SEROPREVALENCE OF HEPATITIS C AMONG HIV INFECTED ADULT PATIENTS ATTENDING COMPREHENSIVE CARE CENTER AT KENYATTA NATIONAL HOSPTIAL

A CROSS SECTIONAL STUDY

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Signature Date

Certification

The undersigned certifies that this dissertation is the work of the candidate carried out during his training in Master of Science under my direct supervision.

The undersigned certifies that I have read and hereby recommend it for consideration by University of Nairobi, the dissertation entitled; **SEROPREVALENCE OF HEPATITIS C AMONG HIV INFECTED ADULT PATIENTS ATTENDING COMPREHENSIVE CARE CENTER AT KENYATTA NATIONAL HOSPITAL**

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Dedication

To Edith, Jezreel and Moriel.

Acknowledgement

I am grateful to God for life, strength, health and other blessings, that am aware and un aware of.

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List of acronyms

ART	Anti-Retroviral Therapy
AIDS	Acquired Immune Deficiency Syndrome
CI	Confidence Interval
CCC	Comprehensive Care Center
DM	Diabetes Mellitus
ELISA	Enzyme Linked Immune Absorbent Assay
ERC	Ethics Review Committee
HAART	Highly Active Antiretroviral Therapy
HBV	Hepatitis B virus
HBsAG	Hepatitis B surface Antigen
HCV	Hepatitis C Virus
HIV	Human Immuno Deficiency Virus
IFN	Interferon
IV	Intravenous
IDUs	Intravenous Drug Users

KNH	Kenyatta National Hospital
MSM	Men who have Sex with Men
OR	Odds Ratio
PCR	Polymerase Chain Reaction
PEG	Pegylated Interferon
PHLIV	People Living with HIV
RIB	Ribavirin
RNA	Ribose Nucleic Acid
RT	Reverse Transcriptase
SVR	Sustained Virologic Response
SPSS	Statistical Package for Social Sciences
STI	Sexually Transmitted Infections
TTI	Transfusion Transmitted Infections
UON	University of Nairobi

Abstract

Background

Hepatitis C virus (HCV) has emerged as the second major viral infection after human immunodeficiency virus within the past two decades and co infection with HIV represents a major problem, with a significant impact in terms of morbidity and mortality associated with liver disease. Routine screening for hepatitis C is not done as part of comprehensive provision of care and treatment for HIV/AIDS.

Objective

The study aimed at assessing the prevalence of Hepatitis C virus infection and associated risk factors amongst HIV/AIDS adult patients attending comprehensive care center at Kenyatta National Hospital.

Methodology

This was a hospital based cross sectional study conducted among HIV/AIDS patients attending comprehensive care center at Kenyatta National Hospital, from July to August 2014 involving 240 participants who were 18 years and above.

Testing for antibodies against HCV was done using SD-Bioline rapid diagnostic test kits and risk for HCV acquisition was assessed using a researcher administered data collection sheet, which also looked at some social demographic features.

Data analysis was done by SPSS version 16 statistical software

Results

The Prevalence of HCV among Adult HIV/AIDS was 0%.Among risk factors assessed, sexually transmitted infections accounted for 20.4% of all risk factors. None of the participants had a history of intravenous drug use.

Conclusion

The sole determinant of HCV infection among adult HIV/AIDS patients is the route by which HIV is acquired, with intravenous drug use accounting for the majority of HCV infection. Sexual transmission accounts for low risk of HCV acquisition.

Screening for HCV infection among HIV/AIDS patients should take into account the presence of possible risk factors contributing to HCV acquisition.

1.0 CHAPTER ONE

Introduction

1.1Background

As hepatitis C virus infection is transmitted with high efficacy via blood to blood contact, the prevalence of HCV within different countries, regions and populations is closely related to the incidence of blood borne (mainly intravenous drug use) HIV infection. HCV infection is one of the most important public health problems today. It is estimated that more than 170 million individuals are infected with HCV worldwide, most of them chronically **(**Lakoseljac *et al*, 2007). Hepatitis C was first recognized as a cause of transfusion associated acute and chronic hepatitis in 1989 and, plays a major role as a cause of chronic liver injury with potential for neoplastic degeneration. It is mainly transmitted by parenteral route; however although with lower efficacy, it may also be transmitted by sexual intercourse and by the mother to child route. HCV is responsible for about 350,000 deaths annually; among western countries, southern Europe and particularly Italy is among the most affected areas (Zaltran *et al*, 2012).

Africa has the highest WHO estimated regional prevalence (5.3%) with Egypt having the highest prevalence (17.5%) of HCV in the world; Kenya's prevalence among high risk groups is 1.7% (Karoney *et al,* 2013). Many HIV-positive individuals in sub-Saharan Africa are co-infected, a systematic review and Meta analysis, showed anti-HCV prevalence rates of 7% among HIV-infected individuals.HIV is associated with a higher prevalence of HCV in this region (Barh et

al, 2010). If untreated, chronic Hepatitis C can progress to cirrhosis and hepatocellular carcinoma in a subset of patients (Kim *et al,* 2013).

1.2 Problem statement

For persons living with HIV, Hepatitis C is a major public health problem that must be controlled and possibly eradicated. The challenge arises because the hepatitis C virus is prevalent among HIV infected persons in most parts of the world, and additionally, HIV worsens all HCV outcomes and may add additional individual, economic and psychosocial complications to HIV disease. The prevalence of HCV infection amongst HIV/AIDS patients in Kenya is still unknown; the study will try to highlight for the first time, the prevalence of HCV infection amongst HIV infected adult patients at KNH Comprehensive care center (CCC).

1.3 Justification

Current ART treatment regimens are not effective against HCV. Tests for the detection of HCV are not readily available, are expensive and therefore HCV screening is not part of regular practice in the care of HIV/AIDS patients. There was a need to conduct this study in Kenya, particularly amongst HIV/AIDS patients attending CCC at KNH so as to know the prevalence of the disease and associated risk factors and possibly provide suggestions to treatment options.

1.4Research question

- What is the prevalence of HCV among HIV infected adult patients attending comprehensive care center at Kenyatta National Hospital?
- What are some of the associated risk factors for HCV acquisition in this population?

1.5 General Objective

To assess the prevalence of Hepatitis C virus infection and associated risk factors amongst HIV/AIDS adult patients attending comprehensive care center at Kenyatta National Hospital.

1.6 Specific Objectives

1. To determine the prevalence of HCV infection among HIV infected adult patients attending comprehensive care center at KNH
2. To determine the gender and age distribution of HCV infection among HIV infected adult patients attending comprehensive care center at KNH

1.7 Literature review

Virology

Hepatitis C virus (HCV) is a hepatotropic RNA virus of the genus *Hepacivirus*, in the Flaviridae family, originally cloned in 1989 as the causative agent of non A,non B hepatitis. It causes acute and chronic hepatitis in humans and chimpanzees with a high propensity for chronicity (Kim *et al*, 2013).

Transmission

Intravenous drug use has been reported as the main risk factor for hepatitis C virus (HCV) infection. Injecting Drug Use (IDU) is a major risk for transmission of HCV, with seroconversion occurring relatively early in injecting careers. Persistent hepatitis C viraemia, increasing age and excessive alcohol consumption independently predicted disease progression in infected patients. While interferon based therapies reduced quality of life during treatment,

improvement on baseline quality of life was achieved post treatment particularly when sustained viral response was achieved. Much of the negative social impact of chronic infection was due to association of infection with IDU and inflated assessment of transmission risks. Perceived discrimination was commonly reported in health care settings, potentially impeding health care access. Perceptions of stigma and experiences of discrimination also had direct negative impacts on wellbeing and social functioning (Miller *et al,* 2012).

Other modes of transmission have also being implicated in the acquisition of HCV infection. In a prospective screening study amongst Native American populations, the most common potential risk factors for chronic HCV infection were IDU or cocaine use, tattoos and having a sexual partner with HCV (Neumeister *et al,* 2007). Available data on HCV in Africa reveal high prevalence in patients with hepatocellular carcinoma or chronic liver disease; (Burundi; 55%, Rwanda 45.7%) and sexually transmitted diseases (Ethiopia; 38.2%) (Karoney *et al,* 2013).

Virus distribution globally

The Arab world has a unique geography and consists of over nineteen countries which share the same heritage and customs and do speak the same language. In this area, the epidemiology of Hepatitis C is not well understood, however Hepatitis C virus was found to be endemic in Arabia (Daw *et al,* 2012). In mashdad, Iran, a population based study to assess the prevalence of Hepatitis C virus, the overall prevalence of Hepatitis C was found to be 0.2% by using ELISA method; however the overall Hepatitis C virus infection prevalence was found to be 0.13% with RT-PCR method (Shakeri *et al,* 2012).

The serostatus of such a virus was found to be variable among these countries with uniform patterns of genotype. Such prevalence varies tremendously according to the risk factors involved such as blood and blood products, haemodialysis, IVand percutaneous drug users and occupational. Habitual and social behaviors were found to be the most important factors involved. Hepatitis C will have major social, economic and even political burdens on such young and dynamic society (Daw *et al*, 2012).

Analysis of public health surveillance data suggests that, in England and Wales, HCV risk prevalence among IDU's declined during the 1990's but that trend reversed after 1998,such that in 2006 in some areas and among some subgroups of IDU's,HCV prevalence was approaching or even greater than in 1992,with marked geographical differences in HCV prevalence remain. The risk of HCV infection was estimated to increase monotonically with injecting duration. Women are more likely to be infected than men, and older injectors are more likely to be infected than younger injectors (Sweeting *et al*, 2013).

The prevalence of HCV in the general population of Africa ranges between 0.1% and 17.5%, depending on the country. The countries with the highest prevalence include Egypt (17.5%), Cameroon (13.8%) and Burundi (11.3%). The countries with the lowest prevalence include Zambia (0.2%), Kenya (0.9%), Malawi (0.7%) and South Africa (0.1%) (Karoney *et al*, 2013).

Treatment

Until recently, the standard care for patients with chronic hepatitis C involved dual therapy with pegylated Interferon (IFN) alpha and Ribavirin (PEG IFN/Riba) in most countries; dual PEG IFN/Riba therapy achieved sustained virologic response (SVR) in only 50% of patients infected

with the more common HCV genotype (genotype 1) compared to 80% SVR rate in patients infected with HCV genotype 2 or 3.

Combined PEG IFN/riba therapy is costly and prolonged (i.e. 24 - 48 weeks) with numerous adverse effects that are difficult to tolerate. In 2011, two inhibitors of the virally encoded NS3/A4 protease became available as a part of standard therapy in some countries, especially against HCV genotype 1 (Kim *et al,* 2013).

HCV-HIV Co infection

Hepatitis C has emerged as the cause of the second major epidemic of viral infection after human immunodeficiency virus (HIV) within the past two decades, with co-infection with HIV and HCV represents a growing problem for the future (Mohsen *et al,* 2002). Considering the high cost of HCV screening, routine HCV testing is not recommended among all HIV patients in health settings with limited resources. HCV screening is recommended to be limited to investigating HIV positive patients with features of liver disease in order to identify HCV as a possible cause (Walusansa *et al*, 2009). Prevalence of HCV amongst HIV infected individuals in TamilNadu state in India was 2.1 % (Padmapriyadarsini *et al*, 2006). Prevalence of HCV in earth quake affected areas of Pakistan, Out of 245 samples tested, 3.26% were found positive for HCV and 0% for HIV, in 2005. The same methods were used to analyze samples collected in the second round of screening in the same area, in September 2006, 5.51% were positive for HCV and 0% for HIV (Khan *et al,* 2008). In India, the prevalence of HCV in HIV infected individuals was 3.02% and co-infection was predominant in the age group 41-50 years (Ponamgi *et al,* 2009). A practical way to regularly screen HIV infected patients for acute HCV irrespective of perceived risks or symptoms is needed. In a cross-sectional study, conducted in young Thai men,

the prevalence of HCV infection in sampled men who were HIV-1 positive was 8.8% whereas it was 2.2% for those who were HIV-1 negative (Jatpai *et al,* 2010). Showing a strong correlation between HIV infection and HCV acquisition.

In a study to determine the prevalence of human immune deficiency Virus type-1(HIV-1) and HCV amongst IDU's who use high risk inner city locales in Miami, Florida, overall 25% were not infected with either virus,31% were HIV-1/HCV co-infected,8% infected by HIV-1only and 36% infected by HCV only. The results of the multivariable analyses showed that more years using heroin was the only significant risk factor for HCV only infection and for HIV-1/HCV co-infection (Mc Coy *et al*,2004). In assessing the prevalence of hepatitis C virus and HIV infection among IDU's in two Mexican cities bordering the US, overall HCV and HIV prevalence was 96% and 2.8% respectively and was similar in both cities. Most IDU's (87.5%) reported passing on their used injection equipment to others and 85.9% had received used equipment from others (White *et al,* 2007).

HCV is infrequently evaluated and treated in an urban HIV clinic population, like KNH and many other comprehensive care centers in Kenya. In a retrospective cohort study of HIV/Hepatitis C (HCV) co infected patients conducted at Washington University in the USA, 44% were evaluated for HCV treatment.Approimately one half of patients in an HIV specialty clinic were evaluated for HCV therapy and 16% received treatment, but the median time to treatment from the time of HCV diagnosis was 4 years. Further efforts to identify and to overcome barriers to HCV treatment are warranted (Scott et *al,* 2009). In a cross-sectional study done at Mulago Hospital in Uganda, the prevalence of HCV among HIV infected adults (Mean age 33.9 years) was 3.3%, no information was found on similar studies done in Kenya.

In a population based cross-sectional study to determine HCV risk factors in southern Brazil, the prevalence of blood transfusion among the people who were interviewed was 14.98%,16.16% of the people had a tattoo,7.23% wore a piercing,1.09% said they had already injected illicit drugs and 12.39% reported previous hospitalization(Kvitko *et al,* 2013).

Blood transfusion is a major risk factor in the acquisition of HCV, in a systematic review in Chinese mainland to assess the prevalence trend of HCV infection among blood donors, the pooled prevalence of HCV infection among blood donors was 8% (Gao *et al*, 2011).

In Canada, between 1994 and 2004, there were 4002 HCV related hospitalizations, 22% were liver related. Liver related hospitalizations, lengths of stay and hospital mortality increased approximately four-fold on an average of 15% to 18% annually (Myers *et al,* 2008).

A study in Europe to examine the impact of HCV on patient reported outcomes, burden of HCV was assessed in terms of work productivity loss, activity impairment, health related quality of life, health care resource utilization and associated costs.HCV patients (n-286) had more work impairment (30% vs. 18%),more impairment in non work activities (34% vs28%) and more annual physician visits per patient (19.8% vs. 13.3%); health related quality of life was also lower among HCV patients (Vietri *et al*, 2013).

Prevalence of HCV infection among sickle cell disease patients, in relation to a background history of blood transfusion, through anti HCV antibody screening test, amongst adult sicklers, 14.4 % were positive by anti-HCV screening, 92.3% had a record of blood transfusion, 70.7% had a record of blood transfusion of various units of which 60% of those transfused had at least up to 4 units of blood transfusion (Olaniyi *et al*, 2008).

There's a strong association between diabetes mellitus and HCV infection in some populations. However, the reason why chronic HCV infection is prevalent in DM remains unknown. In a study to determine the prevalence of HCV infection in a population of Nigerian diabetics compared with the general population, as well as to assess the influence of sex and age on HCV in the same diabetic population, a total of 115 diabetic patients were compared with 2,301 blood donors matched by recognized risk factors to acquire HCV infection. One person tested positive for HCV infection among 115 diabetic patients of whom 60 were males and 55 were females. Among the control group which consisted of 2,301 adults, 2.2% tested positive for HCV (Adegoke *et al,* 2008).Amongst pregnant women in Gabon, 2.1% were infected with HCV and increased significantly with age, being 1.3% at 14 – 20 years, 1.1% at 21-25 years, 1.9% at 26 - 30 years, 1.4% at 31-35 years and 6.0% at >35 years (Adome *et al,* 2008).

Viral hepatitis (HBC and HCV) transmitted by parenteral route is emerging as a far more dreaded public health challenge than any other illness. In a study in Kanpur to assess the prevalence of HBV and HCV in blood donors during the period 1997 through 2005, a total number of cases studied was 115, 073, HBsAG positive cases 1976(1.7%). Anti HCV positive cases 463 (0.4%).The overall picture showed a more or less stable prevalence rate of hepatitis among blood donors, who were apparently healthy (Jaiswal *et al,* 2002).

Results of global systematic reviews to assess the epidemiology of viral hepatitis among people who inject drugs, eligible reports of anti-HCV among IDUs were located for 77 countries. Prevalence was 60-80% in 26 countries and >80% in 12.We estimate worldwide about 10 million (range 6.0 – 15.2million) IDUS might be anti-HCV positive. China (1.6million), the USA (1.5 million) and the Russian federation (1.3 million) had by far the largest such

populations. HBsAG reports were found for 59 countries ranging from 5-10% in 21 countries and over 10% in 10.World wide,6.4 million IDU might be anti-Hbc positive(2.3-9.7 million) and 1.2 million(0.3-2.7 million) HBsAG positive (Nelson *et al*,2011).

In retrospective cohort study among blood donors from rural Ghana to investigate the prevalence of hepatitis B and C infections and co infections among blood donors in a rural community, samples of blood donated between January 2007 and December 2008 were screened for hepatitis B and C viruses at the Agogo Presbyterian hospital. Results obtained showed that the prevalence of hepatitis B viral infection (HBV) was highest in females (21.4%) in 2006 than males in the same year 13.2%. On the other hand, HCV infections was highest among males at 11.6% in 2007. HBV and HCV co infection was higher in males 2.6% than females 1.3% in 2007. The overall prevalence of HBV and HCV was 13.8 % and 9.4% respectively in 2006.The rate of co infection of HBV and HCV however increased from 1.6% in 2006 to 2.2% in 2008 in males and from 0% in 2006 to 1.2% in 2008 in females. The results concluded that, single infections of HBV and HCV reduced but co infection of these transfusion transmitted infections (TTI) increased (Nkrumah *et al*, 2011).

Approximately 98% of HIV-1 infected hemophiliacs are also co infected with hepatitis C.Men with hemophilia exposed to HCV and HIV are 4 fold more likely to progress to liver related death compared with HIV in-infected men. For persons living with HIV, hepatitis C is a major public health problem that must be controlled and could be eliminated. The challenge arises because HCV is prevalent among HIV infected persons in most parts of the world, because HIV worsens all HCV outcomes and because HCV may add additional individual economic and psychosocial complications to HIV disease. Despite major benefits of antiretroviral therapy on

HIV outcomes, antiretroviral therapy is not sufficient to halt the complications of HCV (Thomas *et al*, 2011).

HCV affects all age groups, infected with HIV and those not infected. In a study to evaluate hepatitis C virus and Human immunodeficiency virus-1(HIV) co-infection in children in Benin City, Nigeria, the prevalence of HCV was found to be 0.25% amongst all HIV-1 children screened. There was no obvious influence of previous blood transfusion, exposure to intramuscular injections, place of delivery or educational status of the children's parents on the results obtained (Ogboghodo *et al*, 2008).

Co-infection of HBV or HCV may compromise pediatric antiretroviral therapy (ART) in China. In a study to evaluate the sero-prevalence of HBV and HCV in children receiving ART and associated risk factors, 4.9% of children tested were HBsAG sero-positive and 9.6% were anti-HCV antibody positive. Multivariate analysis revealed that children infected with HIV through transfusion of contaminated blood or blood products were more likely to be anti-HCV antibody positive than those infected through other routes. The results concluded that, high prevalence of HBV and HCV co-infection in HIV infected children in China receiving ART demands routine screening for viral hepatitis co-infection, intensive prevention of childhood HBV and HCV transmission and modification of the management of Pediatric HIV infection (Zhou *et al*, 2010).

HCV can also be vertically transmitted; In a study to assess the prevalence of and factors associated with HCV infection in HIV infected and uninfected Thai pregnant women and the rate of HCV transmission to their infants, of the HIV infected women, 2.9% were HCV infected compared to 0.5% of HIV uninfected women.10% of infants born to co-infected mothers acquired HCV.The risk of transmission was associated with a high maternal HCV RNA but not

with HIV-1 load or CD4 count (Huong *et al,* 2010).In Nigeria, the prevalence of HCV/HIV co infection amongst pregnant women South of Nigeria was 8.3 % (Utoo *et al,* 2010)

Chronic HCV infection has become a major threat to the survival of HIV infected persons in areas where antiretroviral therapy is available. In co-infection, viral eradication has been difficult to attain and HCV therapy is underused. Medical management in co-infection will be improved by enhancing HCV detection, by addressing HCV earlier in co-infected persons and by consideration for HCV therapy (Taylor *et al,* 2012).

In individuals co – infected with HCV/HIV, it is always not easy to differentiate symptoms associated with either HCV or HIV related infection. Four major themes emerged from qualitative interviews;

Difficulty differentiating between HIV and HCV related symptoms

Commonly cited HCV related symptoms

Way to control or manage HCV related symptoms and

Lack of symptoms or tests to monitor HCV disease.

The most common theme that participants discussed was the difficulty of differentiating which symptoms were related to HIV or which were HCV related. Symptoms experienced by more than half of the participants were fatigue, shortness of breath, muscle aches, difficulty sleeping, bone aches, pain and headaches. The results however, suggest that for HIV/HCV co-infected sample, there was no greater symptom burden imposed by co-infection compared with being infected with either virus alone (Bove *et al,* 2008).

Without highly active antiretroviral therapies (HAART), HIV accelerates HCV disease progression including death, histological fibrosis/cirrhosis and decompensated liver disease. However the rate of hepatocellular carcinoma is similar in persons who had HCV and were positive for HIV or negative for HIV (Deny *et al,* 2009).

Since HIV and HCV are transmitted similarly, it is common to become infected by them simultaneously. In a prospective cohort study amongst patients who had a high prevalence of HCV-HIV co infection in Shiraz (South of Iran) to assess the impact of HCV on survival of HIV-infected individuals. The median survival time in HCV infected and un infected patients was 163.8 months and 194.8 months, respectively.HCV was also associated with increased mortality rate 2.13 times more in HIV infected patients than HCV uninfected patients.HCV increases AIDS related deaths (Rezaianzadeh *et al,* 2012).

Co-infection with HIV and HCV is common and has a deleterious effect on the natural history of chronic HCV. As control of HIV improved with HAART, liver disease gained notoriety as a major cause of mortality in co-infected patients. These patients show accelerated liver disease and are more likely to develop liver enzyme abnormalities and clinical liver toxicity when treated with HAART.Treatment of HCV with peg-interferon is thus indicated in most patients and has been shown to be relatively safe and effective (Rotman *et al,* 2009).

2.0 CHAPTER TWO

Methodology

2.1 Study design

This was a hospital based cross-sectional study.

2.2 Study area

The study was carried out at Kenyatta National Hospital (KNH) where the participants were recruited from the Comprehensive Care Center (CCC). The center attends to an average of 9000 HIV/AIDS clients, adults and children, out of which, 7500 are on antiretroviral therapy and sees an average of 150 clients per day. The working staff consists of six doctors, ten nurses, seven clinical officers and nine laboratory personnel that provide care and treatment services during clinic days. The clinic days run from Monday to Friday, from 0800 to 1700hours.

CCC is located within the premises of KNH, in its own building close to the main entrance of the hospital and opposite the university of Nairobi school of Pharmacy.KNH is a referral hospital and as such receives large numbers of patients from different parts of the country. It also serves as a primary health care facility for a significant proportion of the population in Nairobi in the middle and lower socio economic classes.

2.3 Study population

The enrollment strategy was based on adult HIV/AIDS patients/clients attending comprehensive care center at Kenyatta national hospital. All study subjects were at least 18 years old and attending at comprehensive care center at Kenyatta National Hospital, confirmed by a clinic card and center data base.

2.4 Inclusion criteria

Adult HIV/AIDS infected patients including pregnant women attending comprehensive care center at Kenyatta national hospital and willingly consented to participate in the study.

2.5 Exclusion criteria

- Individuals less than 18 years
- Adult patients/clients not attending comprehensive care center at Kenyatta national hospital
- HIV/AIDS adult patients attending comprehensive care center at KNH but refused consent.

2.*6 Sample size*

The prevalence of HCV amongst HIV infected individuals in Mulago Hospital in Uganda was 3.3 %(Walasunsa *et al*, 2009), this is the rate that was used for sample size estimation for the study, since the study was done in a similar setting and there had been no studies of a similar type that were done in Kenya.

The formula for sample size calculation used was; $N = Z^2PQ/d^2$,

Where: N = Minimum sample size

Z = Constant, standard normal deviation (1.96 for 95% confidence interval)

P = Population proportion with characteristic of interest

Q = 1-P

d = Acceptable margin of error

Z = 1.96

P = 0.033

Q = 0.967

d = 0.05

$$N = \frac{(1.96)^2 \times 0.033\ (1- 0.033)}{(0.05)^2}$$

N = 49 HIV/AIDS infected adults (Minimum sample size)

2.7 Sampling method

A random selection of patients attending comprehensive care center at (KNH) Kenyatta national hospital was employed. Every third patient/client was approached for entry during data collection.

2.8 Recruitment and consenting procedures

Local approval was sought from Kenyatta National Hospital/University of Nairobi-Ethics Review Committee (KNH/UoN-ERC). A written informed consent was obtained from the study participants by the principal investigator (Dr Ukio Kusirye Boniface) and a research assistant, prior to data collection and HCV antibody testing. The following information was given to each participant to ensure that they make an informed choice; a complete description of the aims of the study, infectious agent that was being screened, details of sample collection procedures, potential benefits and risks of their participation in the study and assurance of confidentiality of any information given as well as of the test results. Dignity of the study participants was upheld throughout the study. The case report form did not contain any identifying data to maintain participant's confidentiality. Potential risks of the study were minimal.

2.9 Data collection procedures

A standardized researcher administered case report form was used. Specific questions to identify risk factors for HCV infection were added. The questionnaire covered social demographic characteristics, percutaneous risk factors (i.e. history of blood transfusion, injection drug history, sexually transmitted diseases other than HIV).

The study participants received post test HCV infection test results and counseling via the principal investigator and his research assistant prior to result dissemination.

2.10 Variables

Dependent variables – Hepatitis C virus infection,

Independent variables- age (years from the year of birth), sex (gender defined as male/female), risk factors for HCV acquisition.

2.11 Materials

HCV rapid test kits, lancets, gloves, cotton swabs and methylated spirit.

The principal investigator and his research assistant were the only personnel involved in data collection.

2.12 Quality assurance procedures

The case report form was pretested before the actual data collection and the information obtained was used to further fine tune the report form. Specimen collection, labeling, processing, and testing, was done in accordance to the standard operating procedures of the laboratory and according to the manufacturer's recommendations.

2.13 Procedures

Structured case report forms were used to collect demographic information, screening for risk factors such as history of drug use and injection practices, sexually transmitted diseases and history of blood transfusion and then all participants tested for hepatitis C virus infection.

Blood specimens were collected by a finger prick and two drops of blood spread on the test kits' sample well. Results were read after 5 to 20 minutes (refer to the full protocol in Appendix 4-page-)

2.14 Data management and analysis

Data entry was done using Microsoft excel followed by editing and analysis using statistical package for social sciences (SPSS). Descriptive statistics was be done by cross tabulating explanatory variables against outcome variables.

P- Value < 0.05 was considered as statistically significant.

2.15 Study limitations

The study pitfalls included forgotten or lost patient's clinic cards. Cross-checking for missed information with clients and CCC health personnel minimized this limitation.

Risk of behaviors being self reported and possibly subject to bias from recall and socially desirable responding. Assurance of responses to be kept confidential minimized this limitation.

Reliance on Anti-HCV testing as criteria for diagnosing HCV infection, this does not necessarily represent active or early HCV infection as does HCV RNA testing. Relying on previous infection with HCV minimized this limitation.

2.16 Dissemination plan

The results of the study were disseminated to study participants, KNH, CCC, University of Nairobi library, UNITID library and were presented to university of Nairobi-UNITID community academic forum.

For those who tested negative, information on the modes of acquisition of HCV and ways to prevent or reduce risk of acquisition were offered.

3.0 CHAPTER THREE

Results

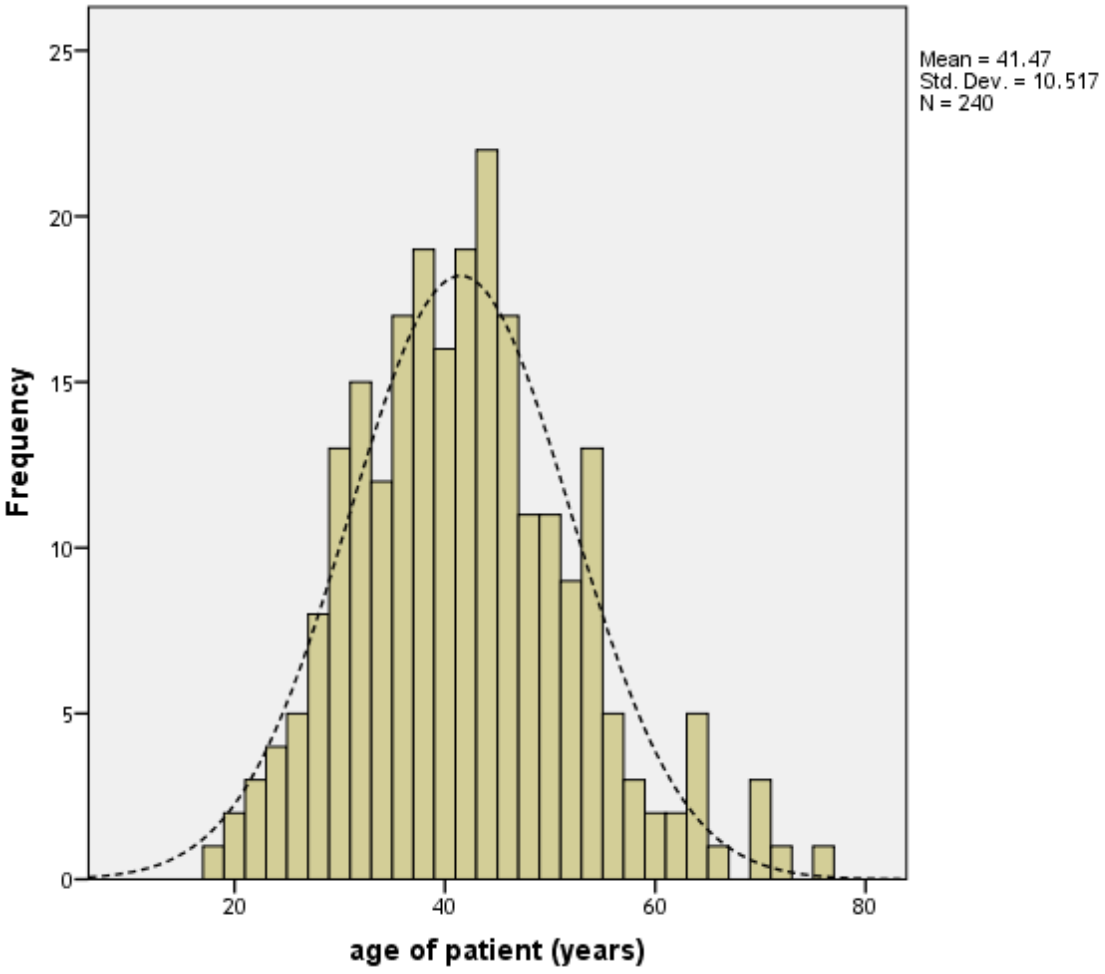
Two hundred and forty (240) HIV/AIDS patients were recruited from Comprehensive Care Center at KNH.

A total of 21 days were spent in the recruitment, each day from Monday to Friday during clinic days.

3.1 Social demographic characteristics of the study participants

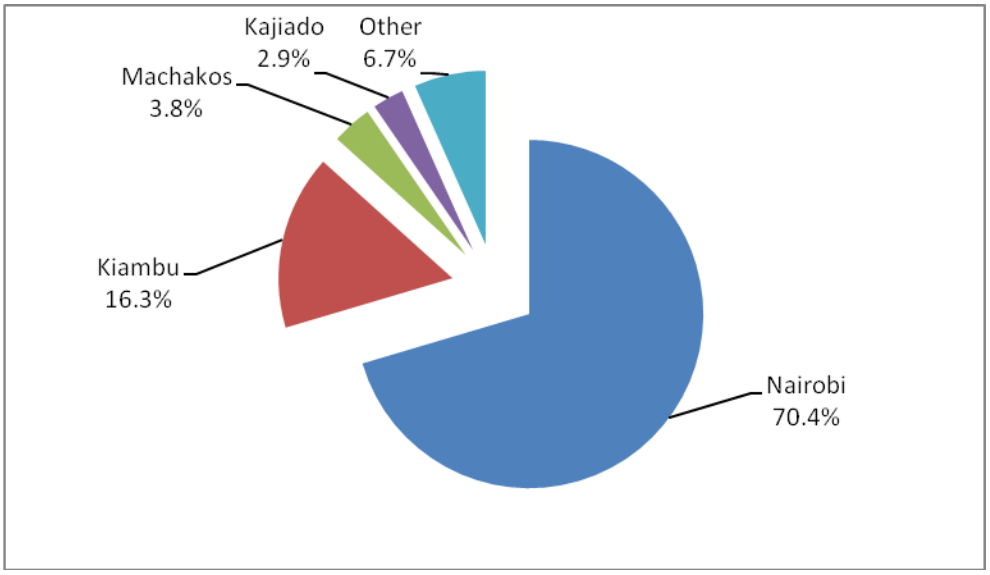
The mean age of the participants was 41 years with a standard deviation of 11. The ages ranged between 18 years and 76 years .Majority of the participants were between 30 and 50 years .The age of the participants followed a normal distribution (see figure 1 below).

Figure 1: Age Distribution of study participants



70% of recruited participants were residing in Nairobi, 16% in Kiambu, 4% in Machakos, 3% in Kajiado and 7% in other counties (See figure 2,below).

Figure 2: Residence of study participants



72% of all recruited participants were females, whereas males accounted for 28%.The mean age among male participants was 44 years and that for females was 41 years, but this observation was not statistically significant. (See table 1 and 2 below).

Table 1.Gender of patients

Gender	Frequency	Percent	Cumulative percent
Female	172	72%	72%
Male	68	28%	100%
Total	**240**	**100%**	

Table 2.Mean age by gender of Patients

Gender of Patient	Total	Ag of Patient		Mean Diff	95%CI (Mean diff)	p-value
		Mean	**Std Deviation**			
Male	68	44	11	3	-0.1-5.8	0.061
Female	172	41	10			

3.2 Risk Factors assessment

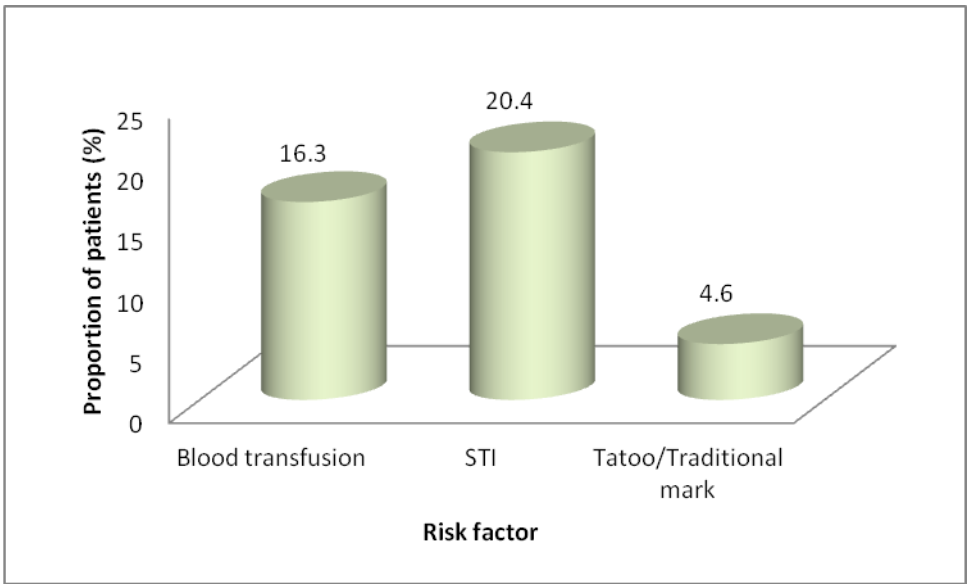
Of all participants recruited, 64% did not have any of the risk factors assessed, 30% reported having one of the risk factor and 6% reported to two of either of the risk factors assessed.

Table 3.Total Number of responses on each risk factor from study participants

No of Responses	Frequency	Percent	Cumulative percent
0	155	64%	64%
1	71	30%	94%
2	14	6%	100%
Total	**240**	**100%**	

20% of the participants, responded positively to a history of sexually transmitted infections other than HIV, 16% admitted to having a history of blood transfusion and 5% admitted to having a tattoo/traditional mark. None of the participants responded positively to a history of illicit drug use. (See figure 3 below).

Figure 3: Distribution of risk factor responses



When the risk factors responses were stratified according to sex, 12% of males responded positively to a history of blood transfusion compared to 18% of females but this was not statistically significant.38% of males responded positively to a history of sexually transmitted infections compared to 13% of females and was statistically significant(P-Value <0.001),while 4% of males admitted to having a tattoo/traditional mark(s),compared to 5% females, but this again was not statistically significant.(see Table 4 below).

Table 4.Risk factor responses by gender

Risk factors	Total	Gender of Patient		OR(95% CI)	P-Value
		Male	Female		
		No. (%)	No. (%)		
Blood transfusion	39	8 (12)	31 (18.0%)	0.6 (0.3-1.4)	0.236
STI	49	26 (38%)	23 (13%)	4.0 (2.1-7.7)	<0.001
Tattoo/traditional mark(s)	11	3 (4%)	8 (5%)	0.9 (0.2-3.7)	1.000

When responses for risk factor assessment were categorized according to age, there was a statistically significant difference in mean age between those who responded positively to a history of blood transfusion and those that did not. There was also a significant difference in mean age between those who responded positively to a history of sexually transmitted infections and those who did not; however no statistically significant difference in mean age was noted in mean age difference between those who responded positively to having a tattoo/traditional mark(s) and those who didn't (see table 5 below).

Table 5.Mean age difference among risk factor responses

Risk Factors	Total	Age of patient		Mean Difference	95% CI(Mean Diff)	p-value
		Mean	Std Deviation			
History of blood transfusion						
Yes	39	46	12.2	5	1.5-8.6	0.006
No	201	41	10.0			
Sexually transmitted infections						
Yes	49	45	8.9	4	1.4-8.0	0.005
No	191	41	10.7			
Tattoos/Traditional Marks						
Yes	11	46	3.9	5	-1.6-11.1	0.144
No	229	41	0.7			

3.3 Prevalence of HCV

Of the 240 HIV/AIDS adult patients tested, none of them tested positive for the presence of HCV antibodies .The patients were screened for anti HCV antibodies using SD-Bioline rapid tests kits which contain recombinant HCV antigens (Core, NS3, NS4 and NS5) similar to Elisa-Rapid test kits. These antigens detect antibodies to HCV.

4.0 CHAPTER FOUR

Discussion of Results

The results of the study showed that the prevalence of HCV using a rapid diagnostic test kit to detect HCV antibodies was 0%.Kenya's HCV prevalence in the general population is low, stands at 0.9%.High risk groups for HCV acquisition include, Intravenous drug users,HIV-infected patients on hemodialysis,patients with a history of blood transfusion or organ transplant, healthcare workers with needle stick injuries, children born to HCV infected mothers and sexually active adults with multiple partners. Kenya still, ranks low among high risk groups.

HCV prevalence in different parts of the world is masked by marked differences based on the route through which HIV was acquired. Intravenous drug use is the most efficient transmission route of HCV.

The most efficient means of HCV transmission is percutaneous exposure to blood, with transmission efficiency 10 times higher for HCV than for HIV.

HCV is less likely transmitted by sexual means, which accounts for the majority of HIV transmission in Kenya and most other parts of the world. A study done among heterosexual couples followed prospectively over many years, established that HCV is not readily spread via heterosexual sexual transmission. Sexual transmission of HCV is increased by indulging in high risk sexual practices such as, men who have sex with men and presence of sexually transmitted diseases (Taylor *et al*, 2012).

The fact that none of the participants had any history of intravenous drug use, could explain the results observed.

However the risk of HIV and HCV acquisition via blood transfusion is highly unlikely in the present era because of improved techniques in detecting early infection with these viruses.

Since the risk of HCV acquisition through sexual means among heterosexuals is minimal, the study should have included more study participants. The study however, was limited by financial constraints. The study also should have looked into more sexual behavior practices and other practices related to increased risk of HCV transmission.

Infection with HCV, through any of the known means is followed after 6-8 weeks of seroconversion to produce antibodies against HCV.In this regard then, early infection could not be detected by rapid chromatographic rapid test method used in the study

The findings cannot be generalized to all HIV/AIDS patients in Kenya, because only a few of the known risk factors were taken into account in this study. Other studies that look into more risk factors need to be conducted.

There are eleven HCV genotypes, 1-11, with many subtypes; a, b, c and about 100 different strains. Genotypes 1-3 are widely distributed globally, with genotypes 1a and 1b accounting for 60% of all infections worldwide. Genotype 4 is characteristic for the Middle East, Egypt and Central Africa. Genotype 5 is almost exclusively found in South Africa (Karoney *et al*, 2013).

Further studies need to be done on the genotype(s) most common in Kenya and development of appropriate rapid testing kits to detect antibodies to the most common available genotype(s).

5.0 CHAPTER FIVE

Conclusion and Recommendations

The study was set out to determine the prevalence of HCV infection among adult HIV/AIDS patients attending comprehensive care center at KNH and to assess some of the risk factors associated with HCV acquisition.

The findings indicate lack of HCV infection among HIV/AIDS adult clients attending CCC, with none of the respondents having any history of intravenous drug use, which is the main risk factor associated with HCV acquisition.

The study is among the first HCV prevalence studies among HIV/AIDS patients, hence provides baseline data that can contribute to knowledge on the magnitude of the disease, stimulate further research on the disease and also inform policy on risk assessment.

Areas where the study can be used include the following;

i. The lack of any patients infected with HCV, together with the absence of a history of intravenous drug use among study participants, illustrates the lower risk of HCV transmission via sexual means while controlling for other sex related practices.

ii. The results can be used to sensitize health care providers on the importance of assessing for sex related and other risks associated with HCV acquisition among HIV/AIDS patients at initial diagnosis of HIV.

iii. The study, being a descriptive one, serves to provide useful baseline information on the magnitude of HCV infection among HIV/AIDS adult patients, as well as the need for future studies using more robust study designs, sample sizes and sampling techniques to further explore suspected risk factors, transmission patterns as well as biological characteristics of the virus in the country in an attempt to fully understand local disease dynamics.

iv. In the long term, there may be need for additional control measures for example, screening for HCV infection among HIV/AIDS patients with high risks for HCV transmission as well as those with symptoms and signs of liver malfunction. This will be arrived upon after careful analysis of studies with stronger evidence on the magnitude of HCV infection among high risk HIV/AIDS patients.

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APPENDICES

Appendix 1: Data collection sheet (Case report form)

SEROPREVALENCE OF HCV AMONG HIV INFECTED ADULT PATIENTS ATTENDING COMPREHENSIVE CARE CENTER AT KENYATTA NATIONAL HOSPITAL.

Study No ……..

Date ……..

A. SOCIAL DEMOGRAPHIC INFORMATION

1 Age .....(Years)

2 Sex:

Male ☐

Female ☐

3 Place of Domicile ……

B. HEPATITIS C VIRUS ACQUISITION RISK ASSESSMENT

		YES	NO
I	History of blood transfusion		
Ii	History of sexually transmitted diseases other than HIV		
iii	History of illicit intravenous drug use		
iv	History of Tattoos or traditional marks		

C. HEPATITIS C STATUS

i. Positive ☐

ii. Negative ☐

Appendix 2

CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY

Project title: SEROPREVALENCE OF HEPATITIS C VIRUS INFECTION AMONG HIV INFECTED ADULT PATIENTS ATTENDING COMPREHENSIVE CARE CENTER AT KENYATTA NATIONAL HOSPITAL

Introduction

Hello, my name is Kusirye Ukio, from the University of Nairobi, Institute of tropical and infectious diseases. I am conducting a study to determine the prevalence of Hepatitis C virus infection among HIV infected adults who are attending care and treatment clinic. All you are required to do is to allow me to screen you for the presence of Hepatitis C virus infection.

You are not obligated to participate and can withdraw from the study at any time.

Purpose of the research

The purpose of this study is to find out the magnitude of Hepatitis C virus infection among HIV infected adult patients. The result will help us review current Anti retroviral treatment regimens and formulate new treatment regimens that combat both HIV and Hepatitis C.

Type of research intervention

The research will involve drawing of blood and using rapid tests to detect the presence of infection with hepatitis C virus. The test will be done at a private location within the premises of Kenyatta national Hospital, care and treatment clinic.

Participant selection

You are being invited to take part in the this research because it will help us understand the magnitude of hepatitis C virus among HIV infected adults and see what interventions can be put in place to address the problem.

Voluntary participation

Your participation in this research is entirely voluntary. It is your choice to participate or not. If you choose not to participate all the services you receive at the clinic will continue and nothing will change.

Procedures

I would like to invite you to participate because; knowing the magnitude of Hepatitis C will help in implementation of strategies to address the problem. 2 milliliters of blood will be drawn. Each test should take approximately ten minutes. Only a single test to determine HCV infection will be performed. Please be assured that the results obtained will not be linked to any names or other identifying information.

Risks and discomforts

I am asking you to allow me to take your blood and perform the test for detecting Hepatitis C virus infection.Drawing of blood will be accompanied by a small amount of pain and bleeding that is short lived and may cause minor discomfort.

You do not have to take part in the study if you don't wish to do so. You do not have to give me any reason for refusing to take part in the study.

Anticipated payments

Participation in the study will not be accompanied by any form of payment (monetary or in kind) to any participant.

Additional expenses

The test is done during your routine clinic visits. It will warrant your additional time to conduct the test and obtain the results.

Benefits

There will be no direct benefits to you, but your participation is likely to help us formulate targeted strategies at addressing Hepatitis C virus infection among HIV-infected adults

Number of individuals to be enrolled

A minimum number of 49 patients will be enrolled into the study

Confidentiality

The results obtained from this research project will be kept private. Any information about you will be reported anonymously and no names will be used. Members of the Ethical review committee of the University of Nairobi can have access to the information while maintaining confidentiality.

You can ask me any questions about any part of the research study; if you wish to. Do you have any questions?

Whom Do I call if I have any questions or problems?

For questions about the study or research related injury, call or contact Kusirye Ukio,UNITID,University of Nairobi, Telephone **0700-479-607** or Dr Marianne Mureithi, PhD, Lecturer, Department of Medical Microbiology, College of Health sciences,UoN,Telephone **0703-704-711**

For questions about your rights as a research participant, contact professor Anastasia Guantai, who is the chair person of the ethical review committee at the University of Nairobi, by calling **(254-020)2726300 Ext 44355**, or make an appointment to see her in the department of medicine at the University of Nairobi.

I have read the following information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to be a participant in the study.

Name of participant _____

Signature of participant _____

Date _____

NB: A copy of this consent form should be given to you

Appendix 3

RIDHAA YA KUSHIRIKI KWENYE UTAFITI

Kichwa cha habari: KIWANGO CHA MAAMBUKIZI YA HOMA YA INI INAYOSABABISHWA NA VIRUSI VYA "HEPATITIS C" MIONGONI MWA WATU WAZIMA WENYE MAAMBUKIZI YA VIRUSI VYA UKIMWI (VVU), KATIKA KITUO CHA KUTOA TIBA NA HUDUMA, HOSPITALI YA TAIFA YA KENYATTA.

Utangulizi

Habari,kwa jina naitwa Kusirye Ukio kutoka chuo kikuu cha tiba Nairobi,ninafanya utafiti kujua ukubwa wa tatizo la homa ya ini, inayosababishwa na virusi vya "Hepatitis C" miongonni mwa watu wazima wanaohudhuria kliniki ya tiba na huduma.Ninachohitaji kutoka kwako ni ruhusa ya kuweza kukupima uwepo wa maambukizi ya homa ya ini inayosababishwa na virusi vya "Hepatitis C".

Sio lazima ushiriki na una weza kujiondoa kwenye ushiriki wakati wowote unapoona inafaa.

Kusudi la utafiti

Kusudi kuu la utafiti huu ni kujua kiwango cha maambukizi ya homa ya ini inayosababishwa na virusi vya "Hepatitis C" miongoni mwa watu wazima wenye maabukizi ya virusi vya ukimwi(VVU).Matokeo ya utafiti huu yatatuwezesha kupitia kwa upya tiba ya sasa kwa watu wenye virusi vya ukimwi na kuweza kuvumbua tiba mpya yenye kutibu virusi vya ukimwi pamoja na virusi visababishavyo homa ya ini (Hepatitis C virus).

Aina ya uchunguzi wa kitafiti

Utafiti huu utahusisha utoaji wa damu na kuiweka katika kipimo cha haraka cha kugundua maambukizi ya homa ya ini.Kipimo hiki kitafanyika katika sehemu yenye usiri,ndani ya chumba cha tiba na huduma katika hosptali ya taifa ya Kenyatta.

Uchaguzi wa washiriki

Unakaribishwa kushiriki katika utafiti huu kwasababu,itatuwezesha kujua ukubwa wa tatizo la homa ya ini isababishwayo na virusi vya "Hepatitis C" miongoni mwa watu wazima wenye maambukizi ya virusi vya ukimwi na kuona ni jitihada gani zinaweza kuchukuliwa kutatua tatizo hilo.

Ushiriki wa hiari

Ushiriki wako katika utafiti huu ni wa hiari.Ni uamuzi wako kushiriki au kutoshiriki.Ukiamua kutoshiriki,huduma zote unazopata katika kliniki hii zitaendelea na hakuna kitakachobadilika.

Utaratibu

Napenda kukukaribisha kushiriki kwenye utafiti huu kwasababu kwa kujua ukubwa wa tatizo la homa ya ini,kutatuwezesha kupanga mikakati ya kutatua tatizo hilo.

Kiasi cha mililita 2 za damu zitatolewa.Kila kipimo kitachukua takriban dakika kumi,ni kipimo kimoja tu cha kugundua maambukizi ya homa ya ini inayosababishwa na virusi vya "Hepatitis C' kitafanyika.

Tafadhali amini kuwa matokeo yoyote yatakayopatikana,hayata ambatanishwa na jina au taarifa yoyote ya utambulisho wako.

Athari

Naomba ridhaa yako ya kuweza kuchukua damu yako kwa ajili ya kupima uwepo wa maambukizi ya homa ya ini.Utoaji huu wa damu utaambatana na maumivu kidogo na uvujaji mdogo wa damu kwa muda mfupi.

Sio lazima kushiriki katika utafiti huu kama hujisikii kufanya hivyo.Huna haja ya kutoa sababu yoyote ya kutoshiriki katika utafiti huu.

Matarajio ya malipo

Ushiriki katika utafiti huu hauta ambatana na malipo ya aina yoyote,(pesa au mbadala wa pesa).

Gharama za ziada

Kipimo hichi kinafanyika katika siku zako za kawaida za kuhudhuria kliniki ya huduma na tiba.Itahitajika muda wako wa ziada kuweza kufanya kipimo hichi.

Manufaa

Hakutakuwa na manufaa ya moja kwa moja kwako,lakini ushiriki wako utatuwezesha kuja na mikakati ya kuweza kukabiliana na maambukizi ya virusi viletavyo homa ya ini,miongoni mwa watu wazima wenye maambukizi ya virusi vya ukimwi.

Idadi ya washiriki watakaohusika

Jumla ya washiriki wasiopungua 49 wanatarajiwa kuhusika katika utafiti huu

Utunzaji wa takwimu

Matokeo ya vipimo vya utafiti huu yatakuwa siri.Taarifa yoyote inayokuhusu haita ambatanishwa na jina .Wajumbe wa kamati ya kusimamia maadili ya utafiti,toka chuo cha tiba Nairobi,wana haki ya kupata matokeo ya vipimo vya utafiti ,kwa kuzingatia vigezo vya usiri.

Unaweza kuuliza maswali yoyote uliyonayo kuhusu jambo au sehemu yoyote ya utafiti huu pale unapotaka kufanya hivyo,je una swali lolote?

Je nitawasiliana na nani,pale ninapokuwa na maswali au matatizo?

Kwa maswali kuhusiana na utafiti huu au madhara yoyote yatokanayo na uchunguzi huu,wasiliana na Kusirye Ukio toka chuo cha tiba Nairobi,namba ya simu **0700-479-607** au Dr Marianne Mureithi, PhD, Mhadhiri,Chuo Cha tiba Nairobi,namba ya simu **0703-704-711.**

Kwa maswali yoyote kuhusiana na haki zako kama mshiriki katika utafiti huu,wasiliana na "professor" Anastasia Guantai,ambaye ni mwenyekiti wa kamati ya kusimamia maadili ya utafiti katika chuo cha tiba Nairobi,kwa kupiga namba **(254-020)2726300 Ext 44355** au weka ahadi ya kukutana naye ana kwa ana katika idara ya tiba,chuo cha tiba,Nairobi.

Nimesoma taarifa husika au imesomwa kwangu.Nimepata fursa ya kuuliza maswali kuhusu utafiti huu na maswali yote niliyouliza yamejibiwa kwa ufasaha.

Nimeridhia kwa hiari yangu mwenyewe kushiriki katika utafiti huu.

Jina la mshiriki _____

Sahihi ya mshiriki _____

Tarehe _____

Angalizo: Nakala ya ridhaa hii inatakiwa kukabidhiwa kwako.

Appendix 4

ONE STEP SD-Bioline Anti-HCV Test

1. Explanation of the test

Hepatitis C virus (HCV) now is recognized as a major agent of chronic hepatitis, transfusion acquired non-A, non-B hepatitis and liver disease throughout the world.

HCV is an enveloped positive sense, single stranded RNA virus.

Clinical diagnostic issues related to HCV are the detection of HCV antibodies in human serum, plasma or whole blood by immunoassay.

The major immunoreactive antigens of these proteins have been reported as core, NS3, NS4 and NS5 regions of HCV genome, which are known to be highly immunodominant regions.

For diagnosis of HCV infection, these recombinant proteins were used as capture materials of a immunochromatographic (rapid) test.

Compared to the first generation HCV test using single recombinant antigens, multiple antigens using recombinant proteins have been added in new serologic tests to avoid nonspecific cross-activity and to increase the sensitivity of the HCV antibody test.

The SD BIOLINE HCV test is an immunochromatographic (rapid) test for the qualitative detection of antibodies specific to HCV, in human serum, plasma or whole blood.

The SD BIOLINE HCV test contains a membrane strip, which is pre-coated with recombinant HCV capture antigen (core, NS3, NS4 and NS5) on test band region.

The protein, A-colloid gold conjugate and serum sample moves along the membrane chromatographically to the test region (T) and froms a visible line as the antigen-antibody protein react.

A gold particle complex forms with high degree of sensitivity and specificity. This test device has letters T and C as “Test Line” and “Control Line” respectively on the surface of the case.

Both the Test Line and Control Line in result window are not visible before applying any samples. The Control Line is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working.

2. Materials provided

SD BIOLINE HCV test kit contains the following items to perform the assay.

1) Test device pouched in a foil with a desiccant

2) Assay diluent

3) Package insert

Precautions / Kit storage and stability

1) The test device should be stored at 1~30^{o}C. Do not store in a refrigerator.

2) The test device is sensitive to humidity as well as to heat.

3) The test should be performed immediately after removing the test device from foil pouch.

4) It should not be used beyond the expiration date.

5) The shelf-life of the kit is as indicated on outer package.

6) Do not use the test kit if the pouch is damaged or the seal is broken.

7) The test device should not be re-used

Warnings

1) For in vitro diagnostic use only.

2) Do not eat or smoke while handling specimens.

3) Wear protective gloves while handling specimens. Wash hands thoroughly afterward.

4) Avoid splashing or aerosol formation.

5) Clean up spills thoroughly using an appropriate disinfectant.

6) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.

7) Do not mix and interchange different specimen.

8) Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test result.

9) Use of hemolytic samples, rheumatoid factors-contained samples and lipidemic, icteric samples impair the test results.

5. Specimen collection, storage and precaution

1) Whole blood

(1) Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture.

(2) If blood specimens are not immediately tested, they should be refrigerated at 2~8^{o}C .

(3) When stored at 2~8^{o}C , the blood specimens should be used within 3 days.

(4) For storage periods longer than 3 days, freezing is recommended. They should be brought to room temperature (1~30^{o}C) prior to use.

(5) Using the blood specimens in the long-term keeping more than 3 days can cause nonspecific Reaction and should be avoided

2) Plasma or Serum

(1) Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.

Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.

(2) If plasma or serum specimens are not tested immediately, they should be refrigerated at 2~8^{o}C . For storage period longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1~30^{o}C) prior to use.

(3) Plasma or serum specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

6. Procedure of the test

1) Remove the test device from foil pouch; place it on a flat, dry surface.

2) Using a micropipette, add 10micro liters of serum, plasma or whole blood into the sample well (s).

3) Add 4 drops of assay diluent into sample well (s).

4) As the test begins to work, you will see purple color move across the result window in the center of the test device.

5) Interpret test results in **5~20 minutes**.

Caution: Do not read test results after 20 minutes. Reading too late can give false results.

Interpretation of the test

1) A color band will appear in the left section of the result window to show that the test is working properly. This band is control line (C).

2) Color band will appear in the right section of the result window. This band s test line.

Negative result: The presence of only one band within the result window indicates a negative

result.

Positive result: The presence of two color bands (T band and C band) within the result window, no matter which band appears first, indicates a positive result.

Invalid result: If the purple color band is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.

8. Limitations of the test

A negative result does not preclude the possibility of infection with HCV. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated

Performance characteristics

1) **Sensitivity and Specificity**

The SD BIOLINE HCV has tested with positive and negative clinical samples tested by confirmatory assay using RT-PCR.

2) **Precision**

(1) Within run precision was determined by using 10 replicates of four different specimens containing different concentrations of antibody. The negative and positive values were correctly identified 100% of the time.

(2) Between run precision was determined by using the four different specimens containing different concentrations of antibody in 3 different replicates with 3 different lots of test

devices. Again negative and positive results were observed 100% of the time.

Appendix 5

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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/207 Link:www.uonbi.ac.ke/activities/KNHUoN 24th June 2014

Ukio Kusirye Boniface
UNITID
College of Health Sciences
University of Nairobi

Dear Boniface

RESEARCH PROPOSAL: PREVALENCE OF HCV AMONG HIV INFECTED ADULT PATIENTS ATTENDING COMPREHENSIVE CARE CENTER AT KENYATTA NATIONAL HOSPITAL: A CROSS SECTIONAL STUDY (P178/04/2014)

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 24th June 2014 to 23rd June 2015.

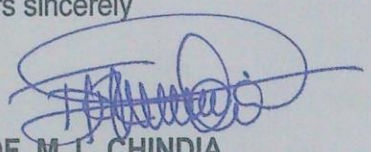
This approval is subject to compliance with the following requirements:

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.uonbi.ac.ke/activities/KNHUoN.**

Protect to Discover

Yours sincerely



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

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The Deputy Director CS, KNH
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