

RUNNING HEAD: Prevalence of HIV Associated Dementia

PREVALENCE OF HIV ASSOCIATED DEMENTIA AMONG HIV/AIDS ADULTS  
ATTENDING COMPREHENSIVE CARE CENTRE-KAPSABET REFERRAL HOSPITAL

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**DECLARATION**

This is to certify that this research proposal is my own work and was submitted to the Kenyatta National Hospital-University of Nairobi Ethics and research committee for review. It was written under the guidance and Supervision of University of Nairobi Lecturers.

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**DEDICATION**

This research is dedicated to my beloved family for their inspiration they gave me throughout my study

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## **LIST OF ABBREVIATIONS AND ACRONYMS**

HIV	Human Immunodeficiency Virus
AIDS	Acquired Immunodeficiency Syndrome
HAND	HIV associated Neurocognitive Disorder
HAD	HIV associated Dementia
CSF	Cerebrospinal Fluid
SD	Standard deviation
ANI	Asymptomatic Neurocognitive Impairment
MND	Mild Neurocognitive Disorder
ICD 10	International Classification of Diseases and Related Health Problems-10 <sup>th</sup> Revision
ADL	Activities of Daily Living
CD4	Cluster of Differentiation 4
ADC	AIDS Dementia Complex
ARV	Antiretroviral
HAART	Highly Active Antiretroviral Therapy
ART	Antiretroviral Therapy
CCC	Comprehensive Care Centre
IHDS	International HIV Dementia scale
CNS	Central Nervous System
WHO	World Health Organization
SPSS	Statistical Package for Social Sciences
LDL	Low detectable levels

## **OPERATIONAL DEFINITION OF TERM**

Adults-Those who are above 18 years

Viral load- Copies of virus per milliliter of blood

CD4 Count- The cells in the body that protect against HIV Infection

Dementia-Chronic or persistent disorder of mental process caused by brain disease or injury and it is characterized by loss of cognitive functioning, which means the loss of the ability to think, remember or reason as well as behavioral abilities.

HIV associated dementia-It is a neurological condition induced by the pre-existence of an HIV infection or AIDS and is associated with direct HIV infection of the central nervous system.

Neurocognitive-Some activities in the nervous system associated with higher brain functioning such as memory, thought process as well as lower brain function such as sensation which can be linked to particular neuronal pathway in the brain.

## **ABSTRACT**

### **Introduction**

HIV associated dementia is the most devastating central nervous system consequence of HIV infection which invades the brain directly. Progression into HIV associated dementia (HAD) has is associated with a number of bio-psychosocial factors. Despite the high prevalence of HIV infection, there are no adequate data on HIV associated dementia both internationally and locally especially in Africa. The aim of this study was to establish the prevalence of HAD, the associated socio-demographic factors, and the association between International HIV Dementia Scale Score and viral load among HIV/AIDS adult patients attending the Kapsabet Comprehensive Care Centre, Nandi County.

### **Methodology**

The study design was descriptive cross-sectional study and the study population was 4,100 HIV positive adults who were drawn from various locations within the county. Sample size was 352 patients who came for their routine clinic appointment. Sampling method used was simple random sampling where the potential participants randomly picked numbers in a container at the triage nurse desk. Those who picked odd numbers from 1 to 31 and met inclusion /exclusion criteria participated in the study. International HIV dementia scale and Socio-demographic questionnaire was used to collect socio-demographic characteristic and HIV related information.

### **Data Analysis**

The data collected was analyzed using SPSS Version 20 and the results were presented in tables, graphs, Charts and narratives.

### **Study results**

The prevalence of HIV associated dementia was 65.6% among HIV patient attending Kapsabet Comprehensive Care Centre, There was no association between viral load and International HIV dementia score with a chi-square of 3.96 and p-value of 0.267

### **Conclusion**

The results indicated that HIV associated dementia is common among HIV patients attending Kapsabet comprehensive Care Centre and is not associated with viral load

## CHAPTER ONE

### Introduction and background

A study done by National Institute of Neurological Disorders and Stroke (2015) defined dementia as the loss of cognitive functioning that involve the ability to reason, , language skills, visual perception, memory ability to focus and pay attention, loss of behavioral abilities, inability to solve problems and presence of delusion. This occur as a result of HIV attacking the brain cells and is severe enough to hinder an individual from performing everyday tasks. This was supported by a study done by the Acquired Immunodeficiency Syndrome.Gov Mission team in 2010 which found found that the Human Immune Virus (HIV) causes real problems in the human central nervous system because it crosses the blood brain barrier into the brain and spinal cord, causing HIV-associated dementia (HAD). The National Institute of Health (2013) highlighted that HIV Associated Dementia occurs in patients who are positive for the human immunodeficiency virus because the virus damages the brain's white matter and leads to social withdrawal, and trouble concentrating. There is need to establish the magnitude of the problem described order to plan for an intervention because it has the ability to interfere with daily functioning of an individual.

According to the AIDS Education & Training Centre (2014), the above effects have been categorized into three neurocognitive disorders (HAND). These include; asymptomatic neurocognitive impairment or disorder (ANI), mild neurocognitive disorder (MND) and HIV associated dementia (HAD) which involves moderate to severe functional impairment. HAD in the Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5) has been associated with major neurocognitive disorders. The study will be narrowed to the third category which is severe.

In terms of severity, Sing (2013) commented that, without treatment HAD has a rapid progression of 3-6 months mean survival rate. Haddow, Floyd, Copas & Gilson (2013) in the "Frascati criteria" research classification system commented that, of the three HIV associated neurocognitive disorder (HAND), HAD is the most sever grade and it involve at least two cognitive domains scoring at least 2 points below demographically-appropriate score of 12 in International HIV Dementia Scale. The above two writers agree on the severity of HAD. The researcher will use a cut-off of  $< 10$  during the study.

There is limited data on the severity of HAD in most parts of the world including Kenya. Sacktor, Nakasujja, Robertson and Cliff (2007) commented that there is inadequate data on HIV dementia patients in many parts of the world, they had hopes that more studies will be carried out in order to shade more light on devastating effects of HIV associated dementia in resource limited, and poorer regions of the world. Studies on prevalence of HIV have been given more weight in Kenya but information on HAD is limited, results on few studies on prevalence HAD have been generalized to represent wider area, for example study done in Nigeria was generalized to represent West Africa and Uganda to represent Sub-Saharan Africa, but specific prevalence in some countries is wanting.

Globally, Huang (2016) found the prevalence of HAD to range between 7 to 27 %, majority affected are those in the late stages of HIV infection. The prevalence was inversely proportional to the CD4 count, the prevalence comprised of both those on ARVs and those without. The

Prevalence could be high if the study was confined to those on ARVs due to the HIV stage and drug side effects. Robertson et al (2007) in a study on prevalence of HAD in United States of America found that it affects 10-15 % of the patients which is lower than the global prevalence, the study also found that prior to the advent of highly active antiretroviral therapy (HAART), dementia was a common source of morbidity and mortality in HIV-infected patients, and it was usually observed in the late stages of the Acquired Immunodeficiency Syndrome (AIDS) when CD4 count fall below 200 cells/ml, this was seen in up to 50% of patients prior to their death. Comparison of the two previous studies in America shows that ARVs had brought about changes in prevalence. This can explain the reason as to why HIV positive patients on ARVs live longer compared to the life span prior to the advent of ARVs, this also increases the prevalence because patient with neurocognitive disorder live longer. WHO recommend that, any patient with dementia should be commenced on ARVs and issues concerning good adherence should be addressed this will slow progression of HAD.

The African continent has also been hit by the scourge of HIV associated dementia. In 2012, Howlette in his study found that, prevalence of HAD among HIV population was 10-20 %. This finding is higher than the prevalence in the United States of America. This could be attributed to disease pattern, poverty and poor health system.

A study done in South Africa by Joska et al (2011) showed that, prevalence of HAD among the under 40 years patients initiating ARVs was 25.4 % and the prevalence among individuals receiving HAART was 10%. This study gives no room for comparison of prevalence among the general HIV population in South Africa and other countries who are yet to commence medication. However it could be lower because of the established health care system compared to other African countries.

In 2013, a study done by Nakkhu et al in Uganda found that, the prevalence of HAD was 64.4 % which was high compared to studies in developed countries. However, previous studies done in Uganda to represent Sub Saharan Africa in 2003 and 2010 was 31% and 64.1% respectively. These show that there has been progressive increase of prevalence from the previously done studies. Uganda is among the countries with high population of patients with dementia, this can be explained by high prevalence of HIV and poor economy. There is need to carry out assessments periodically in order to monitor the trend of dementia and plan for possible intervention. This may include early commencement of ARVs on dementia patients as recommended by WHO even before CD4 count or viral load done.

A pilot study done in western part of Kenya in 2012 by Kwasa et al to test the sensitivity and reliability of dementia assessment tools, found that the prevalence of HAD among general HIV positive patients was 20%. This finding was lower than the three the studies done in Uganda, the sample size was only 30 patients because its objective was to test the tool. Kenya that has been ranked the fourth country in world with high prevalence of HIV, this means that the prevalence of HAD can be high in relation to disease burden.

Many researchers in the previous studies have commented that there is inadequate data on HIV associated dementia. This may hinder planning for intervention because the magnitude of the

problem is unknown. More researches will inform the general public on the magnitude of the problem and will aid in planning for intervention, it will also be used as a baseline for other subsequent researches.

### **Statement of the problem**

According to Florian (2017) HIV associated dementia causes decline in cognitive functioning such as thinking of cognitive functioning, reasoning, judgment, concentration, problem solving, may interfere with problem of daily living and may lead to a vegetative state, in which the person has minimal awareness of his or her surrounding and incapable of interacting. This poses an overwhelming responsibility on families including Child parenting because adult parents cannot meet the expected level of performance. Dementia affect production in all areas which in turn will affect the economy of the country, health care cost has gone up because of the care required in terms of support and medication of HIV patients who could be suffering from dementia. Magnitude of this problem has not been established in many countries despite more data on Prevalence of HIV. This poses a challenge because no intervention can be successful without data that will guide in planning. There is therefore need to carry out more studies on prevalence and plan for intervention in order to halt progression into HAD.

## CHAPTER TWO

### Literature review

According to Haung (2016), HIV associated dementia is chronic, global, and usually irreversible deterioration of cognition that may occur in the late stages of HIV due to brain infection. It causes anatomic changes and neuronal damage. Due to irreversible damage, there is need for early diagnosis and management which is possible through periodic assessment to ascertain the level of dementia and plan for intervention. In support of the above finding, Howlett (2012) described that the HIV invades the Central Nervous System (CNS) within early days of infection and cause neurological disorders related to direct HIV infection and this has been observed during all stages of disease including early infection. This finding informs that dementia can occur at any stage so long as the virus has entered and affected the brain. The damage result into HIV associated dementia which is a severe form of Neurocognitive disorder. The two researchers agrees on the effects of HIV in the brain in which its progression can be halted if diagnosed early through screening and initiation of ARVs.

There are other synonymous terms for HIV associated dementia (HAD). According to study done by Singh (2012) the synonymous terms include: AIDS dementia, AIDS dementia complex (ADC), and HIV encephalopathy. These has been used interchangeably in various studies including prevalence that the researcher seeks to compare the findings of the study.

In 2013, Arora and Sousa found that there has been an increase in prevalence of HAD worldwide due to antiretroviral therapy, the therapy has enhanced the survival of HIV patients with peripheral immunosuppression. The dominance of HIV persist due to poor blood barrier permeability of ARV drugs leading to a gross increase in HAD. However POZ (2016) presented a contrary findings, he found that with the availability of powerful Anti-HIV drug therapy, the prevalence is much lower today. WHO supports POZ's idea that, ARVs can work to halt progression and it goes ahead to recommend the use of ARVs in any patient found to be having dementia during assessment using International dementia scale should be commenced on ARVs. This has not been done because different countries rely more on other test to determine the severity of infection, this include CD4 count and viral load count .However the recommendation from WHO should be embraced because it is cost effective and does not require a lot of time.

A recent study by (Huang, 2016) found that global prevalence of HAD was 7 - 27 % in late stage of HIV, and this was associated with continuous deterioration due to brain infection. This also supports the recommendation by WHO that, any client discovered to be having dementia during assessment should be commenced on ARVs to prevent further deterioration because it is deemed to be in 4th stage of HIV infection, and with continues destruction of brain cells, patient will present with HAD.

Findings by (Keven et al, 2007) revealed that 10-15% of patients with advance disease in United States suffer from HAD and minor cognitive motor dysfunction, this shows that HAD cut across regardless of socioeconomic level though its high in developing countries, before the advent of ARVs, dementia was a common source of morbidity and mortality in HIV-infected patients. It was usually observed in the late stages of acquired immunodeficiency syndrome (AIDS) when CD4

count dropped below 200 cells/ml, and was seen in up to 50% of patients prior to their deaths (Florian, 2016). There has been big decline in prevalence of HAD in those on ARVs, this is an indication that the ARVs works to prevent deterioration into HAD and improve the quality of life of any patient on medication. However good adherence is paramount in prevention of resistance and improvement of general health.

Heaton (2010) in a study done in Europe revealed that 13.7 % of HIV patients had neurological disorders but only 2% had HIV associated dementia, CD4 was found to be strong predictor of impairment. This prevalence of HAD was lower compared to other continents who are stable economically like United States, it was also observed that there are other two categories of asymptomatic and mild neurocognitive disorders which need to be addressed to prevent progression into HAD. Other than economic instability there could be other factors associated with HAD, this study will determine factors associated with dementia.

China has been known to be economically stable country because of its industrialization, this has not prevented development of neurocognitive disorder. (Dang, Wei, Long, Zhou, Han, & Zhao, 2015) study found that, China had prevalence of 8.26% HAD cases related to HIV. This prevalence was lower than United States and Europe though all are developed countries, Brazil record lower than the other countries, the study confirmed that International HIV dementia scale (IHDS) is a convenient and effective screening tool for HAD as it has the following characteristics: It avoids language and cultural issues, it consists of three main entries assessing four aspects, including memory registration, motor speed, psychomotor speed, and memory recall. The tool will be important in this study because patients across all the cultures will be assessed. From the above studies it can be conclude that the HAD in developed countries is lower than the prevalence in developing countries.

The African continent has not been spared either, Howlette (2012) found that, overall prevalence of HAD was between 10-20%. This is a generalized prevalence because the study has not been done in many other countries. Africa is a continent that is stricken by poverty with health challenges, this may increase the prevalence of HAD especially in individual countries with higher HIV burden.

There were no previous data for comparison, this calls for more studies in order to determine HAD prevalence in all African countries than using generalized studies in specific countries for example Nigeria to represent West Africa and Uganda to represent Sab-Saharan Africa.

South Africa is economically better compared to Countries in Sub –Saharan Africa but it also bears the scourge of HIV complication. Robbins et al (2011) found that, among adults under the age of 40 years starting ART, 25.4% met the criteria of HIV associated dementia. There was no data for comparison within the same country. This country has been in different level in terms of development and establishment of health facilities, it is not disadvantaged like East African countries that fall under Sub-Saharan Africa.

West African countries have also been affected, Asekomeh et al, in 2013, found that prevalence of HAD in West Africa among HIV positive population was 66.2%. The research was done in

Nigeria to represent West African countries, those assessed scored low in cognitive domains. This score is much higher compared to South Africa, poverty level is lower than South Africa.

East African countries have been hit hard more than other countries that do not fall Under Sub-Saharan Africa. In Tanzania, Nyundo et al. (2015) on a study at Muhimbili National Hospital Dar salaam-Tanzania, found that the prevalence of Neurocognitive disorder was 68.4 % with a cut of < 10 on IHDS. Another study by Asekomeh et al. (2013) done earlier in the same country but in different location found that the prevalence of dementia in Tanzania was 56%. The difference was brought about by the study site, Muhimbili is a national hospital and could have received more patient as referrals with already existing challenges.

In 2013, Nakku, Kinyanda, and Hoskins in a study done at Entebbe District Hospital-Uganda found that probable HIV dementia in ambulatory HIV adult population was 64.4%. Increasing stress and psychological impairment contributed to the high prevalence. Johns Hopkins University chose Uganda to represent Sub-Saharan Africa in 2007 and 2010, the findings were 31% and 64.1% respectively. These three studies shows that there has been progressive increase in prevalence within a span of 10 years. This calls for extensive and periodic study in various countries in order to determine the prevalence of HAD to aid in planning and intervention in specific countries. The study has also given clear picture that the prevalence changes over time, the above two studies in Tanzania has also shown that changes occur over a period of time. High prevalence could be due to high disease burden and low socio-economic level.

A pilot study done in 2012 by Kwasa et al in western Kenya to test diagnostic tools for HIV associated dementia found that, prevalence of HAD was 20%.The researcher emphasized on the need to train community Health workers on the use of the brief tools in order to reach many. However the sample size was 30 patients which was small to be used as a representative sample of HAD in Kenya the objective was to test the tool.

The available data has shown that, African countries are faced with huge burden of HAD, Nigeria 66.2%,Uganda has a prevalence of 31-64.4%, Tanzania 56-68.4% , South Africa 25.4% (those initiating ARVs), Cameroon 21.1%, western Kenya 20%, Malawi 14.0%. Democratic republic of Congo 8.7% .Carey et al (2012) has also established that, information on dementia in Africa is very limited, further research will not only provide more reliable estimate of disease burden, but will also raise awareness of the problem. Other Countries have not carried out studies to determine prevalence of HAD, therefore the magnitude is unknown. The information on dementia will help in planning for intervention in order to halt progression into HAD. The finding in this study will give the prevalence of HAD which is important in planning for intervention and also it can be used as a baseline in subsequent studies.

**Table 1; Summary of the Prevalence of HIV Associated Dementia.**

(Descending order of prevalence rate)

No	Country	Researcher	Year	Prevalence %	Comments
1	Tanzania	Nyundo et al	2015	68.4	Muhimbili National Hospital
2	Nigeria-West Africa	Asekomeh et al.	2013	66.2	There was no difference in Education
3	Uganda	Nakku, Kanyanda and Hoskins	2013	64.4	Done at Entebbe Health Centre
4	Uganda	Nakku et al.	2010	64.1	Kigungu Health Centre
5	Tanzania	Asekomeh et al.	2013	54	
6	Uganda	John Hopkin University	2003	31	Done to Represent sub-Sahara Africa (Kampala)
7	High Income Countries	Howlette,W.P	2012	1/3	Prevalence is reducing because of ART
8	Brazil	Rodrigues et al	2013	28.5	Symptomatic and Asymptomatic
9	South Africa	Robbin et al	2011	25.4	Under 40 yrs. Initiating ARVs.
10	Europe	Njamnshi et al Valcour et al	2008 2004	25.2	Older people-Age not specified
11	South Africa	Joska et al	2010	24%	Attending HIV clinic-General
12	Zambia	Holguin et al	2012	22	Lower than south Africa
13	Cameroon-	Njamnishi et al	2008	21.1	The first study to be done in Cameroon-Young's .Recommended Use of IHDS
14	Kenya (30 participants)	Kwasa et al	2012	20	Pilot Study –Western Kenya(Expert clinical assessment was used)
15	Uganda	Asekomeh et al	2013	16	Rural Uganda
17	Global	Huang,J	2016	7-27	Late stages of HIV
18	India	Aora and Saosa	2013	15-20	There was increase from the previous prevalence

## Prevalence of HIV Associated Dementia

19	Malawi	Patel et al	2010	14.0	Done at Blantyre ART Clinic
20	Europe	Njamnshi et all Valcour et all	2008 2004	13.7	Younger generation
21	African Continent	Howlette, W.P.	2012	10-20	Some countries have higher than overall role
22	United states	Kevin et al	2007	10-15	Patients with advance disease
23	High Income Countries	Robbin et al	2011	10	General population
24	Democratic Republic of Congo	Asekomeh et al	2013	8.7	Among the lowest in Africa
25	China	Dang et al	2015	8.6	Confirmed IHDS as effective tool
26	South Asia	Chan et al	2011	6.7	132 participants on ARVs
27	Thailand	Charlermchai et al.	2008- 2012	Less than 5	
28	India	Saldanh et al	2011		
29	India	Narayanan et al	2015	1-2	The one done previously had a higher prevalence

## Socio-demographic factors Associated with HIV Dementia

Nekku et al. (2013) in two studies done in Uganda demonstrated association between stress, coping skills, social support, life events and HIV disease progression which lead to HIV associated dementia. These demographic characteristics are important because they determine the health of an individual or the ability of the body to fight against HIV progression and delay the development of HAD. Another study by Joska in 2011, pointed out the association between unemployment and non-adherence to antiretroviral drugs with HAD, ARVs has been found to alter progression into HAD and or reversing the effects of HIV virus in the brain. When there is no adherence, the disease progression become faster. This was supported by Robbin et al. (2011) in a study done in South Africa where the researchers revealed that, HIV associated dementia was attributed to poor ART adherence and alcohol dependence. The two studies above have found that poor ARVs adherence is a socio-demographic factor that should be considered when working at prevention of HIV associated dementia. Poor adherence promote resistance to ARVs, this calls for proper adherence counselling before commencement of ARVs. Poor adherence will facilitate the multiplication of Strain that will not respond to ARVs, instead continue attacking the brain cells causing dementia. Nightingale et al. (2014) found that despite the use of ARVs and individual will develop neurocognitive impairment. This does not support the association between ARVs adherence and the neurocognitive impairment.

National institute of health (2015) commented that alcohol consumption increase the risk of dementia. The above study concur with South African finding by Robbin et al. (2011), who found that there is significant association between presence of alcohol dependence and positive HAD score. Substance and alcohol interferes with ARVs adherence resulting into incomplete suppression of the virus in addition to poor drug interaction. Alcohol has also behavioral impact, it may affect the judgement and decision, and this makes the patient not to adhere to medication as expected, an individual may not be able to practice protected sex and this increase multiplication of the virus which will further attack the brain cells resulting into HAD.

Sex of an individual has been found to play a role in development of dementia. In a study done in Europe by Chiesi et al ; Satz et al; Garrido et al (as cited in Rai, et al., 2011) commented that the rate of cognitive impairment was high in women and among the reason given include; Low socio-economic state, substance abuse, low educational level and greater psychiatric morbidity. However he did not support the association between HAD and the age. Researcher will look at the association of age and HAD.

AETC National Resource Center (2014) also commented that, gender is one of the factors that should be considered when looking at the social factors associated with dementia. This calls for more studies in order to understand the role and contribution of gender in development of HAD. The above studies has not separated the issues of gender and economic issues, this is because women has been known to be weak economically.

Sub-Saharan Africa is known to be the poorest region in the world, this state of poverty is associated with many challenges, and this has also impacted negatively in Education, nutrition and health. Mbirimtengerenji (2007) found that Sab-Saharan Africa is a home to 60% of people who live bellow UN poverty line of US\$ 1 per day, also commented on the studies that found that HIV and poverty are correlated, the also found that sub-Saharan Africa is home to 62% of worlds' HIV cases. This state of poverty and HIV burden explains why it has high prevalence of HAD.

Caitline( 2011) described that religion present a double- edge sword to health in Ghana, they recognize the healing power of faith and its ability to strengthen the body and deter the patient's belief that they will get better based on prayers, herbal remedies, and spirituality alone. This shows clearly that the patient need to be guided well in order to get positive benefit of religion and not stop medication. Religion play a part in prevention of HAD because it will handle psychological issues that interfere with treatment.

Many factors have been associated with progression of HIV associated dementia, others have not yet been concluded and are still under research. This research will also put forward its finding on the association of socio-demographic factors and development of HAD.

### **HIV associated dementia and viral load**

Viral load according to Nam aidsmap (2017) is the amount of HIV in the blood, the more HIV in the blood (and therefore the higher the viral load), then the faster the CD4 will fall, and the greater the risk of becoming ill, further described it as the number of copies of HIV RNA in a milliliter of

blood. In the study site, viral load test is done at least once a year, and more often if the patient is initiating ARVs or have any symptoms of the disease despite the use of ARVs.

Nam aidsmap (2015) also found that the viral load provide important information about the way that HIV affect patient's health. Among people with the same CD4 cell count, those with a high viral load tend to lose CD4 cells and become ill faster and this can be a strong predictor of HIV associated dementia. Continues to say that all viral load tests have a cut-off point below which they cannot reliably detect HIV, this is called the limit of detection and it is usually said to be undetectable if viral load is below 50 copies per milliliter, other sensitive methods give a cut-off point to be below 20 copies per mil and just because the level of HIV is too low to be measured doesn't mean that HIV has disappeared completely from the body.

The current viral load test during research study will show the state of immunity of the patient being interviewed and assessed for dementia, this gives an opportunity for a researcher to assess if there will be any association between the amount of viral load in the body and dementia scores. Reger et al (2005) found that, equivocal results have been reported on the association between viral load and cognitive functioning, the mechanism of cognitive impairment in HIV remains unclear, although dementia appears to be related to neuronal dysfunction and death, continues to say that, Plasma HIV RNA levels may not predict the degree of neuropsychological disturbance in HIV infection among HIV patients receiving antiretroviral treatment and that there were no difference between groups with undetectable, low or moderate plasma HIV RNA levels.

Steinbrink et al. (2013) revealed that, during the course of HIV infection, different changes in the cerebrospinal fluid (CSF) of infected patients have been observed as the infection progresses, this indicates that viral load in plasma CSF continues to raise, the researcher concluded that CD4 count and the viral load represent a strong predictors of the development of HAD and associated it with the severity of cognitive impairment. This supports the idea that high viral load predict the disease progression and impairment.

In support of the above finding, Kaul in his study done in 2009 found that, antiretroviral drugs maintains a significant effect on the incidence of HAD but cannot prevent the development of neurocognitive impairment because infected and activated macrophages and microglia in the blood seems to be a major factor promoting the development of HAD. He also found that, regardless of Viral load an individual will develop HAD in the long run even when taking ARVs though the onset is delayed and severity reduced.

On development of HAD, John Hopkins Medicine (n.d) found that, complication due to neurological challenges may result not only from damage caused by the virus itself, but also from other side effects drugs used to treat HIV and AIDS while attempting to control the rapid spread of the virus. The researcher also found that certain genetic factors can influence the risk of neurological side effects from HIV medicines. This also means that the viral load could be low but individual has neurological due to the effects of HIV drugs.

According to WHO (2007) guidelines, HIV-associated dementia (HAD) is an indication for commencing antiretroviral therapy regardless of patients immunity that is assessed using viral load test and CD4 count and is classified under WHO Stage IV. This calls for utilization of IHDS to

screen patients all the time because it is simple and does not require more time and resources. World Health organization looks at a low scores of below 10 on dementia scale as a baseline to commence ARVs.

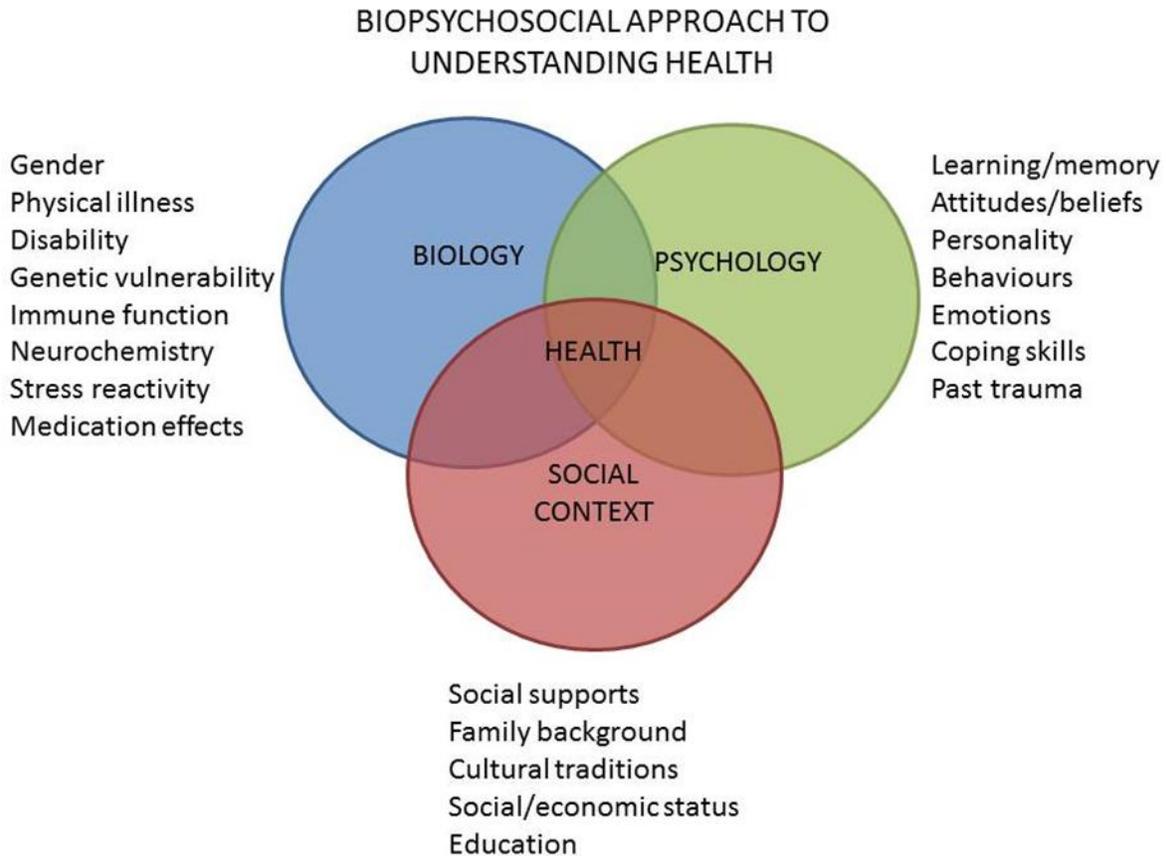
The researcher will retrieve the viral load results for the patient's file to confirm what was given by the patient.

### **Biopsychosocial model**

Biopsychosocial model developed by George Engle and John Romano in 1997, looked at contributing factors involved in illness and approach to management of disease. The theory attributes disease outcome to people's biological factors (genetic, biomedical) psychological actors (behavior, mood, personality) and social factors (cultural, familial, socioeconomic, and medical). Bondness (2016) commented that, the theory asserts that each one of these factors is not sufficient to bring about health or illness, but the interaction between them is what determines outcomes. The two researchers recognized that all diseases have biological, psychological and sociological origin. The above model helped the researcher to understand and give explanation on the development of HIV associated dementia among individuals in various institutions, countries and regions. Biological factor was considered because of the immune response when HIV Virus attacked the cells that protect the body, Psychological factors contributed to the development of the disease because of the behavior and mood which may hasten the disease progression and Sociological factors that include socio-economic status of the patient was a very important factor in low dementia score because patient could not afford medication and proper nutrition, poverty level make the patient engage in behaviors that negatively affect their health. The researcher looked at Viral load and use of ARVs to suppress the virus of each and every client which represent the biological, psychosocial factors which include include stigma , low socio-economic state of the patient. During literature review it was evident that, there were differences in prevalence of HAD in high and low socioeconomic countries. Biopsychosocial model has explanation as to why there was varied prevalence of HIV associated dementia in various region. A study done in Uganda on prevalence of HAD in 2013 by Nakku et al revealed that, increasing stress scores and psychological impairment was associated with the development of HAD. The illustration is presented in figure 1 below

**Figure 1; Venn-diagram Illustration**

Diagrammatic Illustration of biopsychosocial model of health and illness-Venn diagram



The biopsychosocial Model of health and Illness (Shaheen E. L, 2016)

**Broad objective**

To establish the prevalence of HIV associated dementia, Socio-demographic factors associated with dementia and association between International HIV dementia score and viral load among adult patients attending HIV/AIDS Comprehensive Care Centre (CCC) at the Kapsabet County Referral Hospital-Nandi.

**Research questions**

1. What is the prevalence of HIV associated dementia among patients attending Comprehensive Care Centre?
2. What are the socio-demographic factors associated with HIV dementia?
3. What is the association between International HIV associated dementia score and viral load?

### **Specific objective**

1. To determine the prevalence of HIV associated dementia among adult patients attending Comprehensive Care Centre.
2. To determine socio-demographic factors associated with HIV dementia score.
3. To determine the association between viral load and the International HIV dementia score of < 10

### **Scope of the study**

The study will focus on HIV positive patients attending Kapsabet Comprehensive Care Centre who will have done the viral load test. It will focus on patients who are above 18 years who have been registered at the clinic. It will look at prevalence and associated factors. The sample size will be 352 adults who will meet inclusion /exclusion criteria.

### **Rationale**

HIV has remained the most challenging health care problem in the world. According to Avert (2016) Kenya has the fourth highest HIV prevalence rate of HIV in the world. Despite the high prevalence, there is inadequate data on HIV associated dementia. There has been aggressive efforts towards monitoring of HIV trends with a view of preventing new infections, behavior change has been emphasized and it is evident by the presence of voluntary counseling and testing centers in almost every Health Centre. Dementia assessment for those who are already HIV infected has been largely neglected and there is no intervention that can be done if the magnitude of the problem is not known. Current health care policy and practice advocates for evidence based intervention thus, lack of data on the scope of HAD menace means that, complication of HIV will escalate unabated. Three Studies done in Uganda showed varied results between 31-64.4 % in a span of 10 years, this shows that there should be continuous study to monitor the trend. One study that was done in western part of Kenya had a small sample size. Moreover it was a pilot study to test an instrument and thus was not adequate to be generalized as a national or institutional figure. There is therefore need to carry out psychological assessments in order to assess the magnitude of dementia in various institutions in Kenya. The information on dementia will be useful in planning for intervention and will act as a baseline in subsequent researches. It is against this background of the dementia challenge and unavailability of data that has prompted the researcher's interest in the study area.

## CHAPTER THREE

### Research methodology

#### Study design:

The study design for the research was descriptive cross-sectional study.

#### Study site

The research study was carried out at the Comprehensive Care Centre (CCC) at Kapsabet - level 5 Referral Hospital. The CCC was started in 2005 and is located within the Hospital compound 150 meters from Kapsabet town which is the biggest town in Nandi County. It operates as an independent unit where patients receive all services under one roof. Services offered include; consultation, nursing services, general counselling, pharmacy, nutritional counselling, records and laboratory services. The CCC laboratory carries out investigations such as viral load test and other necessary tests as per clinician's request. The nutrition department offers education and nutritional advice depending on the body mass index or as per clinician's recommendation. The records department keep and maintains patients' records. According to the records, over 6,000 patients have been but only but only 4,648 are active (4,100 adults and 548 children), patients are drawn from across Nandi County. The facility has a total of 17 staff, 4 nurses, 3 clinicians, 1 nutritionist, 1 social worker, 2 laboratory staff, 3 records officers, 2 subordinate staff and 1 counselor who have an additional training on HIV management. The facility is supported by Walter reed project (NGO) and Ministry of Health Nandi County. Management falls under the overall Hospital Management team headed by the Medical Superintendent and services are offered 4 days in a week from Monday to Thursday between 8:00 am to 5:00 pm. Friday is reserved for follow-up and defaulter tracing.

#### Study Population

Study population will be 4,100 HIV positive adult patients who have been enrolled between 1 month and 1 year to enable them do the viral load test that is done at the first contact and is repeated between 3 months to one year for those on follow-up. The facility serves an average of 60-70 patients per day. Those who are stable and come from far are given appointment to come after every two months, but they can always come without appointment if they are unwell.

**Table 1; Inclusion/Exclusion criteria**

Inclusion criteria	Exclusion Criteria
Adults (Above 18 years)	Below 18 years
Those willing to consent	Those unwilling to consent by their/ Authorized person
Those confirmed to be HIV positive (indicated in patients files)	Inability to understand and communicate

<p>Those with viral load test (indicated on their files). Routine viral load test is done at first contact during enrolment, repeated at 3 months for those initiating ARVs and one year for those on follow-up( this will be treated as current)</p> <p>Those who can understand Kiswahili, English or Mother tongue of the researcher or be able to consent for a translator.</p> <p>Those without physical challenges on non-dominant hand to enable them act as per the requirement of a tool (IHDS)</p> <p>Those who have been enrolled and attending clinic for 2 months-1 year months. This will ensure that they have done the viral load test and the results are out.</p> <p>Those with hearing ability</p>	<p>Those without HIV results indicated in the file</p> <p>Those without viral load test results</p> <p>Physical challenges on non-dominant hand which prevent them from to taking instruction and acting as per the requirement of a tool</p> <p>Those with hearing disability.</p> <p>Patients with physical challenges on the non-dominant hand.</p> <p>Those patients who have had brain injuries and other serious injuries will be excluded from the study</p> <p>Those who come to clinic to seek medical consultation because they are sick.</p>
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**Sample size determination**

Sample size determination was calculated using Fisher’s formula (Mugenda & Mugenda, 2003)

$$n = \frac{Z^2 pq}{d^2}$$

Where:

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

Z= the normal standard deviation usually set at 1.96 which corresponds to 95% confidence interval.

P=the proportion in the target population estimated to have characteristics being measured.

q=1-P

Prevalence of HIV Associated Dementia

d= the level of statistical significance set (the degree of precision set) at 0.05(5%)

In the case of this research p is not available, the prevalence available was a pilot study done in Western part of Kenya, and it was not representative of National prevalence. In this case the researcher will take 50% to be the population (p) estimated to have estimated characteristic being measured.

Sample size will be drawn from 4100 patient who normally attend comprehensive care center.

$$n = \frac{Z^2 pq}{d^2}$$

$$n = \frac{(1.96)^2(0.50)(0.5)}{(0.05)^2}$$

$$= 384$$

The population is less than 10,000, therefore the required sample will be smaller. The researcher calculated a final sample estimate nf using the following formula:

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

Where:

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

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

N=the estimate of population size for this research is 4,100.

The sample size was as follows;

$$nf = \frac{384}{1 + 384/4100}$$

$$= 352$$

Sample size was 352 Patients.

### **Sampling Method**

The researcher adopted a simple random sampling. This was to ensure that every patient had an equal chance of participating in a study. An average of 60- 70 patients were seen every day. Numbers 1-60 was written on a piece of paper, put in a container and mixed well. After prayers and health talk, explanation about research study was done to prepare them for next step of randomly picking the numbers. The patients who were visiting triage nurse desk for observation picked the numbers randomly, those who picked odd numbers from 1-31 were included in the study, the next patient with the next number was picked to replace those who declined., this was ensure that 16 patients are enrolled in the study every day. By the 22 days, 352 patient had been interviewed and assessed.

### **Recruitment, consenting and data collection procedures**

The researcher sought approval of the research study from the KNH-UoN ERC, Permission was also sought from Hospital Medical superintendent and Comprehensive Care Center in-charge. Arrangement was made to get a private room for privacy within Comprehensive Care Centre

Patients entered through the main entrance and sat at the waiting bay with the first one (to arrive) sitting on the front bench to allow him or her to be attended first. When the quorum was attained, the routine activities of prayer and health talk began. After the routine activities, the in charge introduced and invited the researcher to talk about the study and recruitment procedures, the patients were then allowed to pick numbers randomly. The numbers determined who was included in the study. As they arrived their appointment cards were taken by the records officer who retrieved the files in preparation for consultation and recording of observations before the file were taken to clinician.

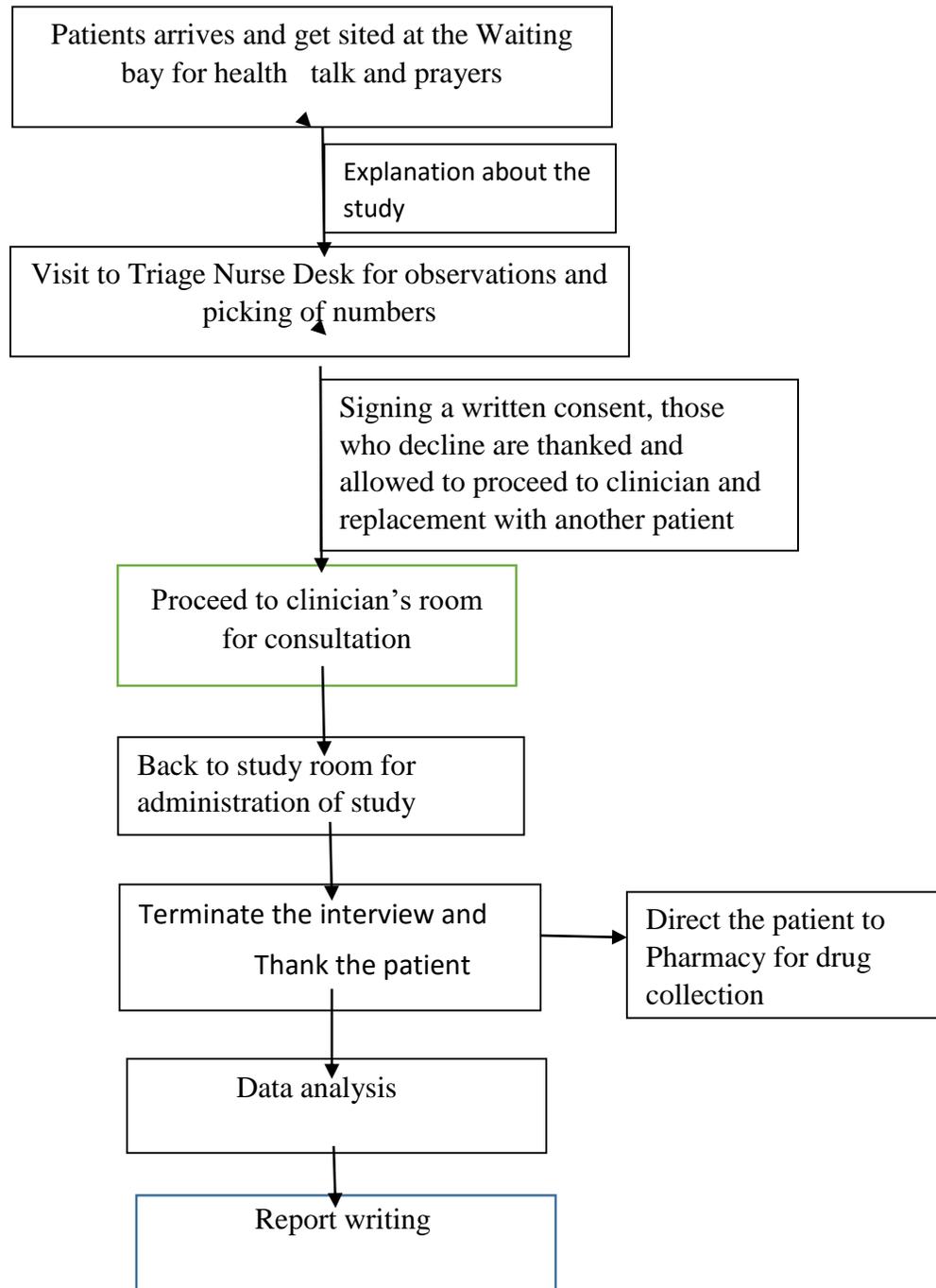
After observation the patients lined up to see the clinician, during this time the researcher discussed the consent in details as shown in the ethical with patients who picked odd numbers between 1 to 31, this was done in a private room to ensure confidentiality. Those who accepted to participate in the study signed a written consent and were consequently requested to come back to the same room for administration of the study instruments after consultation, they were then allowed to join the queue for consultation. The researcher signed his part in consent form.

After consultation, the patients were received back to study room where administration of socio-demographic questionnaire and assessment using the International HIV dementia scale was done. After completion of the study patients were ushered out and directed to pharmacy as another one was ushered in. Every patient was appreciated for participating in research study.

For patients who declined participation, the next patient with the next number was automatically be taken. 16 patients were seen every day making a total of 22 days to complete the data collection. Patients were seen at the clinic four days in a week from Monday to Thursday, Friday was reserved for follow-up, and this meant that patients were seen for 4 days in a week making a total of 16 days in a month. The researcher conducted a study for 22 days, this meant that other patient come back before the study ends, they were excluded from the study as no patient would be interviewed

twice. The process of administering questionnaire and assessment took about 15 to 20 minutes per patient, Socio-demographic questionnaire was administered first followed by assessment using standardized tool (IHDS).Flow of clients is presented in figure 2 bellow.

**Figure 2; Study Flow chart**



### **Data collection Instruments**

The researcher used two tools to collect data, socio-demographic questionnaire and International HIV dementia scale.

#### **Socio-demographic questionnaire**

The researcher designed and administered socio-demographic questionnaire that captured important Socio-demographic profile which include include: Age, sex, marital status, religion, income, occupation and level of education

#### **HIV related factors and viral load questionnaire (Researchers designed questionnaire)**

The researchers designed questionnaire captured information on: period of diagnosis, duration on ARVs, duration of illness, viral load test, drug adherence, HIV disclosure, alcohol involvement, condom use and sexual activity. Psychological factor captured in questionnaire include stigma and discrimination

#### **International HIV dementia scale (IHDS)**

International HIV dementia scale (IHDS) it is a modification of HIV dementia scale which was developed in 1995 and adopted by Sacktor et al. in 2005. It was modified in order suite and be acceptable across all cultures. The tool was used to collect dementia score through assessment. The tool is a simple scoring tool that consist of 3 subsets; finger tapping which measure motor speed, timed alternating and sequence which assess psychomotor speed and recall of 4 items which assess memory registration and recall. It has a standard cut-off of 10 in determining positive or negative results, a score of 10 and below indicate cognitive impairment.

Cross, Orien, Gase, Overton & Aces (2014) commented that, the International HIV dementia scale was developed to help identify individuals with cognitive impairment in outpatient setting. IHDS has been used throughout in numerous resource-limited settings including India, Argentina, Uganda, and Ethiopia with success. Most studies indicated that the IHDS has good sensitivity and specificity in detecting HAD. Two recent studies established validity for use of the IHDS among HIV positive populations in South Africa. Both studies suggested that IHDS is a useful tool to screen for HAD.

According to a study done by Joska et al (2011) in United States of America, the tool had a sensitivity and specificity of 80% and 57% respectively. Sacktor et al. (as cited in study by Nakku et al., 2013) found that the tool has been validated in South Africa and Uganda and was found to have a good psychometric properties in African populations with sensitivity of 88% and 80% and specificity of 50% and 55% respectively at a cut off of 10 and bellow, it is a bed side screening tool for HIV associated dementia and it can be used in a clinic setting and it requires 2–3 minutes to complete

## **ETHICAL CONSIDERATION**

The research was presented to the Kenyatta National Hospital and university of Nairobi Ethics and research committee for approval and was eventually approved. The Medical superintendent of Kapsabet County referral hospital and the In-charge of the Comprehensive Care Centre also granted permission for the research to be carried out in their facility.

### **Ethical issues in dementia**

According to Alzheimer Europe (2009), the provision of the convention on Human rights and biomedical (1997) provide for consent to be given on behalf of a person who does not have the capacity to consent, this could be legal representative or body or anyone who has authority to do so and the results of the research must have potential to produce real and direct benefit to his or her health. This enables the Dementia patients to participate in studies like any other person, but emphasis is laid on the type research that will benefit them, this should be looked at before making decision to include them. The researcher will address the ethical issue by involving a representative, relative or any responsible person who accompanied the patient to consent on behalf of the patient.

**Title of the study:** Prevalence of HIV associated dementia among HIV/AIDS adults attending Comprehensive Care Centre-Kapsabet Referral Hospital.

**Principal investigator:** Joshua Kiptoo Tiparo. **Institution:** University of Nairobi.

I would like explain to you about the study that researcher will conduct in the facility. The aim of this consent form is give you information you will need to enable you make a decision to whether to participate or not. Feel free to ask any question about the research that is not clear or unaddressed before making a decision to participate. The research will involve answering question and participating in assessment that will involve movement of your non dominant hand during the assessment of HIV associated dementia. Once you understand and agree to participate in the study, I will request you to sign on this form. Your decision to participate is entirely voluntary, you may withdraw from the study without necessarily giving reason for withdrawal. Refusal to participate in the study will not affect the services that you are entitled to receive in this health facility.

May I continue? YES /NO

This research was approved by The Kenyatta National Hospital-University of Nairobi and Ethics and research committee Protocol Number 768/16.

### **The study.**

The researcher mentioned above will carry out interview and assessment of individuals who are HIV positive and aged 18 years and above. The purpose of the research is to determine prevalence of HIV associated dementia, associated factors and association between International HIV dementia score and viral load. Participants will also have the choice to undergo assessment in order to determine their dementia score by following/taking instruction from the interviewer and acting as per the instructions given.

There will be 352 participants in this study who will be randomly chosen. I am asking for your consent to consider participating in this study.

**What will happen if you decide to be in this research study?**

If you agree to participate in this study, you will be interviewed and assessed by the researcher in a private area where you will feel comfortable answering questions and participating in assessment. The interview and assessment will last approximately 15-20 minutes. The interview and assessment will cover topics such as your marital status, your HIV information, your income, ARVs information, occupation, Psychosocial issues and sexual relationship. HIV associated dementia assessment will focus on Motor speed, Psychomotor speed and memory recall. After the assessment you will be given feedback concerning your score, referral will be done if found to be necessary. The researcher will also access medical information about your HIV status and viral load results to confirm what you will have provided during the interview.

**Cost and benefits of being in the study.**

The participant were not be required to incur any financial cost nor receive any financial incentive. The information obtained will benefit the institution and patients in terms of management of HIV associated dementia, it will also inform policy makers on the situation or prevalence of HIV associated dementia. It will also be used in subsequent status of the same nature. There will be no refund for any money used as bus fare because it is done during the normal clinic visit.

**Risk, harm and discomfort associated with this study.**

Information that you will give will be held confidential as possible. Code numbers will be used to identify you, all your records will be kept in a lockable cupboard.

You are free to skip any question that you will not be free to answer. The interview will be done in a private room to avoid embarrassment, the interview and assessment will be done by the researcher. Also recalling the past may be stressful, counselor will be consulted to ensure that you leave the facility without any stress.

**Questions that may arise in future.**

If you have further questions concerning your participation in the study, please call or send a text to the researcher through 0722 658493. Email address-jktiparo@yahoo.com

For more information about your rights as a participant you may contact Secretary/Chairperson, Kenyatta National Hospital –University of Nairobi Ethics and Research committee Telephone No.2726300Ext, 44192 email-uonknh\_erc@uonbi.ac.ke. Hospital –University of Nairobi Ethics and research committee Telephone number 2726300 Ext 44102.

**Voluntary participation**



Relationship.....

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

**Researcher’s statement**

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe the participant has understood and has willingly and freely given his/her consent.

Researcher’s

Name.....Date.....

Signature.....

For more information contact.....at.....

From.....to.....

**Data Management**

The questionnaires administration and assessment was done by the researcher. The researcher checked from the file to ensure that the viral load results given by the patient was correct. The information was stored in safe place in preparation for the analysis and after analysis it was kept in a lockable cupboard.

**Data analysis**

The statistical package for social sciences (SPSS) version 20 was used to analyze the data from both Socio-demographic questionnaire and International HIV dementia scale score. Data analysis involved organizing in a ways that allowed researcher to see patterns and make meaning. The frequency of HIV associated dementia was determined by calculating the percentages of the participants who scored 10 and below on International HIV dementia scale. Factors associated with dementia will be calculated from the data obtained in socio-demographic questionnaire and IHDS. Association between viral load and International HIV dementia scale score will be calculated using data from the two study instruments. Analysis and presentation was done as per researcher’s study objectives and were presented in form of tables, graphs, and narrative

## CHAPTER FOUR

### Introduction

The study enrolled 352 participants who were visiting clinic for their routine clinic. All of them managed to complete interview and assessment.

### Socio-demographic characteristics and HIV Dementia score

The majority were female (69.3%) and Predominant age range was 33-47 years (52.6%) of whom 65.9% scored  $\leq 10$  in international dementia score. The youngest respondent aged 18 years and the oldest was 78 years, mean age of the respondents was 39.9. On marital status, the study established that 47.7% were married and living with their spouses while 9.9% had separated. In terms of education level, 60.2 % had attained primary level and 7.7% had no education. 51.7 % of the respondents engaged in informal employment while 9.9% were unemployed. Distribution of the participants according to their religion indicated that 61.1% who were the majority were Protestants. Concerning the income the study found that 47.0% were earning less than 5,000 Kenya shillings per month. Majority of the respondents aged 33-47 years 65.95% of the patients scored 10 and below in dementia score. There was a significant association between income and HIV Dementia score with a p value of 0.029.

The results are shown in Table 3 bellow

**Table 2; Socio-demographic and HIV Dementia score**

Parameter	Category	Overall n (%)	HIV Dementia Score		Group differences
			Above n (%)	10 & below n (%)	
Age	18-32 Years	69(19.6)	27(39.1)	42(60.9)	$\chi^2_{(3, 352)}=1.41;$ $P=0.704$
	33-47 Years	185(52.6)	63(34.1)	122(65.9)	
	48-52 Years	52(14.8)	15(28.8)	37(71.2)	
	52 and above Years	46(13.1)	16(34.8)	30(65.2)	
Sex	Male	108(30.7)	32(29.6)	76(70.4)	$\chi^2_{(1, 352)}=1.56;$ $P=0.212$
	Female	244(69.3)	89(36.5)	155(63.5)	
Marital status	Married	168(47.7)	53(31.5)	115(68.5)	$\chi^2_{(3, 352)}=1.49;$ $P=0.684$
	Single	95(27.0)	37(38.9)	58(61.1)	
	Widowed	54(15.3)	19(35.2)	35(64.8)	
	Separated	35(9.9)	12(34.3)	23(65.7)	
Religion	Protestant	215(61.1)	78(36.3)	137(63.7)	$\chi^2_{(3, 352)}=2.62;$ $P=0.454$
	Catholic	104(29.5)	35(33.7)	69(66.3)	
	Muslim	20(5.7)	6(30.0)	14(70.0)	
	Others	13(3.7)	2(15.4)	11(84.6)	

Prevalence of HIV Associated Dementia

Highest level of education	No formal education	27(7.7)	10(37.0)	17(63.0)	$\chi^2_{(3, 352)}=0.33;$ $P=0.955$
	Primary	212(60.2)	71(33.5)	141(66.5)	
	Secondary	95(27.0)	33(34.7)	62(65.3)	
	Tertiary and above	18(5.1)	7(38.9)	11(61.1)	
Occupation	Student/ Dependent	32(9.1)	15(46.9)	17(53.1)	$\chi^2_{(4, 352)}=3.74;$ $P=0.442$
	Informal employment	181(51.4)	61(33.7)	120(66.3)	
	Formal employment	24(6.8)	6(25.0)	18(75.0)	
	Business	76(21.6)	24(31.6)	52(68.4)	
	Unemployed	39(11.1)	15(38.5)	24(61.5)	
Approximate income per month/ksh	Less than 5000	132(47.0)	36(27.3)	96(72.7)	$\chi^2_{(4, 281)}=10.83;$ $P=0.029$
	5000-10000	89(31.7)	31(34.8)	58(65.2)	
	10001-15000	23(8.2)	9(39.1)	14(60.9)	
	15001-20000	11(3.9)	8(72.7)	3(27.3)	
	20001 and above	26(9.3)	7(26.9)	19(73.1)	
	N/A	71(20.2)			

**HIV Related factors Associated with HIV Dementia Score**

All the participants were confirmed to be HIV positive. Distribution of the participants according to the duration of illness showed that 28.1 % who represented the majority had been sick for 7-8 years, while 3.4% of the respondents acquired through mother to child transmission and they were over 18 years. 17.3 % of the respondents were not adhering to ARVs medication. The researcher determined that 3.4 % of the respondents were involved in alcohol and substance abuse. 33% of the respondent were active sexually and 2.6 % had two sexual partners, among those who were active sexually 71.6 % uses protective while 28.4 were not using. 80.7 % of the respondents had viral load which was low detectable level (LDL). There was significant association between the use of protective and HIV Dementia score with a p value of 0.020. There was no significant association between viral load and International dementia score.

The results are presented in table 4 bellow

**Table 3; HIV Related Factors and Dementia score**

Parameter	Category	Overall n (%)	HIV Dementia Score		Group differences
			Above 10 n (%)	10 & below n (%)	
	1-2	88(25.0)	30(34.1)	58(65.9)	

## Prevalence of HIV Associated Dementia

Number of years passed since diagnosis of HIV	3-4	39(11.1)	13(33.3)	26(66.7)	$\chi^2_{(5, 352)}=3.51;$ $P=0.621$
	5-6	70(19.9)	22(31.4)	48(68.6)	
	7-8	99(28.1)	35(35.4)	64(64.6)	
	9 Years & Above	44(12.5)	14(31.8)	30(68.2)	
	From birth	12(3.4)	7(58.3)	5(41.7)	
HIV status disclosure to any one	Yes	343(97.4)	117(34.1)	226(65.9)	$\chi^2_{(1, 352)}=0.42;$ $P=0.519$
	No	9(2.6)	4(44.4)	5(55.6)	
Length of time on ARVs	1-2	75(21.3)	27(36.0)	48(64.0)	$\chi^2_{(4, 352)}=6.08;$ $P=0.193$
	3-4	69(19.6)	27(39.1)	42(60.9)	
	5-6	60(17.0)	13(21.7)	47(78.3)	
	7-8	53(15.1)	17(32.1)	36(67.9)	
	9 & Above	95(27.0)	37(38.9)	58(61.1)	
Ever stopped taking ARVs since commencement	Yes	42(11.9)	14(33.3)	28(66.7)	$\chi^2_{(1, 352)}=0.02;$ $P=0.880$
	No	310(88.1)	107(34.5)	203(65.5)	
Non-Adherence-Skipping ARVs	Yes	61(17.3)	20(32.8)	41(67.2)	$\chi^2_{(1, 352)}=0.08;$ $P=0.774$
	No	291(82.7)	101(34.7)	190(65.3)	
Viral load test copies per/mil	LDL	284(80.7)	97(34.2)	187(65.8)	$\chi^2_{(3, 352)}=3.95;$ $P=0.267$
	1-500	38(10.8)	17(44.7)	21(55.3)	
	501-1000	2(0.6)	0(0.0)	2(100.0)	
	1001 & Above	28(8.0)	7(25.0)	21(75.0)	
Alcohol involvement	Yes	6(1.7)	0(0.0)	6(100.0)	$\chi^2_{(1, 352)}=3.20;$ $P=0.074$
	No	346(98.3)	121(35.0)	225(65.0)	
psychosocial issues-discrimination	Yes	50(14.2)	21(42.0)	29(58.0)	$\chi^2_{(1, 352)}=1.50;$ $P=0.220$
	No	346(98.3)	121(35.0)	225(65.0)	
Sexual partner	Yes	116(33.0)	44(37.9)	72(62.1)	$\chi^2_{(1, 352)}=0.97;$ $P=0.325$
	No	236(67.0)	77(32.6)	159(67.4)	
Use any protection	Yes	83(71.6)	26(31.3)	57(68.7)	$\chi^2_{(1, 116)}=5.41;$ $P=0.020$
	No	33(28.4)	18(54.5)	15(45.5)	
	N/A	236			

## Prevalence of HIV Associated Dementia among Adults Patients

Participant's scores on motor-speed, psychomotor-speed and Memory-recall were determined. In motor speed 39.5% scored 3, 47.2% scored 4 points out of 4. In psychomotor speed and 66.2% of the respondents scored 4 points in memory recall. In aggregate only 7.7% of the respondents scored 12 points. Results are presented in table 5 below.

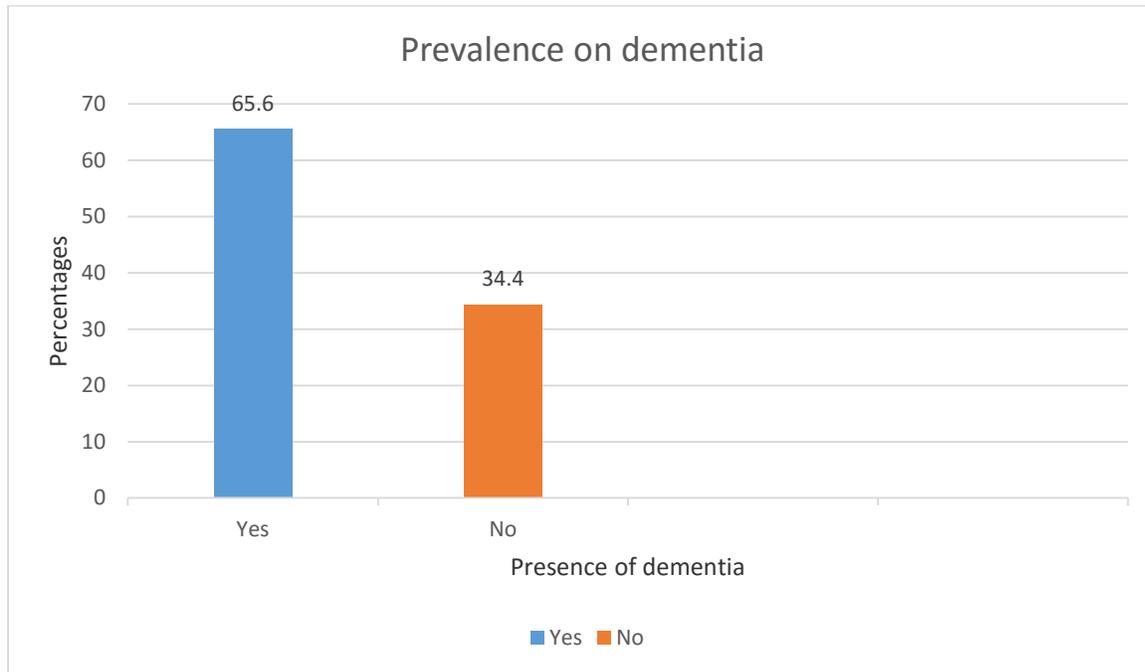
**Table 4; Prevalence of HIV Associated Dementia**

<b>Parameter</b>	<b>Category</b>	<b>Frequency (N=352)</b>	<b>Percentage (95% C.I)</b>
Motor speed score	3-6 in 5seconds	12	3.4(1.7-5.4)
	7-10 in 5seconds	132	37.5(32.4-42.6)
	11-14 in 5seconds	139	39.5(34.7-44.3)
	15 in 5 seconds	69	19.6(15.6-23.9)
Psychomotor speed score	0-Unable to perform	10	2.8(1.1-4.5)
	1- sequence in 10 sec	5	1.4(0.3-2.8)
	2- in 10 sec	49	13.9(10.5-17.6)
	3- in 10 sec	122	34.7(30.1-40.1)
	4- in 10 sec	166	47.2(41.5-52.0)
Memory-recall score	No word	2	0.6(0.0-1.4)
	One word	1	0.3(0.0-0.9)
	Two words	12	3.4(1.7-5.4)
	Three words	104	29.5(25.0-34.4)
	Four words	233	66.2(61.4-71.0)
Motor speed score	1	12	3.4(1.7-5.4)
	2	131	37.2(32.1-42.3)
	3	139	39.5(34.7-44.3)
	4	70	19.9(15.9-24.1)
Total Score (Aggregate of 3 domains)	4	4	1.1(0.3-2.3)
	5	2	0.6(0.0-1.4)
	6	11	3.1(1.1-4.8)
	7	14	4.0(2.0-6.2)
	8	42	11.9(8.5-15.3)
	9	90	25.6(21.0-30.1)
	10	68	19.3(15.3-23.6)
	11	94	26.7(22.2-31.5)
<b>Total category</b>	<b>10 and below</b>	<b>231</b>	<b>65.6(60.8-70.7)</b>
	Above 10	121	34.4(29.3-39.2)

**Overall prevalence of dementia**

The aggregate score in 3 areas assessed were further combined to give prevalence of dementia. The study revealed that prevalence of dementia was 65.6%., this was a group who scored  $\leq 10$  points. Results are presented in figure 3 bellow

**Figure 3; Prevalence of dementia**



The researcher in the study found that 70.4% of men had HAD, compared to women 63.5%

### **Factors associated with HIV Dementia score**

Summary of other factors that had been found to have significant association with HIV dementia scores include: Level of income with a p value of 0.029, use of protective with a p values of 0.02 and duration on ARVs with a p value of 0.002 and

Further calculation was done on HIV Related Factors Associated with HIV dementia score using mean and standard deviation, the results abstained indicate that there was a significant association between Psychosocial issue –discrimination and sexual activity with a p values of 0.038 and 0.039 respectively.

The results are presented in table 6 bellow.

**Table 5; Factors Associated with Dementia score (Mean and standard deviation calculation)**

Parameter	Category	HIV Dementia Score		Group differences	P-Value
		Mean	SD		
psychosocial issues -discrimination)	Yes	10.02	1.45	$t_{(350)}=2.09$	<b>0.038</b>
	No	9.51	1.61		
Sexual activity	Yes	9.84	1.62	$t_{(350)}=2.08$	<b>0.039</b>
	No	9.46	1.57		

**Association between Viral Load and HIV Dementia Score**

Chi-square was used to determine association between viral load and the International HIV dementia score, the study revealed that there was no significant association between the Viral load and International HIV dementia score ( $P=0.267$ )

**Multivariate Logistic Regression on Factors Associated With HIV Dementia**

After adjusting for all the factors that were associated with HIV induced dementia at the bivariate level ( $P<0.300$ ). The only significant factors associated with HIV induced dementia was Length of time of ARV's use and having psychosocial problems (Stigma/ discrimination). The odds of having HIV induced dementia was 0.07 times less among those who have been using ARV's for 3-4 years as compared to those who have been using it for 9 years and above. The risk of HIV dementia was about 4 times more among the participants who reported to have psychosocial problems (Stigma /discrimination) as compared to those who did not report psychosocial problems.

**Table 6; Multivariate Logistic Regression on Factors Associated With Dementia**

Parameter	Category	HIV dementia Score			A.O.R	95% C.I	P-Value
		Above 10	Ten and below				
Sex	Male	32(29.6)	76(70.4)	1.80	0.6-5.6	0.306	
	Female	89(36.5)	155(63.5)	Ref.			
Approximate income per month/ksh	Less than 5000	36(27.3)	96(72.7)	0.47	0.1-3.2	0.440	
	5000-10000	31(34.8)	58(65.2)	0.51			
	10001-15000	9(39.1)	14(60.9)	0.21			
	15001-20000	8(72.7)	3(27.3)	0.23			
	20001& above	7(26.9)	19(73.1)	Ref.			
	1-2	27(36.0)	48(64.0)	1.41	0.3-7.5	0.688	

Prevalence of HIV Associated Dementia

Length of time on ARVs in years	3-4	27(39.1)	42(60.9)	0.07	0.0-0.4	<b>0.002</b>
	5-6	13(21.7)	47(78.3)	0.33	0.1-1.8	0.205
	7-8	17(32.1)	36(67.9)	0.24	0.0-1.3	0.099
	9 & above	37(38.9)	58(61.1)	Ref.		
Viral load test copies per/mil	LDL	97(34.2)	187(65.8)	2.22	0.4-12.6	0.368
	1-500	17(44.7)	21(55.3)	0.51	0.1-4.0	0.519
	1001 & Above	7(25.0)	21(75.0)	Ref.		
psychosocial issues - discrimination	Yes	21(42.0)	29(58.0)	3.84	1.1-13.6	<b>0.038</b>
	No	100(33.1)	202(66.9)	Ref.		
Use any protection	Yes	26(31.3)	57(68.7)	2.99	0.9-10.1	0.078
	No	18(54.5)	15(45.5)	Ref.		

*Note;* Ref-Reference category; A.O.R.-Adjusted Odds Ratio

## DISCUSSION

Majority of the respondents were females who accounted for 69.3 %, this shows that disease burden was high among women compared to men. In support of the above Avert (2017b) found that, women account for more than a half the number of people living with HIV worldwide because of vulnerabilities created by unequal cultural practices, social and economic status. This scenario is replicated in HIV clinics where patients visit to seek medical help which was observed during the study.

The finding of this study revealed that 17.3 % of the respondents were not adhering to ARVs and this pose a danger of incomplete suppression of the virus creating resistance which will result into HIV associated dementia. Asmare et al. (2014) in Journal of antiretroviral and antiviral emphasized 95% adherence to ARVs in order to be fully effective.

The overall prevalence of HIV associated dementia was (65.6%) with a cut off score of < 10, only 34.4 % of the patients who participated in this study scored above the cut-off. This prevalence could be lower if done in a different facility within county because Comprehensive Care Centre receives patients across the county including referrals who need further consultation because of medical problems, and they could be suffering from neurocognitive disorders that leads to poor progress.

Varied prevalence have been reported in different countries both developed and developing. Tanzania has the highest prevalence in Africa though it was confined to a National hospital. Nyundo et al. (2015) on a study on neurocognitive correlates of the use of combined Antiretroviral Therapy at Muhimbili National Hospital Dar salaam-Tanzania, revealed that the prevalence of Neurocognitive disorder was 68.4 %. With the cut-off of < 10 on IHDS. Another study by Asekomeh et al. (2013) done earlier in the same country but in different location showed that the prevalence of dementia in Tanzania was 56%. The difference was brought about by the study site, Muhimbili is a national hospital and could have received more patient as referrals with already existing challenges. This can be compared with the study site at Kapsabet because it receives referrals together with general HIV clients though it is lower than Muhimbili National Hospital.

The second highest prevalence of HIV associated dementia was from the country of Nigeria.

Asekomoth et al. (2013) found that prevalence of HIV dementia was 66.2% and it was done to represent West African countries, the prevalence could have been high because it was done on patients with an advanced level of disease progression. Advance level of disease progression is as a result of high level of virus which increase the chance of brain injury, these are a group of patients who already have medical challenges by the fact that they had an advanced infection. If the study is replicated in general HIV population the prevalence could be lower.

Uganda has also reported a high prevalence of HIV associated dementia. In 2013, Nakku, Kinyanda, & Hoskins study at Entebbe District Hospital-Uganda, the researchers found that probable HIV dementia in ambulatory HIV adult population was 64.4%. The prevalence could have gone high because of the study site. District hospital serves a big population and is acting like a referral hospital. District Hospital in Uganda could be equated to a county hospital in Kenya

though the difference could be the population and the prevalence of HIV within the location of the hospital or town.

Africa countries have something in common, they are low economically, unestablished health care system, low education and nutritional challenges, this affect the health of the individuals. The three East African countries are in Sub-Sahara Africa where disease burden and poverty is high, this increase the prevalence of HIV associated dementia.

Developed countries have also experienced HIV associated dementia. Heathon (2010) found that prevalence of HAD in Europe was 2%. Robin et al. (2007) found that United Nations had 10-15 %. The difference in prevalence can be explained by the disease burden in Africa countries, low economic level, cultural practices, low education and poor health care system.

The study found that there was significant association between income of the patient and the score on International HIV dementia scale with p-value of 0.029. Rai, Y.et al. (2011) found that, low socio-economic state, substance abuse, low educational level and greater psychiatric morbidity were associated with the Neurocognitive impairment. However there were no figures that gives association. During the study it was revealed that 47% of the respondents were earning below 5,000 Kenya shillings per month, this denied them access to education, proper health care and nutrition. Generally their living standards was low, this hasten the development of neurocognitive disorder resulting into HAD.

Sub-Sahara Africa is known to be the poorest region in the world, this state of poverty is associated with many challenges, this has also impacted negatively on Education, nutrition, and health as mentioned above. Mbirimtengerenji (2007) commented that Sab-Saharan Africa is a home to 60% of people who live bellow UN poverty line of US\$ 1 per day, also commented on the studies that found that HIV and poverty are correlated, the study also revealed that sub-Saharan Africa is home to 62% of worlds' HIV cases. This state of poverty and HIV burden explains why it has a high prevalence of HAD. Sahn (2009) in his study showed that poverty level hinders individuals from accessing health care and weaken the immunity during infection, the intervention is delayed due to late diagnosis and ARVs initiation, this result into HAD. The distribution of earning among the patients who participated in the study showed that 78.7% earn 10,000 Ksh and bellow, this shows clearly the level of poverty that exists among the participants.

There was an association between use of protective and HIV dementia with  $p=0.020$ . 28.4 % of those who were active sexually were not using any protective, this increases the chance of cross infection and multiplication of HIV virus which injures the brain, this also predispose the development of resistant strain that continues to attack brain cells. Those who were not using protective during sexual intercourse had wider margin standard deviation compared to the users.

Females patients living in rural areas, uneducated groups, and new ART users in Ethiopia were less likely to use condoms consistently (Shewamene, 2015).The above scenario in Ethiopia depict the state of respondent in the study, the study interviewed and assessed respondents from across the county, from rural setting and town, majority had primary level of education (60.2%), some had no formal education, and this means that they fall under the group of those who are likely to engage in sexual relationship without condom use.

Wilton (2013) found that consistent use of a condom is important in prevention of the virus during sexual relationship, both female and male condoms are equally effective and there is no reason to think they are not protective at all. This prevents cross-transmission between people who are HIV positive and reduce the rate of multiplication and development of resistance virus. The two studies emphasize on the importance of use of protective in order to prevent more harm, continuous exposure increases the chance of brain injury leading to HAD.

The researcher determined that there exist a significant association between stigma/discrimination with International dementia score with a p value of 0.038. This was calculated from the mean and standard deviation. (AVERT, 2017) in the study pointed out that there is cyclical relationship between stigma and HIV, people who experience stigma and discrimination are marginalized, this result into poor care within health sector and also they are not likely to access health care, loss of hope and feelings of worthless, loss of reputation, poverty and being reluctant to take antiretroviral therapy, this makes treatment less effective and may cause early death, Stigma has a damaging effect on the mental wellbeing of people living with HIV, this lower the score on HIV dementia scale.

Santoso et al, (2016) in a study done in Dominican republic found that stigma is associated with HAD because it prevents individual from disclosing her status and seeking proper treatment and support, when patient's HIV is unmanaged it will result in severe HAD. This supports the previous researcher on the effects of stigma. The study found a small number of respondents who had not disclosed their HIV status to anyone, this makes it difficult for them to access services and get support. This will affect their mental wellbeing leading to poor performance and low HIV Dementia score.

The researcher noted that there was no association between the viral load and the IHDS score of < 10 with (p-value of 0.267). There were respondents who had a low detectable level of virus who scored as low as 4 points and others had over 1,001 virus per cubic milliliters and scored higher. The respondents with low detectable level of virus were 80.7 % yet 65.6% of all respondents had dementia, 4% with LDL scored 4 in IHDS, this shows that there is no association,

Reger et al. (2005) found that equivocal results have been reported on the association between plasma viral load and cognitive functioning, the mechanism of cognitive impairment in HIV remains unclear, although dementia appears to be related to neuronal dysfunction and death. Continues to say that, Plasma HIV RNA levels may not predict the degree of neuropsychological disturbance in HIV infection among patients receiving antiretroviral treatment and that there was no difference between groups with undetectable, low or moderate plasma HIV RNA levels. The findings support what this study found because there were those who had LDL but scored high on dementia scale.

Kaul, 2009 found that though HAART maintains a significant effect on the incidence of HAD, it cannot prevent the progression of neurocognitive impairment because infected and activated macrophages and microglia in the blood seems to be a major factor promoting the development of HAD. He also found that regardless of Viral load an individual will develop HAD in the long run even when taking ARVs though the onset is delayed and severity reduced. He also found that there

are other factors that may contribute to Cognitive impairment other than viral load. Certain genetic factors can influence the risk of neurological side effects from HIV medicines.

AETC. (2014) in a recent research found that neuro-inflammation rather than the HIV viral load in Central nervous system is primarily responsible for cognitive impairment in HIV-Infected Individuals. This also means that the viral load could be low as it was shown in this study but an individual has neurological impairment. The study supported the finding of this research that there is no significant association between viral load and International HIV dementia score, cognitive impairment can be caused by injury of ARVs drugs, this explain why some patients had Low level of detectable virus but still scored low in IHDS.

Generally, the findings show that majority (80.7 %) of the respondents had low detectable levels (LDL) yet they performed poorly in International HIV scale, this confirms that there is no association

According to Nam aidsmap, 2007 the more the HIV in the blood the greater the risk of becoming ill, this includes HIV associated dementia among other complications. Steinbrink et al (2013) supported the association between the viral load and dementia score he found that during the course of HIV infection different changes in the cerebrospinal fluid (CSF) of HIV infected patients have been observed as the infection progresses, when there is high viral load there is destruction of the brain cells, the researcher concluded that CD4 count and the viral load represent a strong predictors of the development of HAD and associated it with the severity of cognitive impairment. From the above studies it is evident that two observation have been made concerning association, this study supported the finding of those who found that there is no association between viral load and IHDS score. However, there is need to study more in order to arrive at conclusion.

Further analysis using logistic regression revealed that those who had used ARVs for over 9 years and above had 0.07 times higher in developing dementia compared to those who had used it for a short time. This is explained by John Hopkins hospital (n.d) found that neurological complications may result not only from damage caused by the virus itself but also from other side effects of HIV and AIDS drugs used to treat HIV and AIDS while attempting to control the rapid spread of the virus, this means that the person who has used for long may experience more effects. Kaul (2009) found that infected and activated Microphages and microglia is a factor in developing HAD, they injure the brain and the longer they are in the body the higher the destruction of the brain cells. The risk of HIV associated dementia was about 4 times more among the participants who reported to have psychosocial problems (Stigma /discrimination). AVERT (2017) found that found that Stigma and discrimination have a damaging effect on the mental wellbeing of people living with HIV, also found that 50% of the people report having discriminatory attitudes towards People living with HIV, this lowers the score because of disease progression. In Support of the finding, a study by Santoso et al. (2016) in the Dominican Republic determined that stigma is associated with HAD because it prevents an individual from disclosing her status and seeking proper treatment and support. This explains why they are 4 times more likely to develop HAD than those without stigma.

### **Limitation of the study**

1. The study lacked neurocognitive diagnostic battery to confirm the diagnosis of HIV associated because IHDS is a screening tool.
2. The study was not able to establish the previous state of an individual prior to HIV infection if she or he already had dementia.
3. Issues of mental disability that require assessment were not ruled out during the study, this may affect the results.
4. The sample size was small to be generalized to give the country or county prevalence

### **Recommendations for the Study**

1. Screening patients after every 2 months using IHDS.
2. Health messages should emphasize on HIV, the importance of drug compliance and the use of protective.
3. Availability of counseling services for those in need
4. Psychoeducation on alcohol and its effects on ARVs drug interaction
5. Psycho-educate religious leaders on ARVs action and include them in the care of HIV positive patients.
6. Screen patient for depression and alcohol before IHDS assessment

### **Conclusion**

There is a high prevalence of HIV associated dementia among HIV patient attending Kapsabet Comprehensive Care center. This however is not associated with viral load.

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**APPENDICES**

**APPENDIX 1: Socio-Demographic and Viral load questionnaire**

Date.....

The information obtained will be held confidential.

Serial no.....CCC no.....

1. What is your age? .....

2. Sex.            M            F

3. Marital status (i) Married            (ii) Single            (iii) Widow (er)            (iv) Separated  
(v) Divorced            (VI) Cohabiting

4. What is your religion? (i) Protestant            (ii) Catholic            (iii) Muslim  
iv) Others (specify).....

5. What is your highest level of education? (i) No formal Education            (ii) Primary Education  
(iii.) Secondary Education            (iv) Tertiary Education (v) University

6. What is your Occupation?

7. (a) If you are employed, doing business or farming, what is your approximate income per month in Ksh? .....

(b) Is the money adequate for your basic needs of food, shelter and clothing? (i) Yes    (ii) No

8. Do you know your HIV status? (Yes)            ( No)

9. If question 8 is yes, how many years have passed since you were first diagnosed of HIV?

(i) 1-2 years ago            (ii) 3 to 4 years ago            (iii) 5 to 6 years ago  
(iv) 7 to 8 years ago    (v) 9 years and above

10. Have you ever disclosed your HIV status to any one? (i) Yes    (ii) No

11. If the answer in question 10 is no, what could be the reason of not being able to disclose your status? Specify.....

12. Are you on ARVs medication? (i) Yes    (ii) No

If no what could be the reason? Specify.....

13. (a) Since you started ARVs, has your medications been changed? (i) Yes    (ii) No

(b) If your medication has been changed, what was the reason?

Reason for change	Tick/Fill where appropriately
Resistance	
Side effects	
Others (specify)	

14. How long have you been on ARVs? .....

15. (a) Have you ever stopped ARVs after being commenced? (i) Yes (ii) No

(b) If you stopped ARVs after being commenced, what could have been the reason? ((i) Unavailability (ii) I recovered (iii) Side effects (iv) Others (Specify.....

.....

16. (a) Have you skipped taking drugs on daily basis from the time you were commenced? (i) Yes (ii) No

(b) If yes what was the reason? (a) Forgetting (b) Side effects (c) Others (specify)

17. What was your last viral load (done not more than 1 year ago) test-Copies per/Mil

..... (Confirmation will be done by retrieving information on the file)

18. Have you suffered any of the following diseases?

(i) Diabetes (ii) Epilepsy (iii) Stroke (iv) Head injury

(v) Psychiatric disease (vi) none

19. (a) Do you take any alcohol and substance (i) Alcohol (i) Yes (ii) No

(ii) Substance (i) Yes (ii) No

(b) If yes, which Brands(s).....

(c) How much? .....

(d) How often? .....

c) How long have you been using substance? .....

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20. Do you have any challenging problem on your life on how people look at you or relate (Psychological issue -Sigma/discrimination) (i) Yes (ii) No

If yes, which one? .....

21. (a) Do you have sexual partner(s) Yes No

(b) If Yes, How many.....

(c) Do you use any protective (Condom)? .....

## **APPENDIX II: International HIV Dementia Scale (IHDS)**

Memory-Registration – Give four words to recall (dog, hat, bean, red) – 1 second to say each. Then ask the patient all four words after you have said them. Repeat the words if the patient does not recall them all immediately. Tell the patient you will ask for recall of the words again a bit later.

1. Motor Speed: Have the patient tap the first two fingers of the non-dominant hand as widely and as quickly as possible.

4 = 15 in 5 seconds

3 = 11-14 in 5 seconds

2 = 7-10 in 5 seconds

1 = 3-6 in 5 seconds

0 = 0-2 in 5 second

---

2. Psychomotor Speed: Have the patient perform the following movements with the non-dominant hand as quickly as possible: 1) Clench hand in fist on flat surface. 2) Put hand flat on surface with palm down. 3) Put perpendicular to flat surface on the side of the 5th digit. Demonstrate and have the patient perform twice for practice.

4 = 4 sequences in 10 seconds

3 = 3 sequences in 10 seconds

2 = 2 sequences in 10 seconds

1 = 1 sequence in 10 seconds

0 = unable to perform

---

3. Memory-Recall: Ask the patient to recall the four words. For words not recalled, prompt with a semantic clue as follows: animal (dog); piece of clothing (hat); vegetable (bean); color (red).

Give 1 point for each word spontaneously recalled

Give 0.5 point for each correct answer after prompting

Maximum – 4 points per question

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Total International HIV Dementia Scale Score: This is the sum of the scores on items 1-3. The maximum possible score is 12. Patients with a score of  $\leq 10$  should be evaluated further.

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**Consent Form (Consent Statement) 2**

**Authorized person/Next of kin’s statement giving consent on behalf of the patient**

I have read this consent form /heard information read to me. I had a chance to discuss this research study with the researcher on behalf of the patient. I have had my questions answered in a language that I understand. The risk and benefit have been explained to me. I understand that my patient participation in the study is voluntary and that I may choose to withdraw the patient from the study any time.

I understand that all efforts will be made to keep information regarding personal identity of the patient confidential. By signing this consent, I have not given up any of the legal rights that the patient have as a participant in research study

I agree that the patient participate in this research study      Yes                      No

I agree that the patient provide required information and participate in the interview and assessment as per the research tools      Yes                      No

Participant name (Patient).....Date.....

Name of the Person signing on behalf of the patient .....

Relationship.....

Signature.....      Date.....

**Researcher’s statement**

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe the participant has understood and has willingly and freely given his/her consent.

Researcher’s  
Name.....Date.....

Signature.....

For more information contact.....at.....

From.....to.....

**APENDIX IV: Time schedule**

<b>ACTIVITY</b>	April- August 2016	Sept- Oct 2016	Oct- Dec 2016	Jan-Feb 2017	March 2017	April 2017	May 2017	June- October 2017
Proposal Development								
Departmental Approval								
Research & Ethics committee approval								
Data collection								
Data Analysis								
Presentation of the results								
Report Writing and submission								

**APENDIX V: Budget Estimate**

<b>Item</b>	<b>Cost in Ksh</b>
Stationary and Tools	20,000
Ethical approval cost	2,000
Typing, Printing, Photocopy, Binding and Purchasing a clock	24,000
Internet services	12,000
Report writing, Printing and binding	10,000
Consultancy-Data analysis	20,000
Communication and Transport	16,000
Contingencies	9,900
<b>Totals</b>	<b>108,900</b>