PREVALENCE AND RISK FACTORS ASSOCIATED WITH GONORRHEA AND CHLAMYDIA INFECTIONS AMONG HIV INFECTED PATIENTS AT BURNT FOREST AMPATH CLINIC, UASIN-GISHU COUNTY

BY

VICTORIA MWENDE MICHENI

A THESIS SUBMITTED TO THE SCHOOL OF PUBLIC HEALTH, COLLEGE OF HEALTH SCIENCES, DEPARTMENT OF EPIDEMIOLOGY AND BIOSTATISTICS, IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF PUBLIC HEALTH (MPH)

MOI UNIVERSITY

OCTOBER, 2015

DECLARATION

Declaration by the candidate:

This thesis is my original work and has not been presented for a degree in any other University. No part of this thesis may be reproduced without the prior permission of the author and or Moi University.

Signature ……....Date: ……...…..……

Victoria Mwende Micheni

SPH/PGH/25/11

Declaration by Supervisors

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

Signature ……Date ……

Dr. Samson K. Ndege

Senior Lecturer,

School of Public Health,

Department of Epidemiology & Biostatistics,

Moi University,

ELDORET.

Signature ……Date ……

Dr. Alice Kaaria,

Lecturer,

School of Medicine,

Department of Reproductive Health,

Moi University,

ELDORET.

DEDICATION

I dedicate this work to all patients and clinicians who struggle every day to contain the spread of sexually transmitted diseases in our society.

ABSTRACT

Background: Sexually transmitted infections (STIs), is one of the major public health burden globally. Among the Human Immune-deficiency Virus (HIV) infected individuals, STI enhances HIV transmission. Thus if HIV infection has to be properly managed, there is need to first focus on the management of STIs which begins by getting the actual magnitude of the problem by screening, and finding out the associated risk factors.

Objectives: The main objective of this study was to determine the prevalence of Gonorrhea and Chlamydia infections and their associated risk factors among HIV infected patients seeking care at Burnt Forest AMPATH clinic.

Methods: This cross sectional descriptive study was carried out in Burnt forest AMPATH clinic where the study population included all HIV/AIDS patients seeking care at AMPATH clinic. The sample size was derived using the Fisher's formula to get 150 subjects. Sampling of the study participant was systematic. Data was collected using interviewer administered questionnaire. Urine samples were also collected for laboratory analysis using the CT/NG PCR assay on the Abbott m2000 system. Data analysis was performed using STATA version 12 special edition. Categorical variables were summarized as frequency and corresponding percentages. Age, the only continuous variable was summarized as mean. The outcome was being positive for Gonorrhea and/or Chlamydia. The point prevalence of these infections was reported and alongside it were the corresponding 95% confidence limits (95% CL). The test for association between the categorical variables was done using Pearson's Chi Square test.

Results: The point prevalence for Gonorrhea was found to be 3.3% (95% CL: 1.1%-7.6%), while that of Chlamydia was 0%. Age was the only variable that was significantly associated with the outcome of being positive for Gonorrhea infection. The odds ratio and the corresponding 95% confidence limits were OR: 0.78 (95% CL: 0.66-0.92). This implies that a subject who was one year older than the other was 22% less likely to be suffering from Gonorrhea compared to someone younger than him/ her by a year. This effect was statistically significant at 5% level of significance.

Conclusion: The prevalence of Gonorrhea among the HIV infected in this study was comparable to the reported prevalence of Gonorrhea among the HIV infected in Kenya. Age was significantly associated with the outcome of being positive for Gonorrhea thus the younger would benefit more from STI screening than the elderly. There was no documented case for Chlamydia in this study and so the risk factors for Chlamydia infection among the HIV infected in this population could not be determined.

TABLE OF CONTENTS

DECLARATION ii
DEDICATION iii
ABSTRACT iv
TABLE OF CONTENTS v
LIST OF TABLES vii
ABBREVIATIONS AND ACRONYMS viii
OPERATIONAL DEFINITION OF TERMS ix
ACKNOWLEGDEMENT x
CHAPTER ONE: 1
INTRODUCTION 1
1.1 Background 1
1.2 Problem Statement 2
1.3 Justification of the Study 3
1.4 Research Questions 4
1.5 Objectives 4
1.5.1 Main Objective 4
1.5.2 Specific Objectives 4
CHAPTER TWO: 5
LITERATURE REVIEW 5
2.1 Introduction 5
2.2 Burden of Sexually Transmitted Infections 6
2.3 Burden of Gonorrhea and Chlamydia Infections 7
2.4 Risk Factors for STIs 8
2.5 Laboratory Diagnosis ff STIs 9
CHAPTER THREE: 11
METHODOLOGY 11
3.1 Study Site 11
3.2 Study Population 11
3.3 Study Design 12
3.4 Sample Size Determination 12
3.5 Sampling Procedure 12
3.6 Study Participant Recruitment 13
3.7 Eligibility Criteria 13

3.7.1 Inclusion Criteria 13
3.7.2 Exclusion Criteria 13
3.8 Data Collection and Tools 13
3.9 Pilot Study 14
3.10 Handling of Urine Specimens 14
3.11 Sample Preparation and Processing 14
3.12 Ethical Consideration 15
3.13 Data Analysis 15
CHAPTER FOUR: 17
RESULTS 17
CHAPTER FIVE: 21
DISCUSSION 21
CHAPTER SIX: 24
CONCLUSION AND RECOMMENDATION 24
6.1 Conclusion 24
6.2 Recommendations 24
REFERENCES 25
APPENDICES 28
APPENDIX I: Information Leaflet and Consent Form 28
APPENDIX II: Questionnaire 32
APPENDIX III: Instructions for Urine Collection 34
APPENDIX IV: Laboratory Request Form 35
APPENDIX V: Sample Processing 36
APPENDIX VI: Referral Plan 40

LIST OF TABLES

Table 1: Pearson's Chi Square test for association between the outcome and the independent variables.....18

Table 2: Multivariable logistic regression model analysis 19

ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immune-Deficiency Syndrome
AMPATH	Academic Model Providing Access To Healthcare
ARV	Antiretroviral
CT/NG PCR	*Chlamydia trachomatis* and *Neisseria gonorrhea* Polymerase Chain Reaction
DNA	Deoxy-ribonucleic acid
HIV	Human Immuno-deficiency Virus
HSV-2	Herpes Simplex Virus type -2
IREC	Institutional Research and Ethics Committee
KAIS	Kenya AIDS Indicator Survey
NAATs	Nucleic Acid Amplification Tests
PCR	Polymerase Chain Reaction
PID	Pelvic Inflammatory Disease
STIs	Sexually transmitted infections
USP	The United States Pharmacopeia
WHO	World Health Organization

OPERATIONAL DEFINITION OF TERMS

PCR- This is a technique for amplifying one or a few strands of DNA generating millions of copies of that particular DNA strand.

USP- It is written and physical standards for medicines, food ingredients, dietary supplement products and ingredients. Regulatory agencies and manufacturers uses it to help in ensuring that these products are of the appropriate identity, as well as strength, quality, purity, and consistency use these standards.

CT/NG PCR assay- is a real time PCR assay for the detection of Chlamydia plasmid DNA and the genomic DNA of Gonorrhea.

Screening- This is the identification and detection of an infection in a population by application of tests, where intervention can modify the natural course of the infection.

Tubal infertility- Failure to achieve clinical pregnancy due to blocked or damaged fallopian tubes.

Prevalence- The new and old cases of a disease in a given population at a given time.

ACKNOWLEGDEMENT

I sincerely thank my supervisors Dr. Samson Ndege and Dr. Alice Kaaria for their valuable contributions in the development of this thesis. I acknowledge AMPATH management for allowing me to carry out this study in their organization. I would also like to thank my family for their love and support. I also thank my colleagues in the School of Public Health, Moi University for their encouragement.

CHAPTER ONE:

INTRODUCTION

1.1 Background

Globally, sexually transmitted infections (STIs) constitute a major public health problem and pose a great threat to the health of populations (Gross and Tyring, 2011). The World Health Organization (WHO) estimates in 1999 showed that 340 million new cases of STIs occurred globally with the largest incidence of approximately 80-90% occurring in the sub–Saharan Africa (population council, 1993). From this report, there were 92 million Chlamydia, and 62 million Gonorrhea cases. In the sub-Saharan Africa, there were 16 million Chlamydia infections and 17 million Gonorrhea infections (population council, 1993). It has been found that Chlamydia is responsible for the biggest bacterial STI public health burden worldwide (Gross and Tyring, 2011).

STIs play a very important role in HIV transmission (CDC fact sheet, 2010). The available data on STI/HIV co-infection show a median prevalence of 12.4% and a mean point-prevalence of 16.3% in developed and developing countries and a prevalence of 11.3% in Africa alone (Seth *et al.*, 2011). The same study reports the prevalence of Gonorrhea at 9.5% while that of Chlamydia is 5% (Seth *et al.*, 2011). A report from Virginia for the year 2009 showed that new cases of Gonorrhea infections occurring among people with HIV was 526 per 100,000 while the cases for Chlamydia infections was 391 per 100,000 HIV infected persons (Chen *et al.*, 2011). Both ulcerative and non-ulcerative STI types can lead to increased transmission and infectiousness of Human Immune-deficiency Virus (HIV). HIV infected individuals are much more susceptible to STIs because their immunity is already compromised (Chen *et al.*, 2011).

There are various causative agents for sexually transmitted infections and these include bacteria, fungi, viruses, and other microorganisms (Kazhila, 2009). The World Health Organization (WHO) enlists only 19 causative agents for STIs among the 30 different transmissible bacteria, viruses and parasites (Kazhila, 2009). These infections are passed from one person to another through sexual contact (Kazhila, 2009), vertical transmission from mother to child and through contaminated tissue and contaminated blood contact (WHO fact sheet, 2013).

Gonorrhea and Chlamydia infections can be symptomatic or asymptomatic in both males and females. Whether these infections present with symptoms or not, serious complications can arise if un-treated. Such complications include pelvic inflammatory disease (PID), infertility, spontaneous abortions, ectopic pregnancy and premature deliveries. It has been found that untreated Gonorrhea infection is responsible for approximately 35% of the premature deliveries and spontaneous abortions among women. In addition to the health consequences, STI also lead to reduced quality of life (Gina *et al.,* 1998) and huge economic losses (CDC Grand Rounds, 2011).

Therefore, this study seeks to document the prevalence of Chlamydia and Gonorrhea among HIV/AIDS infected patients with the aim of improving screening, diagnosis and treatment.

1.2 Problem Statement

The prevalence of HIV co-infection with Chlamydia and Gonorrhea is estimated to be between 2.5 and 11% (Stephen *et al.,* 2011). In Kenya the prevalence of HIV co-infection with Gonorrhea and Chlamydia is between <1 to 2% (Singa *et al.,* 2013).

Presence of STIs among the HIV infected individuals poses a great problem to this population because HIV/STI co-infection facilitates the transmission of HIV and also predisposes the HIV infected individuals to other HIV strains and opportunistic infections that complicate the course of both diseases (CDC fact sheet, 2010). It has been found that untreated Gonorrhea infection is responsible for approximately 35% of the premature deliveries and spontaneous abortions among women (Haggerty *et al.*, 2010 and Oakeshott, 2010). Furthermore, STI/HIV reduces the quality of life (Gina *et al.*, 1998) and leads to huge economic losses (CDC Grand Rounds, 2011).

1.3 Justification of the Study

In many countries, factors involved in secondary HIV transmission have been studied (Clark e*t al.*, 2008). However, similar studies have not been carried out in HIV-infected population in Burnt forest AMPATH clinic and thus analytic framework for designing intervention to prevent secondary HIV transmission have not been developed. To reduce the spread of HIV, WHO recommends that STI screening and treatment be an integral part of HIV management and that national STI prevalence surveys should be conducted every 3 to 5 years (Singa e*t al.*, 2013). This however is not possible in resource limited settings like Kenya.

Gonorrhea and Chlamydia infections were chosen for this study because they are part of the high priority STIs recommended for inclusion in any STI survey (WHO, 1999). The burden of HIV co-infection with Gonorrhea and Chlamydia infections among HIV infected individuals is not known within the Burnt Forest AMPATH clinic due to lack of screening for these infections. The risk factors associated with these infections are also not known in this region. Knowledge of risk factors plays an

important role in designing effective control measures and they are presumptive indicators for therapy.

It was thus necessary to carry out this study to determine the magnitude of the problem with the purpose of putting up proper interventions for its control. Burnt Forest was chosen because of its cosmopolitan nature with heightened socioeconomic activities, some of which could lead to transmission of sexually transmitted diseases.

1.4 Research Questions

What is the prevalence of Gonorrhea and Chlamydia infections among HIV positive patients seeking care at Academic Model Providing Access To Healthcare (AMPATH) clinic based in Burnt Forest?

What are the risk factors associated with Gonorrhea and Chlamydia infections among HIV positive patients seeking care at AMPATH clinic based in Burnt Forest?

1.5 Objectives

1.5.1 Main Objective

To determine the prevalence and associated risk factors for Gonorrhea and Chlamydia infections among HIV infected patients seeking care at Burnt Forest AMPATH clinic.

1.5.2 Specific Objectives

1) To determine the prevalence of Gonorrhea and Chlamydia infections among the HIV infected individuals seeking care at Burnt Forest AMPATH Clinic.
2) To describe risk factors associated with Chlamydia and Gonorrhea infections among the HIV infected individuals seeking care at Burnt Forest AMPATH Clinic

CHAPTER TWO:

LITERATURE REVIEW

2.1 Introduction

The global estimate of STI globally by the WHO in 1999 showed that 340 million new cases of STIs occurred with the largest incidence of approximately 80-90% occurring in the sub–Saharan Africa. The developing nations are the ones that bear the greatest proportion of STIs. From the reported cases there were 92 million cases of Chlamydia, 62 million cases of Gonorrhea, 12 million cases of syphilis and 173 million cases of trichomoniasis (Population council, 1993).

Data on HIV co-infection with other STIs in developed and developing countries show a median prevalence of 12.4% and a mean prevalence of 16.3%. STI prevalence in Africa alone was found to be 11.3%. The same study reports the prevalence of Gonorrhea at 9.5% while the prevalence of Chlamydia is reported at 5% (Seth *et al.,* 2011). Reports from various studies carried in different HIV clinics show that the prevalence of HIV co-infection with Gonorrhea and Chlamydia infections ranges between 2.5 and 11%, with an incidence of 15/100 person-years (Stephen *et al.*, 2011).

A report from Virginia for the year 2009 showed that the new cases of Gonorrhea infections occurring among people with HIV was 526 per 100,000. This figure was far too high compared to a rate of 99 new Gonorrhea cases in the general population per 100,000 persons. The cases for Gonorrhea in HIV infected persons were 34.5% more in comparison to Chlamydia cases. In the same report, among the people living with HIV the rates for Chlamydia infection were reported to be slightly lower than the rates in the general population. The new cases of Chlamydia infections occurring

among people with HIV was 391 per 100,000 compared to a rate of 396 per 100,000 persons in the general population (Chen *et al.*, 2011).

In Kenya the prevalence of HIV co-infection with Gonorrhea and Chlamydia has been estimated to be between <1% to 2%. This is according to a study carried out among 1661 HIV infected patients selected from various HIV clinics in Kenya (Singa *et al.*, 2013).

2.2 Burden of Sexually Transmitted Infections

Complications' arising from STI infections causes huge health burden and great economic losses globally (CDC Grand Rounds, 2011). Ill health caused by STIs account for 17% of economic losses (Seth *et al.*, 2011). 51 million years of healthy life are lost in a yearly basis as a result of STIs (Gina *et al.*, 1998). The second cause of healthy life years lost among women aged between 15 and 45 years in developing countries is STIs after maternal morbidity and mortality. Among the men of the same age bracket who are STI/HIV co-infected, STI account for 15% of healthy life year's lost (Gina *et al.*, 1998).

STIs both ulcerative and non-ulcerative types lead to increased transmission and infectiousness of Human Immune-deficiency Virus (HIV) (CDC fact sheet, 2010). Among those individuals that are HIV infected, the STIs lead to increased susceptibility to acquiring other HIV virus strains. STIs increase susceptibility to HIV by increasing the concentration of cells that serve as target for HIV in the genital secretion and by causing breakages of the mucosal lining thus creating portals of entry for the virus. Increased HIV infectiousness is due to the increased viral shedding in genital secretion as a result of the STI infection (CDC fact sheet, 2010).

Any attempt to reduce HIV burden must therefore first focus on STI management. For instance, a randomized community based study carried out in Tanzania showed that management of cases presenting for health care with STIs signs and symptoms leads to a reduction in HIV transmission (Deborah *et al.*, 2000).

2.3 Burden of Gonorrhea and Chlamydia Infections

Neisseria gonorrhea is the causative agent for Gonorrhea. It is a gram negative, oxidase positive diplococcus (Abbott real time CT/NG customer service manual). *Neisseria gonorrhea* is adapted to multiply in multiple sites within the reproductive system and this includes uterus, fallopian tubes, and cervix in women and urethra in both females and males. It has also the ability to multiply in eyes, throat and anus. The infection could present with or without symptoms in both males and females. In females symptoms such as pain during urination and vaginal discharge may present. In men symptoms such as epididymitis, urethritis, and penile discharge may be observed. Women usually experience complications such as infertility, chronic pelvic pain and ectopic pregnancy in cases where the infection is not treated (Haggerty *et al.*, 2010, and Oakeshott, 2010).

Chlamydia trachomatis is one of the three Chlamydia species that is responsible for causing sexually transmitted Chlamydia infections. It is a non-motile, gram negative bacterium (Population council, 1998). *Chlamydia trachomatis* is majorly transmitted via sexual contact though it can also be transmitted via infected birth canal causing ophthalmia neonatorum, infected hands, droplets, and infected clothing (Gross and Tyring, 2011). Following exposure to an infected partner, the infection presents as cervical infection in women but may also be asymptomatic in some people. Untreated infection whether presenting with symptoms or not may lead to complications such as

ectopic pregnancy. The commonest cause of non-gonococci urethritis in men is Chlamydia. This infection may also present with symptoms such as pain and penile discharge, but other cases are asymptomatic (Gross and Tyring, 2011). Chlamydia has been documented to be the leading cause of tubal infertility and that it is very costly to treat Chlamydia associated infertility which has been estimated at 701 million dollars annually in the United States (CDC Grand Rounds, 2011). Chlamydia infection may also be associated with cancer of the cervix (Wallin *et al.*, 2002). It is therefore important to have early case management of these infections in order to prevent PID, infertility and other complications (Schulz, 2004). It is reported that 40% of untreated Gonorrhea and Chlamydia infections lead to PID and out of these one out of four results to infertility (Stephen *et al.*, 2011).

2.4 Risk Factors for STIs

Complete understanding of the various risk factors associated with STI is important in the design and implementation of STI control programs (Population council, 1998). There are several risk factors that have been associated with STIs. Some of these factors are common to many STIs such as having multiple sexual partners, and having unprotected sex with an infected individual (Gross and Tyring, 2011). Young age has been associated with Chlamydia infection. Young people are especially at risk of contracting STIs because majority are sexually active, their reproductive and immune systems are immature, and because of socioeconomic factors such as poverty, and homelessness which are associated with sexual abuse and exchange of sex for money. Young people are also ill-informed about STIs, their symptoms, and the need for treatment, and these lead to delays in seeking health care (Cheng, 2002).

Young females are more likely to be infected with an STI compared to their male counterparts (Dehne *et al.,* 2005*).* Certain sexual behaviors such as early sexual activity, selection of older sexual partners, and inconsistent use of condoms increase susceptibility STIs (Hill *et al.,* 2009). Limited preventive and treatment of STI is also a factor that contributes to high rate of STIs (STD surveillance, 2003). Demographic and ecological variables such as poor neighborhood are a risk for STIs among certain groups of adolescents. Drug users, especially parenteral drug users, commercial sex workers, runaway and jailed youths are at greater risk of STIs (STD surveillance, 2003).

Other factors such as past STI history, and living in urban areas have also been associated with Chlamydia and Gonorrhea infections (Gross and Tyring, 2011). A study carried out among HIV positive women clinic attendees in Alabama showed that smoking, use of illicit drugs, exchange of sex for money, low education levels and presenting with genitourinary symptoms were associated with STIs (Cheryl-Ann, e*t al.*, 2004). Being single, employed, and less than 30 years of age has also been found as a factor associated with STI infection (Claeys e*t al.*, 2002).

2.5 Laboratory Diagnosis ff STIs

Culture, microscopy, serology, antigen detection and nucleic acid amplification tests are some of the techniques used for the laboratory diagnosis of STIs (Michael *et al.*, 2004). Culture has been considered to be the standard criterion for the diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhea*. This method is however time-consuming and labor intensive and technically difficult (Emma e*t al.*, 2002). Tests that use the nucleic acid amplification technique are very sensitive and specific in the detection of *Chlamydia trachomatis* and *Neisseria gonorrhea* and non-invasive

specimens such as urine can be used (Michael *et al.*, 2004 and Canadian guidelines on sexually transmitted infections, 2006).

The procedure for collecting urine samples is non-invasive making it more acceptable to patients unlike the procedures for obtaining cervical, vaginal, vulva and rectal swabs in women and urethral swabs in men. For the women without a cervix and those who do not readily submit for a pelvic examination, urine is the preferred specimen (Michael e*t al.*, 2004).

Polymerase chain reaction is a nucleic acid amplification test which uses primers to rapidly make copies of the genetic material of the organism if present. For the diagnosis of acute Chlamydia infection, serological test cannot be used. Serological techniques are also not available for the diagnosis of Gonorrhea (Michael e*t al.* 2004 and Emma e*t al.*, 2002). In this study, urine samples were used for the diagnosis of Gonorrhea and Chlamydia.

CHAPTER THREE:

METHODOLOGY

3.1 Study Site

The study was conducted in Burnt Forest AMPATH clinic. AMPATH is a partnership comprising of Moi University, Moi Teaching and Referral Hospital and a consortium of North America Institutions led by Indiana University School of Medicine. It is involved with activities geared towards control and management of HIV infection and other chronic diseases and opportunistic infections among the HIV infected individuals.

Within a month, Burnt Forest AMPATH clinic receives approximately 900 clients, both new and old clients, for their scheduled appointments and emergencies. This figure is what comprised of the sampling frame for this study. The clinic is located near the Burnt Forest center which is a cosmopolitan market and has many economic and agricultural activities going on. This center is located along the Nakuru – Eldoret highway and is famous for mutton and beef thus making it a good stop for truck drivers and long distance travelers. The long distance truck drivers have long been associated with risky sexual behavior thus facilitating the transmission of STIs and predisposing the local population within this Burnt Forest AMPATH clinic catchment area to STIs.

3.2 Study Population

The study population included all HIV positive adult patients presenting for care at Burnt Forest AMPATH clinic during the period of the study.

3.3 Study Design

Cross-sectional study design was used to determine the prevalence of Gonorrhea and Chlamydia infection, and examine the relationship between these STIs and possible predisposing factors among HIV individuals seeking care at AMPATH clinic in Burnt Forest.

3.4 Sample Size Determination

The sample size was determined using Fisher's formula (Fisher *et al*, 1998). The study prevalence results were measured at 95% confidence level. The Fisher's formula is as shown below:

$n_o = (z^2 \times p \times q) / e^2$

Where: n_o is the desired sample size

Z is 1.96 (Area under the normal curve at 95% confidence level)

P=0.11 (The prevalence of HIV co-infection with Gonorrhea and Chlamydia: 11% according to Stephen., *et al.*, 2011).

q= 1-p (1 - 0.11 = 0.89)

e = 0.05

The sample size was thus calculated to get 150 study participants.

3.5 Sampling Procedure

Systematic sampling was used to obtain the study sample. The index case was the first patient on the queue to see the clinician and subsequent subjects/participants were picked at the interval of k, where k=N/n=6. K was the sampling interval, N the population size of 900 patients and this comprised the sampling frame, and n was the sample size of 150 subjects. The study took place between 1st July, 2013 and 2nd August, 2013.

3.6 Study Participant Recruitment

The prospective study participant was approached and the nature and aims of the study explained to him / her by either the principal investigator or the research assistant. The principal investigator / the research assistant answered any questions concerning the study asked by the prospective study participants. The individuals who agreed to participate in the study that is, those who agreed to be interviewed and give out a urine sample, were given the consent form to sign. A unique study number was allocated to each of the participant and this number was noted on the questionnaire, laboratory request form and on the sample.

3.7 Eligibility Criteria

3.7.1 Inclusion Criteria

Any patient aged 18 years and above, and was registered within the Burnt Forest AMPATH HIV care program.

3.7.2 Exclusion Criteria

Those with psychiatric disorders and those who were on any antibiotic drugs were excluded from the study.

3.8 Data Collection and Tools

Interviewer administered questionnaire (appendix 2) was used to collect data on participant's demographics, behavioral information and medical history. This involved interviewing the participant face to face by the principal investigator/the research assistant in a secluded consultation room that offered the necessary privacy needed for the interview. Urine sample from every participant was also obtained for laboratory analysis of Gonorrhea and Chlamydia genome. The laboratory result for

every participant was later entered into the structured questionnaire as soon as the results were released.

3.9 Pilot Study

To test the content and face validity of the questionnaire, a pilot study was carried out in Uasin Gishu District Hospital.

3.10 Handling of Urine Specimens

The participant was provided with a labeled screw-top urine collection cup/universal container and he/she was advised to collect 5 – 20 ml of the first portion of the urine stream from a designated wash room (see urine collection instructions on appendix 3). The participant then screwed the lid on tightly and securely and delivered the sample to the principal investigator / the research assistant who took it to the AMPATH clinic laboratory in Burnt forest. The sample was received by the AMPATH laboratory technician and stored in the clinic's refrigerator within a temperature range of 2ºc to 30ºc for a period that did not exceed 14 days awaiting delivery to the AMPATH reference laboratory.

During transportation of the specimens to the AMPATH Reference laboratory, each tube was placed in a sealable plastic bag. The specimens were then packaged and labeled in accordance to Kenya regulation governing the transportation of clinical specimen. Upon receipt in the reference laboratory, the specimens were frozen at -80ºc waiting processing using CT/NG assay.

3.11 Sample Preparation and Processing

PCR was used to amplify sequences of *Chlamydia trachomatis* and *Neisseria gonorrhea genome.* Specimens were first treated to release the Chlamydia and

Gonorrhea DNA if present and make it accessible for replication and detection. PCR then utilized a pair of primers which were complimentary to a defined sequence of the Chlamydia and Gonorrhea DNA. These primers were extended by a DNA polymerase and a copy strand was made after each cycle, leading to a logarithmic amplification. The PCR test has the ability to include an internal amplification control that enables the laboratory to determine the presence of inhibitors that may produce a false negative result. Refer to appendix 5 for detailed instructions on how to the samples were processed.

3.12 Ethical Consideration

- Ethical clearance was obtained from research ethics committee (IREC) of the institution before the study commenced
- Permission was sought from AMPATH management to collect data in Burnt forest AMPATH clinic
- Permission was also sought from health management team
- Informed consent was obtained from the study participants after the aims of the study had been explained to them
- Each participant was given their laboratory results
- Individuals whose laboratory results turned out positive were accordingly referred to seek care and treatment. (Refer to referral plan-appendix 6)

3.13 Data Analysis

Data analysis was performed using STATA version 12 special edition (STATA 12, SE). Categorical variables were summarized as frequency and corresponding percentages. Age, the only continuous variable was summarized as mean and its corresponding standard deviation calculated. The outcome was being positive

Gonorrhea or Chlamydia. The prevalence of these diseases was reported and alongside it were the corresponding 95% confidence limits (95% CL). The test for association between the categorical variables was done using Pearson's Chi Square test. Predictors of sexually transmitted diseases (STI) were assessed using a logistic regression model. The associated odds ratios (OR) and the corresponding 95% confidence limits were reported. The variables included in the multivariable logistic regression model were first assessed for their association with the outcome of interest using a bivariable logistic regression model. If the reported p-value associated with that variable in the univariate model was below 0.25, then it qualified to be included in the multivariable model. Due to a few number of events some variables were collapsed into fewer categories to facilitate convergence of the models and test for associations. Such variables include civil status collapsed into single, separated, widowed, widower vs. married; education level: elementary or absence of formal education vs. secondary or post-secondary education; occupation: employed or self-employed vs. unemployed.

CHAPTER FOUR:

RESULTS

There were 150 subjects with a mean age of 39 and standard deviation of 10.6 years who were included in this study and whose data were analyzed. Of this number, 110 (73%) were females, and 40 (27%) were males. There were 71(47%) married respondents, 24 (16%) were separated, 25 (17%) single, 29 (19%) widowed and 1 (1%) widower.

A larger proportion of the subjects, 98 (65%), had an elementary level of education, 8 (5%), had no formal education while 43 (29%) had at least a secondary education. Of all the participants, 149 (99%) were Christians and 1 (1%) Muslim. There were 40 (27%) unemployed subjects, 21 (14%) employed, and 89 (59%) self-employed respondents who participated in this study. Information on use of two substances, alcohol and cigarette, was collected. It was established that 27 (18%) and 9 (6%) were alcohol users and cigarette smokers respectively.

Sex related characteristics were also assessed. Among them is engagement in sexual intercourse under drug influence, number of intimate partners, and use of condom during sex. There were 16 (11%) subjects who reported that they had engaged in sex under the influence of drugs. One hundred and twenty participants reported to have an active sex life. Of those who had an active sexual life, 110 (91.7%) said that they have one intimate partner, 7 (5.8%) reported that they have two while 3 (2.5%) said that they have more than two intimate partners. Among those with reported active sex life 68 (57%) reported that they use a condom during sexual intercourse.

Presence of STI symptoms of infection was assessed. The results showed that 40 (27%) had a discharge from genitals while 43 (29%) experienced pain during

urination. Of the total number interviewed, 24 (16%) said that the ARVs are important in protecting them against STIs while 110 (73%) said that ARVs do not protect them from contracting STIs. The rest did not know if ARVs protect them from STI's or not. There were 5 (3.3%) participants who were diagnosed with Gonorrhea. All the participants were negative on PCR test for Chlamydia. This implies that the incidence of Gonorrhea is 3.3% (95% CL: 1.1%-7.6%).

Table 1: Pearson's Chi Square test for association between the outcome and the independent variables

		STIs		Chi Square test
Variables	**Levels**	**No**	**Yes**	**p-value**
Sex	Female vs. Male	106 (73%)	4 (80%)	1.000
Civil status	Separated/single/widowed/ widower vs. married	103 (71%)	3 (60%)	0.370
Education level	Primary/no elementary education vs. Secondary/post-secondary	103 (71%)	3 (60%)	0.631
Religion	Christian vs. Muslim	144 (99%)	5 (100%)	1.000
Occupation	Employed/self-employed vs. unemployed	107 (74%)	4 (80%)	1.000
Alcohol use	Yes vs. No	26 (18%)	1 (20%)	1.000
Cigarette use	Yes vs. No	9 (6%)	0	1.000
Sex under drug influence	Yes vs. No	15 (10%)	1 (20%)	0.436
Active sex life	Yes vs. No	115 (79%)	5 (100%)	0.583
Number of sex partners	One vs. More than one	136 (94%)	4 (80%)	0.295
Condom use	Yes vs. No	68 (47%)	3 (60%)	0.668
Discharge from genital of respondent	Yes vs. No	38 (26%)	2 (40%)	0.610
Pain during urination by the respondent	Yes vs. No	40 (28%)	3 (60%)	0.142
Discharge from genital of the partner	Yes vs. No	11(8%)	0	1.000
Pain during urination by the partner	Yes vs. No	9(6%)	0	1.000
Are ARVs important in protecting one against STIs?	Yes vs. No	23 (16%)	1 (20%)	0.587

The table 1 above shows the univariate association between the variables and the outcome. The variable, Pain during urination by the respondent met the threshold for inclusion in the multivariable logistic regression model analysis. The test for association between age and the outcome was done using a binary regression model and the results showed that this variable was highly associated with the outcome (p-value=0.004). Civil status, education level and employment status were also included in the multivariable regression model analysis though there was no evidence of association between these variables and the outcome. They were included because they were considered to be important confounders.

Table 2: Multivariable logistic regression model analysis

STIs	**UOR (95% CL)**	**AOR(95 % CL)**	**Std. Err.**	**z**	**P>z**
Age (years)	0.78(0.66-0.92)	0.79(0.68-0.92)	0.06	-3.00	0.003
Education (Elementary vs. secondary or post-secondary)	0.61(0.10-3.79)	0.44(0.04-4.26)	0.51	-0.71	0.475
Occupation (Employed or self-employed vs. Unemployed)	1.42(0.15-13.11)	12.13(0.50-295.81)	19.77	1.53	0.126
Civil status (Separated, single, widowed, widower vs. married)	3.73(0.41-34.22)	4.72(0.45-48.94)	5.63	1.30	0.194
Pain during urination by the respondent (yes vs. no)	3.94(0.63-24.45)	5.62(0.66-48.07)	6.16	1.58	0.115

The results in Table 2 indicate that the only variable that was significantly associated with the outcome is age. The odds ratio and the corresponding 95% confidence limits (95% CL) was AOR: 0.79 (95% CL: 0.68-0.92). Variables such as occupation, Civil

status (Separated, single, widowed, widower vs. married), and pain during urination by the respondent (yes vs. no) were not statistically significant in this model but point in the direction of increased risk. Education level (Elementary vs. secondary or post-secondary) point in the direction of reduced risk among those with elementary or no formal education.

CHAPTER FIVE:

DISCUSSION

This is the first study to report the prevalence of Gonorrhea and Chlamydia infection in burnt forest AMPATH clinic by molecular testing. Diagnosis of any STI among persons infected with HIV has significant public health implications that indicate continuing risky behaviors by these people and their partners, which may lead to further HIV transmission to others.

In this study, the point prevalence of Gonorrhea at AMPATH clinic in Burnt forest was found to be 3.3% (95% CL: 1.1%-7.6%), while that of Chlamydia was 0%. This prevalence results are close to the reported prevalence of HIV co-infection with Gonorrhea and Chlamydia in Kenya of between <1 to 2% (Singa *et al.*, 2013) and an estimated prevalence of between 2.5 and 11% global HIV co-infection with Gonorrhea and Chlamydia (Stephen e*t al.*, 2011). These findings suggest that the burden of disease has not decreased suggesting that relevant intervention strategies are still relevant. There were no cases of Chlamydia infection therefore it can be concluded that the rates for Gonorrhea infection are high compared to Chlamydia infection. This finding is similar to that report drawn from Virginia where the cases for Gonorrhea were higher compared to Chlamydia infection rates (Chen *et al.*, 2011).

Age was the only variable that was significantly associated with the outcome of being positive for Gonorrhea (OR: 0.78; 95% CL) in this study. The analytical results indicate that with every one year increase in age, the odds of having Gonorrhea infection was reduced by 22%. This effect was statistically significant at 5% level of significance. Other studies have reported similar findings where increase in age led to reduced risk of acquiring Gonorrhea infection (Claeys e*t al.*, 2002). The risk of

infection has been associated with the maturity of epithelial cells, where immature cervix is more vulnerable to infection (Faber *et al*., 2011). Other studies have associated younger age with increased sexual activity, more intimate partners and a possibility of inadequate knowledge of STIs and how they can be prevented (Thuong *et al.*, 2008*).*

Some studies have found low education level and low socio-economic status to be associated with STIs. This has been attributed to risk taking behavior among the group with low education and low socio-economic status (Faber, *et al..*, 2011). This is contrary to the observation made in this study where there is reduced risk among those with low or no education, and among those who are not employed.

This study reports that among those who have active sexual life, 68 (57%) reported that they had been using a condom during sexual intercourse. This results are consistent with findings from a cross sectional study in Kibera of HIV infected where 65% of the men and78% of women reported to use a condom during sexual intercourse. All the five subjects who were positive for Gonorrhea infection in this study had an active sexual life with one sexual partner except for one subject who reported to have two sexual partners. Several studies have postulated that multiple sexual partners increase the likelihood of acquiring STIs due to increased probably of encountering a partner who is already infected (Kohli *et al*., 2013).

The findings in this study suggest that smoking and alcohol consumption were not likely to be associated with Gonorrhea infection. This is consistent with some studies that have drawn similar conclusion though smoking and alcohol consumption might

have indirect effect through a high-risk sexual behavior (Faber, *et al*.., 2011). There was a higher proportion of females positive for Gonorrhea. This finding was consistent with a study that established that females are more likely to be infected with an STI compared to their male counterparts (Dehne *et al.,* 2005*).*

CHAPTER SIX:

CONCLUSION AND RECOMMENDATION

6.1 Conclusion

The prevalence of Gonorrhea among the HIV infected in this study was comparable to the reported prevalence of Gonorrhea among the HIV infected in Kenya. The young were at more risk of Gonorrhea infection compared to the older. There was no documented case for Chlamydia in this study and so the risk factors for Chlamydia infection among the HIV infected in this population could not be determined.

6.2 Recommendations

There is need for increased emphasis on Gonorrhea infection screening compared to screening for Chlamydia infections. There is a need for more research to determine if truly there are no cases for Chlamydia infection in the study population.

Younger HIV infected individuals would benefit more from STI screening and health education concerning STIs compared to the older.

REFERENCES

Abbott real time Chlamydia trachomatis (CT)/Neisseria gonorrhea (NG) customer service manual: http://www.abbottmolecular.com/static/cms_workspace/pdfs/US/CTNG_8L07-91_US_FINAL.pdf

Behets F.M.T, Genece E, Narcisse M, Liautaud B, Cohen M,and Dallabetta G.A (1998). Approaches to control of sexually transmitted diseases in Haiti. *Bull world health organ*, 76(2):189-194

Canadian guidelines on sexually transmitted infections (2006). Laboratory diagnosis of sexually transmitted infections: http://www.phac-aspc.gc.ca/std-mts/sti_2006/pdf/01sti2006a_e.pdf

Center for Disease Control (CDC) Grand Rounds (2011). Chlamydia Prevention: Challenges and Strategies for Reducing Disease Burden and Sequelae. Center for disease control and prevention: *Morbidity and Mortality Weekly Report (MMWR)*, 60(12):370-373

Center for Disease Control fact sheet (CDC) (2011): The Role of STD Detection and Treatment in HIV Prevention, 2010: http://www.cdc.gov/std/hiv/STDFact-STD-HIV.htm

Chen Y, Carter A, Embrey K, Henderson D, Hulburt C, Rees R, Rhodes A, Robertson H, Vasiliu O, Zehner A (2011). Virginia HIV Epidemiology Profile 2011. Richmond, VA: Division of Disease Prevention, Virginia Department of Health. https://www.vdh.virginia.gov/epidemiology/DiseasePrevention/Profile2011/Epi_Profile_2011.pdf

Cheng S.Y (2002). Sexually transmitted infections in adolescents. *Hong Kong Journal of Paediatric*, 1(7):76-84

Cheryl-Ann Monteiro, Laura H. Bachmann, Renee A. Desmond, Kathleen E. Squires, Sten H. Vermund, Edward W. Hook, Jane R. Schwebke, and Craig J. Hoesley (2004). Incidence and risk factors for sexually transmitted infections among women in an Alabama HIV clinic. *AIDS research and human retroviruses*, 20(6):577–583

Clark J.L, Konda K.A, Segura E.R, Salvatierra H.J, Leon S.R, Hall E.R, Caceres C.F, Klausner J.D, Coates T.J (2008). Risk factors for the spread of HIV and other sexually transmitted infections among HIV-infected men who have sex with men in lima, peru. *Sexually transmitted infections*, 84(6):449-454

Claeys P, Gonzalez C, Gonzalez M, Van Renterghem L, Temmerman L (2002). Prevalence and risk factors of sexually transmitted infections and cervical neoplasia in women's health clinics in Nicaragua. *Sexually Transmitted Infections*, 78:204–207

Deborah Watson-Jones, Kokungoza Mugeye, Philippe Mayaud, Leonard Ndeki, James Todd, Frank Mosha, Beryl West, Bernadette Cleophas-Frisch, Heiner Grosskurth, Marie Laga, Richard Hayes, David Mabey, and Anne Buvé (2000). High prevalence of trichomoniasis in rural men in Mwanza, Tanzania: results from a population based study. *Sexually Transmitted Infections*, 76:355-362.

Dehne K.L, Riedner G (2005). Sexually transmitted infections among adolescents: the need for adequate health care. World Health Organization (WHO) bulletin http://apps.who.int/iris/bitstream/10665/43221/1/9241562889.pdf

Emma J. Watson, Allan Templeton, Ian Russell, Jorma Paavonen, Per-Anders Mardh, Angelika Stary, Babil Stray Pederson (2002). The accuracy and efficacy of screening tests for Chlamydia trachomatis: a systematic review. *Medical Microbiology*, 51(12):1021-1031

Faber MetteTuxen, Nielsen Ann, Nygård Mari, Sparén Pär, Tryggvadottir Laufey, Hansen Bo Terning, Liaw Kai-Li, and Kjaer Susanne K (2011). Genital Chlamydia, Genital Herpes, Trichomonas vaginalis and Gonorrhea Prevalence, and Risk Factors Among Nearly 70,000 Randomly Selected Women in 4 Nordic Countries. *Sexually Transmitted Diseases*, 38(8):727-734

Gross and Tyring 2011. Epidemiology of sexually transmitted infections. *Sexually Transmitted Infections and Sexually Transmitted Diseases*,http://link.springer.com/book/10.1007/978-3-642-14663-3

Haggerty C. Gottlieb, Sami L. Gottlieb, Brandie D. Taylor, Nicola Low, Fujie Xu, and Roberta B. Ness (2010). Risk of sequelae after Chlamydia trachomatis genital infection in women. *Journal of Infectious Diseases*, 201(2):134-55 http://www.who.int/mediacentre/factsheets/fs110/en/

Kazhila C. Chinsembu, 2009. Sexually Transmitted Infections in Adolescents. *The Open Infectious Diseases Journal*, 3:107-117

Keng-Ling Wallin, Fredrik Wiklund, Tapio Luostarinen , Tord A Ngstrom, Tarja Anttila , Frank Bergman, Go¨Ran Hallmans , Irma Ikaheimo, Pentti Koskela, Matti Lehtinen, Ulf Stendahl0, Jorma Paavonen and Joakim Dillner (2002). A population-based prospective study of Chlamydia trachomatis infection and cervical carcinoma. *International Journal of Cancer*, 101:371-374

Michael G. Spigarelli and Frank M. Biro (2004). Sexually transmitted disease testing: evaluation of diagnostic tests and methods. *Adolescent Medicine* 15:287–299

Oakeshott P, Kerry S, Aghaizu A, Atherton H, Hay S, Taylor-Robinson D, Simms I, Hay P (2010). Randomised controlled trial of screening for Chlamydia trachomatis to prevent pelvic inflammatory disease: the POPI (prevention of pelvic infection) trial. *British Medical Journal* 340:1642

Population council, 1993; "Reproductive Tract Infections"
http://www.popcouncil.org/uploads/pdfs/frontiers/reports/RTIS_GEP_FINALl .pdf

Ruchika Kohli, Walter P Konya, Timona Obura, William Stones and Gunturu Revathi (2013). Prevalence of genital Chlamydia infection in urban women of reproductive age, Nairobi, Kenya. *Biomed Central Research Notes*, 6:44

Schulz (2004). Population-based interventions for reducing sexually transmitted infections, including HIV infection: RHL commentary. The World Health Organization (WHO) Reproductive Health Library Geneva http://apps.who.int/rhl/rti_sti/cd001220_lown_com/en/

Seth C. Kalichman, Jennifer Pellowski, and Christina Turner (2011). Prevalence of sexually transmitted co-infections in people living with HIV/AIDS: systematic review with implications for using HIV treatments for prevention. *SexuallyTransmitted Infections*, 87:183-190

Sexually Transmitted Disease Surveillance (2003). Special Focus Profiles, Sexually Transmitted Diseases in adolescents and young adults
http://www.cdc.gov/std/stats13/surv2013-print.pdf

Singa Benson, Glick Sara Nelson, Bock Naomi, Walson Judd, Chaba Linda, Odek James, McClelland R. Scott, Djomand Gaston, Gao Hongjiang, John-Stewart, and Grace MD (2013). Sexually Transmitted Infections among HIV-Infected Adults in HIV Care Programs in Kenya: A National Sample of HIV Clinics. *Sexually transmitted diseases*, 40(2):148 – 153

Stephen A. Berry, Khalil G. Ghanem, Kathleen R. Page, Stephen J. Gange, Chloe L. Thio, Richard D. Moore, and Kelly A. Gebo (2011). Increased gonorrhoea and Chlamydia testing did not increase case detection in an HIV clinical cohort 1999-2007. *Sexually transmitted Infections*, 87(6):469-475

The training course in women's health, module 9, 2nd edition
1993http://www.popcouncil.org/pdfs/RTIFacsheetsRev.pdf

Thuong Vu Nguye, Nghia Van Khuu, Truc Thanh Thi Le, Anh Phuong Nguyen, Dung Chi Tham, And Roger Detels (2008). Sexually Transmitted Infections and Risk Factors for Gonorrhea and Chlamydia in Female Sex Workers in Soc Trang, Vietnam. *Sexually transmitted Infections* 35(11): 935–940

WHO fact sheet 110 Sexually transmitted infections, 2013
World Health Organization, 1999. Guidelines for the implementation of STI prevalence surveys
http://www.who.int/hiv/topics/en/STI_prevalence_study_methodology_WPRO.pdf

APPENDICES

APPENDIX I: Information Leaflet and Consent Form

MOI UNIVESRITY
SCHOOL OF PUBLIC HEALTH

Information leaflet

Note: All the information that you wish to know about this study is contained in this information sheet. Before you decide to participate in the study, read through the information provided carefully and ask for clarification where need be.

Research Title: Prevalence and risk factors associated with Gonorrhea and Chlamydia infections among HIV infected patients at Burnt forest AMPATH clinic, Uasin-Gishu county

The aim of the study: To determine the prevalence of Gonorrhea and Chlamydia among HIV positive adults seeking care at AMPATH clinic in Burnt forest, and to determine the risk factors associated with Gonorrhea and Chlamydia infections.

Researcher: Victoria Mwende Micheni, Moi University student pursuing Master in Public Health.

Supervisors: Dr. Samson Ndege and Dr. Alice Kaaria.

Procedures: If you voluntarily agree to participate in the study, we will ask you to give out information concerning your demographics, sexual behavior and medical history. Then you will be required to collect 5 – 20 ml of the first portion of the urine stream (see appendix 3) for instructions on urine sample collection) that will be used in screening for Gonorrhea and Chlamydia infections.

Risks and Benefits: The laboratory results will be communicated to you and if your results are positive we will advise you accordingly and refer you for treatment. The study does not predispose you to any risks.

Confidentiality: The information that you provide will be kept confidential and assigned a unique study number and the listing that link this number to the information provided will be kept in a cabinet that will only be accessible to the principal researcher. Upon the completion of the study, the findings of the study will be presented in summaries and your name will not be used. The list linking your information to the study number will also be destroyed at the end of the study.

Voluntary participation: Participation in the study is voluntary. There is no penalty for not agreeing to participate in the study.

Please sign the following consent form if you agree to participate in the study.

Agreement:

Having read and understood the information provided concerning the study, I voluntarily agree to participate in the study.

Name: _____

Signature: _____

Date: _____

Principal Investigator: _____ Date: _____

CONSENT FORM (KISWAHILI)

Kijikaratasi cha taarifa

Kumbuka: Taarifa zote zinazo takikana kujulikana kuhusu utafiti huu ziko katika karatasi hii ya habari. Kabla ya kuamua kushiriki katika utafiti, soma taarifa zinazotolewa kwa uangalifu.

Kichwa cha Utafiti: Maambukizi na hatari zinazohusiana na magonjwa ya kisonono na klamidia katika watu wazima kwenye kliniki ya AMPATH Burnt forest

Lengo la utafiti: Kupima kiwango cha maambukizi ya Kisonono na Klamidia miongoni mwa watu wazima wanaotafuta huduma katika kliniki ya AMPATH, Burnt forest, na kuamua mambo ya hatari inayohusiana na maambukizi ya magonjwa ya kisonono na klamidia.

Mtafiti: Victoria Mwende Micheni, mwanafunzi katika Chuo Kikuu cha Moi anayetafuta shahada katika kitengo cha Afya ya Umma.

Wasimamizi: Dk. Samson Ndege na Dk. Alice Kaaria.

Utaratibu: Kama umejitolea kushiriki katika utafiti huu, baadhi ya maswali utakayo ulizwa ni kuhusu demografi yako, tabia ya ngono na historia ya matibabu. Kisha utahitajika Kukusanya milimita tano ya mkojo ambayo itatumika katika uchunguzi kwa Kisonono na Klamidia.

Hatari na Faida: Matokeo ya maabara itawasilishwa kwako. Kama una magonjwa haya, utashauriwa ipasavyo na utaelekezwa jinsi ya kupata matibabu. Utafiti huu hauna hatari yoyote.

Usiri: Habari itakayo tolewa itakuwa siri. Baada ya kumaliza utafiti huu, matokeo yatawasilishwa katika muhtasari na jina yako haitatumika.

Hiari ya kushiriki: Ushiriki katika utafiti huu ni wa hiari. Hakuna adhabu kwa kutokubali kushiriki katika utafiti.

Mkataba:

Baada ya kusoma na kuelewa maelezo iliyotolewa kuhusu utafiti huo, mimi kwa hiari nakubali kushiriki katika utafiti.

Jina: _____

Sahihi: _____

Tarehe: _____

Mpelelezi mkuu: _____ Tarehe: _____

APPENDIX II: Questionnaire

Date: …… Questionnaire number: ……

Part one: Demographic information

1. Age (years)…….
2. Sex: M ( ) F ( )
3. Marital status: Single ( ) Married ( ) Divorced ( ) Separated ( )
4. Education level: Primary ( ) Secondary ( ) Post secondary ( )
5. Religion: Christian ( ) Muslim ( ) Hindu ( ) others specify ……
6. Occupation: Employed ( ) Self-employed ( ) Unemployed ( )

Part two: Behavioral information

7. Do you ever use alcohol? Yes ( ) No ( )
8. Do you smoke cigarette? Yes ( ) No ( )
9. Have you ever had sexual intercourse under the influence of alcohol or other drug?
   Yes ( ) No ( )
10. Do you have active sex life? Yes ( ) No ( )
    If yes, how many sexual partners do you have?
    One ( ) Two ( ) More than two ( )
    Do you use a condom? Yes ( ) No ( )

Part three: Medical history

11. Do you have/have you ever had some discharge from your genitals? Yes ( ) No ( )
12. Do you experience / have your experienced pain during urination? Yea ( ) No ( )
13. Has your partner ever had/has a discharge from the genitals? Yes ( ) No ( )
14. Has your partner ever complained of painful urination? Yes ( ) No ( )
15. Do you think the use of ARVs is important in protecting against STIs?
    Yes ( ) No ( )

Part four: Laboratory results

Gonorrhea: Positive ( ) Negative ( )

Chlamydia: Positive ( ) Negative ( )

Tarehe: ..... Namba ya dodoso: .....

Sehemu ya kwanza: Taarifa kuhusu demografi yako

1. Umri (miaka):……..

2. Jinsia: kiume ( ) kike ( )

3. Hadhi ya ndoa: Sijaoa ( ) Ndoa ( ) Talaka ( ) Kutengwa ( )

4. Elimu: Shule ya msingi ( ) Shule ya sekondari ( ) Elimu ya juu ( )

5. Dini: Mkistu ( ) Muislamu ( ) Hindu ( ) Nyingine.....

6. Kazi: Ajiriwa ( ) Kazi binafsi ( ) Sina kazi ( )

Sehemu ya pili: Madawa ya kulevya na tabia za ngono

7. Je, unatumia pombe? Ndiyo ( ) Hapana ( )

8. Je, unavuta sigara? Ndiyo ( ) Hapana ( )

9. Umewahi kujamiiana chini ya ushawishi wa madawa ya kulevya? Ndiyo ( ) Hapana ( )

10. Hivi sasa, unashiriki ngono? Ndiyo ( ) Hapana ( )

Kama ndiyo, washiriki wako wa ngono ni wangapi? Mmoja ( ) wawili ( ) Zaidi ya wawili ( )

Unatumia kondom kushiriki ngono? Ndiyo ( ) Hapana ( )

Sehemu ya tatu: historia ya matibabu

11. Umewahi kutokwa na usaha kwenye sehemu zako za siri? Ndiyo ( ) Hapana ( )

12. Usha wahi kuwa na maumivu kwenye sehemu za siri unapokojoa? Ndiyo ( ) Hapana ( )

13. Mpenzi wako amewahi kutokwa na usaha kwenye sehemu zake za siri? Ndiyo ( ) Hapana ( )

14. Mpenzi wako asha wahi kuwa na maumivu kwenye sehemu za siri anapokojoa? Ndiyo ( ) Hapana ( )

15. Unadhani matumizi ya ARVs ni muhimu katika kulinda dhidi ya magonjwa ya zinaa? Ndiyo ( ) Hapana ( )

Sehemu ya nne: Matokeo ya maabara

Kisonono: Chanya ( ) Hasi ( )

Klamidia: Chanya ( ) Hasi ( )

APPENDIX III: Instructions for Urine Collection

Urine collection procedure for Female participants

1. Wash hands with soap and water and dry them well with the provided paper towel.
2. Separate the skin folds around the urinary opening. Wash the area with the provided towelette using a front to back motion. Repeat twice.
3. Begin urinating with the skin folds held apart with the fingers.
4. Insert collection container into urine stream without allowing container to touch the skin area.
5. Fill half of the container and remove from the urine stream.
6. Finish voiding and the replace the container lid and seal completely.
7. Take the specimen to the principal investigator / research assistant immediately.

Urine collection procedure for male participants

1. Wash hands thoroughly with soap and water; rinse and dry well with paper towels.
2. Wash the head of the penis with the towelette or soap pad provided.
3. Begin urinating.
4. Insert collection container into urine stream without allowing container to touch the skin area.
5. Fill half of the container and remove from the urine stream.
6. Finish voiding and then replace the container lid and seal completely.
7. Take the specimen to the principal investigator / research assistant immediately.

APPENDIX IV: Laboratory Request Form

Laboratory requisition form for Gonorrhea and Chlamydia screening by PCR method

Prevalence and risk factors associated with Gonorrhea and Chlamydia infections among HIV infected patients at Burnt forest AMPATH clinic, Uasin-Gishu county

Patient study number: …….....

Date sample collected: ……

Date sample run: …….

RESULTS:

Gonorrhea: Positive ( ) Negative ( )

Chlamydia: Positive ( ) Negative ( )

Tested by: ……..

Reviewed by: …….

APPENDIX V: Sample Processing

REQUIREMENTS

- Abbott m2000 instrument
- 5 ml reaction vessels
- Bulk solid caps
- Vortex mixer
- Abbott optical adhesive covers
- Abbott splash free support base
- Master mix tubes
- 200 ml reagent vessels
- Abbott 96 deep well plate
- 13 mm sample racks
- Control kit
- Sealable plastic bags
- DNAse free water
- Abbott m2000rt instrument
- Abbott mSample preparation system NB: one kit is sufficient to complete 192 CT/NG sample preparation
- Abbott m2000 system *Chlamydia trachomatis and Neisseria gonorrhea* application CD-ROM
- Abbott real time CT/NG amplification reagent kit
- Aerosol barrier pipette tips for 20 – 1000 µl pipettes
- Multi-collect specimen collection kit
- USP Grade 190 – 200 proof ethanol
- Adhesive labels for sample identification

- Abbott optical adhesive cover applicator
- Abbott m2000rt optical calibration kit
- Calibrated pipettes capable of delivering 20 – 1000 µl
- Abbott 96 well optical reaction plate

PROCESSING PROCEDURE

1. The urine samples, two tubes of CT/NG cutoff control, CT/NG negative control, and one vial of CT/NG internal control and amplification reagent were allowed to thaw at a temperature between 2ºc and 30ºc.
2. To ensure specimen uniformity, each specimen was thoroughly mixed
3. The two tubes of CT/NG cutoff control, CT/NG negative control, and specimens were placed in the m2000sp 13mm sample racks without skipping any position after all the caps had been removed from the controls and specimens. All the positions of the sample rack were filled before loading specimens on another sample rack
4. The filled sample racks were then loaded in the m2000sp in the consecutive sample rack positions, with the first rack farthest to the right on the work table and any additional racks progressively to the left of the first rack
5. The internal control was then vortexed and then using a calibrated precision pipette, 250µl of the internal control was added to the bottle of mlysis buffer. The bottle was then swirled 20 to 30 times to mix the contents without forming bubbles or foam
6. The mWash2 solution was prepared by adding 70 ml of USP Grade 190 – 200 proof ethanol (95-100%) as described in mSample preparation system product information

7. All the reagent bottles were gently inverted to ensure homogenous solution and the contents poured to the appropriate reagent vessels per the Abbott m2000sp operations manual, operating instructions. Incase crystals were observed in any reagent bottle, the reagent was allowed to equilibrate at room temperature until the crystals disappeared
8. mMicroparticles were thoroughly mixed until mMicroparticles were fully suspended.
9. The m2000sp sample extraction protocol was then initiated as described in Abbott m2000sp operations manual, operating instructions
10. While m2000sp was performing sample preparation, the m2000rt was switched on
11. After sample preparation was complete, the amplification reagent and master mix tube were loaded on the m2000sp worktable after removing the caps
12. The m2000sp master mix addition protocol was initiated as described in the Abbott m2000sp operation manual, operating instruction
13. After the m2000sp instrument completed addition of samples and amplification reagents, the 96 well optical reaction plate was sealed according to the instructions in Abbott m2000sp operation manual. The splash free support base was used to transport 96-well optical reaction plate to the m2000rt to minimize contamination
14. The 96-well optical reaction plate was placed in the m2000rt and the CT/NG real time assay was initiated as described in Abbott m2000rt operations manual
15. At the completion of the run, assay results were reported on the m2000rt

16. Once the m2000rt completed the amplification and detection, the 96-well optical reaction plate was removed from the instrument and placed in a sealable bag for disposal in accordance to the Abbott m2000rt operations manual along with the gloves used to handle the plate

POST PROCESSING PROCEDURE

1. Upon completion of the sample preparation, the specimens were recapped using new unused caps and stored at -80ºc
2. At the end of each run, all remaining reagents were removed from the instrument and discarded as stated in m2000rt operations manual
3. All the surfaces were decontaminated in accordance with the laboratory regulations
4. The splash free support base was cleared according to the Abbott m2000rt operations manual

APPENDIX VI: Referral Plan