion
   1. Islam ☐
   2. Christian ☐
   3. Hindu ☐

4. Others

(specify)……

Section B: Socio economic factors

5. The highest level of education achieved

0. No education ☐
1. Primary school ☐
2. Secondary school ☐
3. Tertiary ☐

6. What is your employment status?

1. Unemployed [ ] 2. Employed [ ] 3. Private business [ ]

7. What is your occupation?……

8. What is your household income per month? Ksh ……..……

9. What type of fuel does your household use for cooking?

i. Electricity 1. YES ☐ 0. NO ☐
ii. Gas 1. YES ☐ 0. NO ☐
iii. Kerosene 1. YES ☐ 0. NO ☐
iv. Charcoal 1. YES ☐ 0. NO ☐
v. Firewood 1. YES ☐ 0. NO ☐
vi. Others (specify)……

10. What is the main roofing material of the house you live in? Tick as appropriate.

1. No roof ☐
2. Thatch ☐

3. Iron sheet (mabati) ☐

4. Tiles ☐

5. Others

(specify)……

11. What is the main material of the exterior walls of the house you live in? Tick as appropriate.

0. No walls ☐

1. Dung/mud with stone ☐

2. Iron sheets ☐

3. Wood ☐

4. Stone with cement ☐

5. Others (specify)……

12. Which of these do you have in the house?

i. Radio: 1. Yes [ ] 0. No [ ]

ii. TV : 1. Yes [ ] 0. No [ ]

Section C: HAART & herbal medicine use

13. Which year were you diagnosed HIV positive?.....

14. What date were you started on ARVs? ……

15. Do you know any benefits of taking ARVS?

1. Yes ☐

0. No ☐

16. If yes, name any two

i. ……

……

ii. ……

……

	QUESTION	1. YES	0. NO
17.	Do you sometimes forget to take your ARV pills?		
18.	Over the past 2 weeks, were there any days when you did not take your ARV medicine?		
19.	Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?		
20.	When you travel or leave home, do you sometimes forget to bring along your medications?		
21.	Did you take your ARV medicine yesterday?		
22.	When you feel like your health is under control, do you sometimes stop taking your medicine?		
23.	Do you ever feel hassled about sticking to your ARV treatment plan?		

24. How often do you have difficulty remembering to take all your ARV medication?

A. Never/rarely ☐

B. Once in a while ☐

C. Sometimes ☐

D. Usually ☐

E. All times ☐

25. Have you experienced any side effects since you started using ARVS?

1. Yes ☐

0. No ☐

26. If yes, what were the side effects?

i. …….

ii. ……... ……..…

27. How did you manage the side effects? Tick as appropriate.

i. By using herbal medicine 1. YES ☐ 0. NO ☐

ii. Through self-medication 1. YES ☐ 0. NO ☐

iii. By informing the doctor at the CCC clinic 1. YES ☐ 0. NO ☐

iv. Others (specify)……..

28. Do you know of any herbal medicine used in treatment of HIV?

1. Yes ☐

0. No ☐

29. If yes, name any two

i. …….

ii. ……..

30. How did you learn about them?

i. Self 1. YES ☐ 0. NO ☐

ii. Friend 1. YES ☐ 0. NO ☐

iii. Relative 1. YES ☐ 0. NO ☐

iv. Media 1. YES ☐ 0. NO ☐

v. Others (specify)…….

31. Would you advise a person living with HIV/AIDS to take herbal medicine?

1. Yes ☐

0. No ☐

32. If yes, give two reasons

i. ……

ii. ……

33. Have you heard of any education program on herbal medicine for HIV treatment?

1. Yes ☐

0. No ☐

34. If yes, where?

i. TV 1. YES ☐ 0. NO ☐

ii. Radio 1. YES ☐ 0. NO ☐

iii. Newspaper 1. YES ☐ 0. NO ☐

iv. Magazines 1. YES ☐ 0. NO ☐

v. Books 1. YES ☐ 0. NO ☐

vi. Internet 1. YES ☐ 0. NO ☐

vii. Market place 1. YES ☐ 0. NO ☐

viii. Religious gathering 1. YES ☐ 0. NO ☐

ix. Others (specify)……

35. Before you were diagnosed HIV positive, were you using herbal medicine for treatment of ailments?

1. Yes ☐

0. No ☐

36. Did you take any herbal medicine between the time you were diagnosed HIV positive and the time you were started on HAART?

1. Yes ☐
0. No ☐

37. Have you ever taken any herbal medicine since you started taking HAART?

1. Yes ☐
0. No ☐

38. If yes, what was the name of the herbal medicine

A. . ……
B. …….
C. ……....

39. What was the rout of administration?

i. Oral 1. YES ☐ 0. NO ☐
ii. Topical 1. YES ☐ 0. NO ☐
iii. Inhalation 1. YES ☐ 0. NO ☐
iv. Rectal 1. YES ☐ 0. NO ☐
v. Vaginal 1. YES ☐ 0. NO ☐
vi. Others (specify)…….

40. For how long did you take the herbal medication……

41. Who introduced you to the medicine

i. Yourself 1. YES ☐ 0. NO ☐

ii. Health care professional l. YES 0. NO

iii. Traditional herbalist 1. YES 0. NO

iv. Family member 1. YES 0. NO

v. Friends 1. YES 0. NO

vi. Other HIV patients 1. YES 0. NO

vii. Others (specify)……

42. What made you prefer Herbal medicine to modern medicine?

i. Cheap 1. Yes [ ] 0. No [ ]

ii. Easily accessible 1. Yes [ ] 0. No [ ]

iii. More Acceptable 1. Yes [ ] 0. No [ ]

iv. Other reasons (Specify)…… …….

43. Where do/did you get your herbal medicines from?

i. Herbalist 1. YES ☐ 0. NO ☐

ii. Garden 1. YES ☐ 0. NO ☐

iii. Friends/relatives 1. YES ☐ 0. NO ☐

iv. Pharmacy 1. YES ☐ 0. NO ☐

v. Others (specify) ……

44. On average how much did/do you spend on herbal medicine per month?.....

45. What were your reasons for taking herbal medication?

i. …….

ii. ……..

46. Have you ever disclosed to the doctor or any health care worker at the CCC clinic about your herbal medicine use?

1. Yes ☐
0. No ☐

47. If no, what hindered you from disclosing?

i. ……

ii. ……...

48. If yes, what motivated you to disclose?

i. ……

49. ……

50. After taking herbal medicine, do/ did you feel that your health improved?

1. Yes ☐
0. No ☐

51. Have you ever stopped taking ARVs so that you can take herbal medicine?

1. Yes ☐
1. No ☐

52. In case you got sick, what would you consider as the first choice for treatment?

1. Traditional herbal medicine ☐
2. Modern medicine ☐

Section D: Perception of Herbal medicine among HIV positive patients on HAART

	Question	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
53.	Herbal medicine is more effective in treatment of illnesses as compared to conventional medicines					
54.	Herbal medicines are entirely safe since they are natural.					
55.	It is okay for persons on HAART to take herbal medicine.					
56.	Herbal medicine can cure all diseases affecting mankind.					
57.	All the information in the media about herbal medicine is true					
58.	Use of HAART and herbal medicine concurrently could lead to occurrence of adverse drug reactions.					
59.	It is not important to disclose herbal medicine use to the doctor?					

Appendix III: Swahili version of the consent form.
Kibali cha utafiti

Mada ya utafiti : kiwango cha utumiaji na mambo yanayohusishwa na matumizi ya dawa za kiasili kwa wahadhiriwa wa ugongwa wa ukimwi wanaotumia HAART katika hospitali teule katika kaunti/jimbo la Nairobi.

Mtafiti mkuu: Aaron Murithi Mungiria

Mwanafunzi katika chuo kikuu cha Jomo Kenyatta cha kilimo na teknolojia

Utangulizi

Salamu. Majina zangu ni ……. Nina fanya utafiti ili kutimiza mahitaji yanayotarajiwa kwa ajili ya kutuzwa shahada ya sayansi katika afya ya umma ya chuo kikuu cha Jomo Kenyatta. Mada ya utafiti ni "kiwango cha utumiaji na mambo yanayohusishwa na matumizi ya dawa za kiasili kwa wahadhiriwa wa ugongwa wa ukimwi wanaotumia dawa za kupunguza makali ya virusi vya ukimwi mwilini (HAART) katika hospitali teule katika kaunti/jimbo yaNairobi". Utafiti pana umefanywa kuhusu matumizi ya dawa za kiasili kwa magonjwa tofauti kwa binadamu na wanyama lakini kuna habari haba zinazopatika na zinazoeleza kiwango cha utumiaji na mambo yanayohusishwa na matumizi ya dawa Za kiasili kwa wahadhiriwa wa ugongwa wa ukimwi wanaotumia HAART. Utafiti utafanywa katika hospitali ya wilaya ya Mbangathi na hospitali kuu ya Kenyatta. Washiriki watakuwa 370 waliona umri wa miaka 18 na zaidi ambao niwakaazi wa Nairobi na ni wahadhiriwa wa ugonjwa wa ukimwi wanaotumia HAART.

Kusudi la utafiti

Kusudi la utafiti ni kuchunguza uenezaji na mambo yanayohusishwa na matumizi ya dawa za kiasili kwa wahadhiriwa wa ugongwa wa ukimwi wanaotumia HAART.

Hatua za utafiti

Mtafiti atakuuliza seti ya maswali kama yalivyo kwenye dodoso ili kukusanya habari. Utahojiwa mara moja tu katika utafiti huu.

Hadhari kwa washiriki

Utafiti hauna hadhari zozote za kimwili kwa washiriki. Baadhi ya maswali ya utafiti yanaweza kuwa ya kibinafsi lakini washiriki wana uhuru wa kutojibu baadhi ya maswali ambayo watapata ugumu kujibu.

Manufaa ya utafiti

Hautapokea fidia yoyote ya kibinafsi kwa kushiriki katika utafiti huu lakini hata hivyo matokeo ya utafiti huu yatatoa habari muhimu zitakazo saidia kubuni sera na mikakati inayoweza kutumiwa katika kukabiliana na matumizi ya dawa za mitishamba kati ya wagonja wanaotumia HAART. Hii itahakikisha kuna afya jema kwa wahadhiri wa wa ukimwi wanaotumia HAART.

Gharama ya utafiti

Mbali na wakati utakaotumiwa ,hakuna gharama za kifedha kwa kushiriki katika utafiti huu na kwa hivyo hautapokea fidia ya kifedha kwa kushiriki.

Faragha na usiri

Utahakikishwiwa faragha wakati wanapotoa habari. Habari utakazo toa zitashughulikiwa kwa siri. Majina yako hayata tumika katika dodoso au ripoti ya utafiti na badala yake nambali za siri zitatumika.

Njia ya mawasiliano

Iwapo kuna swala ama jambo linalo hitaji ufafanuzi zaidi unaweza kutumia nambari zifuatazo:

Mtafiti mkuu : Aaron Murithi Mungiria 0721683982

Msimamizi : Mr. Lawrence Muthami 0721235136

KEMRI Ethics Review Committee P.O BOX 54840-00200 NAIROBI, Nambari za simu 0202722542, 0722205901, 0733400003, anwani ya barua pepe ERCAdmin@kemri.org

Mimi ----------nimekubali kushiriki katika utafiti huu kama nilivyoelezwa. Nimeelewa kikamilifu mahitaji na majukumu yangu kama mshiriki. Nimeelewa naweza kujiuzuru iwapo sita ridhishwa na jambo lolote katika utafiti huu.

Sahihi ya mshiriki----------Tarehe----------

(Alama ya kidole cha mshiriki asiyeweza kutia sahihi)

Majina ya shahidi----------Sahihi----------Tarehe---------

Majina ya mtafiti/mhoji----------Sahihi----------Tarehe---------

Appendix IV: Swahili version of the questionnaire.
Dodoso

Mada ya utafiti : "kiwango cha utumiaji na mambo yanayohusishwa na matumizi ya dawa za kiasili kwa wahadhiriwa wa ugongwa wa ukimwi wanaotumia HAART katika hospitali teule katika kaunti/jimbo yaNairobi."

Nambari ya dodoso……..

Tarehe ……..

Hosipitali……..

Majina ya Mhoji …….

Weka alama hii (✓) kwa kijisanduku

Sehemu A: Maelezo ya Kibinafsi

1. Jinsia 1. Mwanaume [ ] 2. Mwanamke [ ]
2. Tarehe ya kuzaliwa……..
3. Hali ya ndoa
    1. Katika ndoa ☐
    2. Bado funga ndoa ☐
    3. Talaka ☐
    4. Tengana ☐
    5. Zinginezo (elezea)……

4. Dini

    1. Muisilamu ☐
    2. Mkiristo ☐
    3. Mhindu ☐
    4. Zinginezo ☐

    (elezea)……

Sehemu B: Hali ya uchumi na kijamii

5. kiwango cha juu cha elimu kuhitimiwa

    0. hakuna masomo ☐
    1. shule ya mzingi ☐
    2. Shule ya sekondari ☐
    3. Elimu ya juu ☐

6. Ni ipi hali yako ya ajira?

    1. Hujaajiriwa [ ] 2. Umeajiriwa [ ] 3. Mfanyabiashara [ ]

7. Unafanya kazi gani?……

8. Mapato ya jumla ya familia kwa mwezi . Ksh……

9. Je, ni gani kati ya hizi familia yako hutumia kwa ajili ya kupikia?

i.	Umeme	1. NDIO	☐	0.	LA	☐
ii.	Gesi	1. NDIO	☐	0.	LA	☐
iii.	Mafuta ya taa	1. NDIO	☐	0.	LA	☐
iv.	Makaa	1. NDIO	☐	0.	LA	☐
v.	Kuni	1. NDIO	☐	0.	LA	☐

vi. Zinginezo (elezea)…… ……..

10. Je, paa ya nyumba unayoishi imetengenezwa na nyenzo gani?

1. Hakuna paa ☐
2. Makuti (nyasi) ☐
3. Mabati ☐
4. Matofali ☐
5. Zinginezo (elezea)…….

11. Ukuta wa nje wa nyumba unayoishi umetengenezwa na nyenzo gani?

0. Hakuna ukuta ☐
1. Matope na mawe ☐
2. Mabati ☐
3. Mbao ☐
4. Mawe na seruji ☐
5. Zinginezo (elezea)……

12. Ni gani kati ya hizi unayo nyumbani?

i. Radio: 1. Ndiyo [ ] 0. La [ ]

ii. Televisheni: 1. Ndiyo [ ] 0. La [ ]

Sehemu C: Utumiaji wa dawa za HAART na miti shamba

13. Ni mwaka gani uliopimwa na kupatikana na virusi vya ukimwi?.....

14. Ni tarehe gani ulioanza kutumia madawa ya ARV?.....

15. Je, wajua manufaa yoyote ya kutumia madawa ya kurefusha maisha (ARVs)?

1. Ndiyo [ ]
0. La [ ]

16. Kama ndiyo, yataje manufaa mawili.

i. ……

ii. ……

	Swali	1. NDIO	0. LA
.	kuna wakati unasahau kutumia dawa za ARV?		
.	Kwa majuma mawili yaliyopita,kunazo siku haukutumia dawa za ARV?		
.	Kunao wakati uliacha kutumia dawa hizo bila idhini ya daktari kwa sababu zilikudhuru?		
.	Unapo safari ama kutoka nyumbani, Kunao wakati unasahau kubeba dawa zako?		
.	Je, jana ulitumia dawa zako za ARV?		
.	unapojihisi vyema huwa una acha kutumia dawa?		
.	Je, kuna nyakati unajihisi kutatizika na mpangilio wa matibabu ya ARV?		

24. Ni mara ngapi unashindwa kumbuka kutumia dawa zako za ARV?

0. Hakuna [ ]
1. Mara moja kwa muda mrefu [ ]
2. wakati mwingine [ ]

3. Kwa kawaida ☐

4. kila wakati ☐

25. Je umepata madhara yoyote yanayohusiana na dawa tangu uanze kutumia ARV ?

1. Ndiyo ☐

0. La ☐

26. Kama ndiyo, uliyapata madhara gani?

i. .....

ii. …….

27. Uliyashughulikia aje madhara hayo?

i. Kwa kutumia dawa za mitishamba 1. Ndiyo ☐ 0. La ☐

ii. Kujitibu mwenyewe 1. Ndiyo ☐ 0. La ☐

iii. Kumwelezea daktari wa CCC 1. Ndiyo ☐ 0. La ☐

iv. Njia zinginezo (zitaje)……

28. Je unajua dawa yoyote ya mitishamba inayotumika dhidi ya virusi vya ukimwi?

1. Ndiyo ☐

0. La ☐

29. kama unayajua, yataje madawa mawili

i. …….

ii. ……

30. Uliyajua kwa njia gani?

1. Mwenyewe 1. Ndiyo ☐ 0. La ☐

2. Rafiki 1. Ndiyo ☐ 0. La ☐

3. Familia 1. Ndiyo ☐ 0. La ☐

4. Vyombo vya habari 1. Ndiyo ☐ 0. La ☐

5. zinginezo (elezea) …….....

31. Unaweza kumshauri mtu yeyote anayeishi na virusi vya ukimwi kutumia madawa ya mitishamba?

1. Ndiyo ☐

0. La ☐

32. Kama ndiyo,zitaje sababu mbili

i. ……...

ii. ……...……

33. Ume visikia vipindi vyovyote vinavyo elimisha watu kuhusu kutumia madawa ya mitishamba ili kupambana na virusi vya ukimwi?

1. Ndiyo ☐

0. La ☐

34. Kama ndiyo,wapi?

i. TV 1. NDIO ☐ 0. LA ☐

ii. Radio 1. NDIO ☐ 0. LA ☐

iii. Gazeti 1. NDIO ☐ 0. LA ☐

iv. Magazine 1. NDIO ☐ 0. LA ☐

v. Vitabu 1. NDIO ☐ 0. LA ☐

vi. Internet 1. NDIO ☐ 0. LA ☐

vii. Sokoni 1. NDIO ☐ 0. LA ☐

viii. Mikutano ya kidini 1. NDIO ☐ 0. LA ☐

ix. Kwingineko (elezea)……

35. Kabla ya kupimwa na kupatikana na virusi vya ukimwi, ulikuwa unatumia dawa za mitishamba kutibu maradhi?

1. Ndiyo ☐
0. La ☐

36. Je, umewahi kutumia dawa za mitishamba kati ya wakati uliopimwa na kupatikana na virusi vya ukimwi na wakati ulipoanza kutumia ARV?

1. Ndiyo ☐
0. La ☐

37. Je, umewahi kutumia madawa ya mitishamba tangu uanze kutumia ARVs ?

1. Ndiyo ☐
0. La ☐

38. Kama ndiyo,uliitumia dawa gani?

1. .....……
2. …….
3. ……......

39. Uliitumia kwa njia gani?

i. Mdomo 1. NDIO ☐ 0. LA ☐
ii. Kupaka kwa ngozi 1. NDIO ☐ 0. LA ☐
iii. Kuvuta pumzi 1. NDIO ☐ 0. LA ☐
iv. Njia ya mavi 1. NDIO ☐ 0. LA ☐

v. Ukeni 1. NDIO ☐ 0. LA ☐

vi. Zinginezo (elezea)……

40. Ulizitumia hizo dawa za mitishamba kwa muda gani?……

41. Ni nani alikuanzisha hiyo dawa?

i. Mwenyewe I. NDIO ☐ 0. LA ☐

ii. Mtaalamu wa afya I. NDIO ☐ 0. LA ☐

iii. Daktari wa mitishamba I. NDIO ☐ 0. LA ☐

iv. Familia I. NDIO ☐ 0. LA ☐

v. Marafiki I. NDIO ☐ 0. LA ☐

vi. Wagonjwa wengine wa virusi vya ukimwi I.NDIO ☐ 0.LA ☐

vii. wengineo (elezea)……

42. Nini kilichokufanya kupendelea dawa za mitishamba?

1. Bei rahisi 1. Ndiyo [ ] 0. La [ ]

2. Kupatikana kwa urahisi 1. Ndiyo [ ] 0. La [ ]

3. Kukubalika rahisi 1. Ndiyo [ ] 0. La [ ]

4. Sababu zinginezo (zitaje)……

43. Je, huwa unazipata hizi dawa za mitishamba kutoka wapi?

1. Daktari wa kienyeji 1. Ndiyo ☐ 0. La ☐

2. Kwa shamba 1. Ndiyo ☐ 0. La ☐

3. Marafiki/jamaa 1. Ndiyo ☐ 0. La ☐

4. Duka rasmi la dawa 1. Ndiyo ☐ 0. La ☐

5. Kwingineko (taja)……

44. Kwa mwezi mmoja huwa unatumia pesa ngapi kwa hizi dawa za mitishamba?.....

45. Zitaje sababu mbili zinazokufanya utumie madawa ya mitishamba kulingana na umuhimu

    i. ……

    ii. …….

46. Umewahi kumjulisha daktari au mfanyikazi yeyote wa huduma za afya katika kliniki ya CCC kuhusu utumiaji wako wa dawa za mitishamba?

    1. Ndiyo ☐

    0. La ☐

47. Kama huja mwelezea, ni nini kilichokuzuia kumwelezea?

    i. …….

    ii. ……..

48. Ikiwa umemwelezea, ni nini kilikilichokupa motisha ya kumwelezea?

    i. ……...

    ii. ……...

49. Baada ya kutumia dawa za mitishamba, ulijihisi yakwamba zimeboresha afya yako?

    1. Ndiyo ☐

    0. La ☐

50. Je, umewahi kushimamisha kutumia ARVs iliutumie dawa za mitishamba?

    1. Ndiyo ☐

0. La ☐

51. Ungeugua leo, ni nini ingekuwa chaguo lako la kwanza la matibabu?

1. Dawa za mitishamba ☐
2. Dawa rasmi ☐

Sehemu ya D: Mitazamo juu ya madawa ya mitishamba kati ya wagonjwa waliona virusi vya ukimwi na wanaotumia dawa za ARV.

	Swali	Nakubalia na kabisa	Nakubaliana	Sina msimamo	sikubali ani	sikubalian i kabisa
52.	Dawa za mitishamba zina uwezo zaidi wa kutibu magonjwa ukilinganisha na dawa za kawaida.					
53.	Dawa za mitishamba hazina madhara yoyote kasababu ni za kiasili.					
54.	Ni sawa watu wanaotumia madawa ya ARV kutumia dawa za mitishamba.					
55.	Dawa za mitishamba zinaweza kutibu magonjwa yote yanayompata mwanadamu.					
56.	Taarifa zote katika vyombo vya habari kuhusu dawa za mitishamba ni za kweli.					
57.	Utumiaji wa dawa za mitishamba pamoja na ARV unaweza kusababisha madhara ya kiafya.					
58.	Si jambo la muhimu kumwelezea daktari kuhusu utumiaji wa dawa za mitishamba.					

Appendix V: Morisky Medication Adherence Scale (MMAS-8)

	QUESTION	YES	NO
	Do you sometimes forget to take your ARV pills?	1	0
	Over the past 2 weeks, were there any days when you did not take your ARV medicine?	1	0
	Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?	1	0
	When you travel or leave home, do you sometimes forget to bring along your medications?	1	0
	Did you take your ARV medicine yesterday?	0	1
	When you feel like your health is under control, do you sometimes stop taking your medicine?	1	0
	Do you ever feel hassled about sticking to your ARV treatment plan?	1	0
	How often do you have difficulty remembering to take all your ARV medication? Never/rarely ☐ Once in a while ☐ Sometimes ☐ Usually ☐ All times ☐	Points 0 ¼ ½ ¾ 1	
Total Score (sum of all items)			

Interpretation of MMAS-8 Score

MMAS-8 Score	**Adherence Rating**
0	Good
1-2	Inadequate/fair
3-8	Poor

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KEMRI/RES/7/3/1 **December 8, 2014**

TO: **AARON MURITHI MUNGIRIA,**
PRINCIPAL INVESTIGATOR

THROUGH: **DR. PETER MWITARI,**
THE DIRECTOR, CTMDR,
NAIROBI

Forwarded 15/12/2014

Dear Sir,

RE: SSC PROTOCOL NO. 2780 (*RESUBMISSION2*): PREVALENCE AND FACTORS ASSOCIATED WITH HERBAL MEDICINE USE AMONG HIV POSITIVE PATIENTS ON HIGHLY ACTIVE ANTIRETROVIRAL THERAPY IN SELECTED HOSPITALS IN NAIROBI COUNTY. (*VERSION 4 DATED 2ND DECEMBER 2014*)

Reference is made to your letter dated 2nd December 2014 and received at the KEMRI Scientific and Ethics Review Unit on 3rd December 2014.

This is to inform you that the Committee notes that the issues raised at the 230th meeting of the KEMRI ERC held on 19th August, 2014 have been adequately addressed.

Consequently, the study is granted approval for implementation effective this **8th December 2014** for a period of one year. Please note that authorization to conduct this study will automatically expire on **December 7, 2015.** If you plan to continue data collection or analysis beyond this date, please submit an application for continuation approval to SERU by **October 26, 2015**.

You are required to submit any proposed changes to this study to SERU for review and the changes should not be initiated until written approval from SERU is received. Please note that any unanticipated problems resulting from the implementation of this study should be brought to the attention of SERU and you should advise SERU when the study is completed or discontinued.

You may embark on the study.

Yours faithfully,

EAB

PROF. ELIZABETH BUKUSI,
ACTING SECRETARY,
KEMRI/ETHICS REVIEW COMMITTEE

Appendix VII: KNH/UON Ethical Approval

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/20

27th January 2015

Aaron Murithi Mungiria
Principal investigator
KEMRI

Dear Mr. Mungiria

Research Proposal: Prevalence and Factors associated with herbal Medicine use among HIV Positive patients on Highly Active Antiretroviral Therapy in selected hospitals in Nairobi county (P27/01/2015)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and approved your above proposal. The approval periods are 27th January 2015 to 26th January 2016.

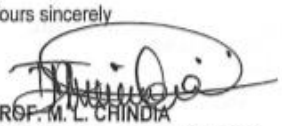
This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect 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.
e) 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*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.erc.uonbi.ac.ke**

Protect to discover

Yours sincerely



PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Assistant Director, Health Information, KNH
The Chairperson, KNH/UON-ERC
Supervisors: Dr. Karanja S.M., Mr. Lawrence N. Muthami, Prof. Mutai Charles