PREVALENCE AND QUALITY OF SYNDROMIC DIAGNOSIS OF SEXUALLY TRANSMITTED INFECTIONS WITHIN THE KISUMU INCIDENCE COHORT STUDY IN KISUMU, KENYA

FREDRICK ODHIAMBO OTIENO

A mini-thesis submitted in partial fulfilment of the requirements for the degree of Masters in Public Health at the School of Public Health, University of the Western Cape

Supervisor: Ernesta Kunneke

September 2009

Declaration

I declare that "Prevalence and quality of syndromic diagnosis of sexually transmitted infections within the Kisumu incidence cohort study in Kisumu, Kenya", is my own independent work, that it has not been submitted before for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged as complete references.

_____

Fredrick O. Otieno

August 2009

Keywords

Kenya

Kisumu

Partner tracing

Prevalence of STIs

Quality of STI management

Risk factors

Sexually Transmitted Infections

Syndromic diagnosis

Abstract

Background

STIs are of major public health concern in developing countries, not least because they facilitate transmission of HIV, but also because they are important causes of mortality and morbidity among African populations, resulting in, among other things, adverse birth outcomes, neonatal and infant infections, ectopic pregnancy, anogenital cancer, infertility, pelvic inflammatory disease, and death. Thus, effective treatment needs to be prompt and accurate to control the spread, and morbidity and mortality of STIs. Even though syndromic approach to the management of STIs is effective, most evaluations have focused on syndromic STI management within STI clinics as opposed to research studies. Partner notification is an integral component of the syndromic approach and is aimed at preventing onward transmission of infection as well as re-infection. It includes informing sexual partners of infected people of their exposure, administering presumptive treatment, and providing advice about the prevention of future infection.

Methods

This is a cross sectional descriptive study based on a retrospective review of STI data of study participants in KICoS aged 18 to 34 years. A non probability convenience sampling method was used to recruit study participants. A total of 1,277 participants were pre-screened into KICoS of whom 847 were enrolled into this study. Data was collected using CAPI and ACASI questionnaires as well as Teleforms which was analysed in SAS for windows 9.1.

Results

Syndromic prevalence of STIs was 5.7% while the aetiological prevalence was 32.8%. Risk factors to STI acquisition included, being female, having multiple sexual partners, having lower than tertiary education, using recreational drugs and being HIV. Agreement between the interviewing methods as well between the syndromic and laboratory diagnosis ranged from fair to substantial. This was also true for the agreement between laboratory and CAPI as well as between the laboratory and ACASI. Sensitivity was generally low while specificity was high. Uptake of contact tracing cards was high

though with very low uptake of contact treatment with only 2.1% and 0.4% partners of the syndromically and aetiologically diagnosed participants coming for treatment.

Conclusions

STI is a problem in this community and thus there should be more emphasis on risk reduction messages in patient education to mitigate the spread of STIs. The performance of syndromic management was very poor against the aetiological diagnosis thus there needs to further review the use of syndromic diagnosis of STIs in research settings. Partner tracing needs to be intensified since there was very poor partner treatment even with high uptake of contact cards.

Acknowledgements

This study would have not been what it was without the immense support I received from many individuals all of whom cannot be mentioned here. I would however want to thank the Dr Wairimu Chege (Principal Investigator, KICoS) for her inspiration and encouragement. I would also like to thank my supervisor, Ernie Kunneke for going through this study with me repeated times including on a ride to the airport. On the same note I would also like to thank my lecturers and student administrators at the SOPH. My gratitude also goes to my colleagues Richard Ndivo, Sherri Pals and Eleanor McLellan-Lemal for all the support they accorded me throughout this research.

I would also want to give my heartfelt gratitude to my family. My daughter Akinyi who used to type with me at night, her mother Auma for understanding my late nights up and finally to my Parents Mr and Mrs Gideon and Monica Otieno for understanding the importance of education and taking me to school through all the difficulties. Last but not least I would like to express my gratitude to the almighty God for having seen me through this process.

Table of Contents

List of Tables and Figures

List of Tables

List of Figures

Abbreviations

ACASI:	Audio Computer Assisted Self Interview
CAPI:	Computer Assisted Personal Interview
CDC:	Centres for Disease Control and Prevention
ERC	Ethical Review Committee
GCLP:	Good Clinical and Laboratory Practice
HSV 2:	Herpes Simplex Virus type 2
IRB:	Institutional Review Board
KEMRI:	Kenya Medical Research Institute
KICoS:	Kisumu Incidence Cohort Study
LIMS:	Laboratory Information Management System
SAS:	Statistical Analysis Software
SOP:	Standard Operating Procedures
SSC:	Scientific Steering Committee
STI:	Sexually Transmitted Infection
Study ID:	Study Identification Number

Definition of Terms

Aetiological Diagnosis:	Laboratory based diagnosis of STI with isolation of the causative organism
Epidemiological Treatment:	The treatment of the sexual partners of STI infected persons whether or not there is laboratory evidence of infection
Index Partner:	The main partner who is enrolled in the study and infected with STI
Inheritance Status:	The status of an individual as to whether they went through rites of widow/widower inheritance after the death of the husband or wife
Laboratory Cards:	Contact cards given to participants following aetiological diagnosis and management
Mainstream Christian:	Mainstream churches like Catholics, Anglicans and large protestant churches
Monodose:	Single dosage where a drug or drugs is/are administered once
One day Treatment Regimen:	Provision of STI treatment in one day without any subsequent follow ups.
Other Christians:	Independent African Christian churches
Patient Screening:	Symptomatic, clinical and/or laboratory screening of patients for STI
Syndromic Cards:	Contact cards given to participants following syndromic management
Syndromic Management:	Treatment of STI signs and symptoms (syndromes) without laboratory diagnosis
Teleform:	Optical character recognition enabled forms

CHAPTER ONE

INTRODUCTION

1. INTRODUCTION

1.1. Background

"Sexually Transmitted Infections (STIs) are a major global cause of acute illness, infertility, long term disability and death, with severe medical and psychological consequences for millions of men, women and infants (WHO, 2001a)."

More than 30 bacterial, viral and parasitic pathogens are sexually transmitted with STIs being transmitted mostly through sex (WHO, 2007). STIs are of major public health concern in developing countries, not least because they facilitate transmission of Human Immunodeficiency Virus (HIV) (Laga et al., 1993, Cohen et al., 1997, Gilson et al., 1997, Wawer et al., 1999, Kamali et al., 2003, WHO, 1999, Mayaud et al., 1997), but also because they are important causes of mortality and morbidity among African populations, resulting in, among other things, adverse birth outcomes, neonatal and infant infections, ectopic pregnancy, anogenital cancer, infertility, pelvic inflammatory disease, and death (Buve et al., 1993, WHO, 2003, WHO, 2005, WHO, 2007). Thus, effective treatment needs to be prompt and accurate to control the spread, and morbidity and mortality of STIs (WHO, 2007).

Proper management of STIs should include strategies for patient screening and notifying their sexual partners, mono-dose and simplified therapies to improve compliance, and increase accessibility of services (Catchpole, 2001). Over the years, the management of STIs has improved considerably with introduction of new diagnostic tools as well as algorithms. The World Health Organisation (WHO) gives recommendations on these diagnostic tools and algorithms and different regions and countries are expected to adapt them to their situations (WHO, 2003, WHO, 2005, WHO, 2008). Even though aetiological diagnosis is considered to be the gold standard for diagnosis and management of STIs (Workowski et al., 2002), syndromic management is presented as a simplified and affordable approach that does not involve extra clinic visits, which may result in treatment delays (WHO, 2005). In 1985, the WHO developed simplified STI treatment guidelines at primary healthcare levels, which it revised severally and now recommends a purely syndromic approach to STI management (WHO, 2003).

Syndromic management of STIs is the diagnosis and treatment of STIs based on identification and treatment of a group of symptoms and signs (syndromes) associated with a number of well defined causative organisms. Following identification of the syndrome, treatment is provided to cover majority of the organisms that can cause the syndrome. This approach allows health workers to make diagnosis of the STIs without sophisticated laboratory tests thus allowing for faster and easier management. This information if further simplified and presented to health workers in easy to interpret flow charts both for diagnosis and treatment (WHO, 2003, WHO, 2005, WHO, 2008).

1.2. Problem Statement

Even though literature shows that syndromic approach to the management of STIs is effective (Mayaud et al., 1997, Mbofana et al., 2002, Wolday et al., 2004, Pickering et al., 2005), most of these evaluations have focused on syndromic STI management within STI clinics as opposed to research studies. Typically, STI clinic patients present with constitutional signs and symptoms while research study participants are asked a battery of questions about specific symptoms with the goal of providing treatment. Syndromic questions are based on WHO (2005) classification; urethritis/cervicitis and pelvic inflammatory disease (PID) for gonorrhoea and chlamydia, vaginitis for candida and trichomonas, and genital ulcer disease (GUD) for syphilis and herpes simplex virus type 2 (HSV-2).

Not all people with STIs are symptomatic and not all those that are symptomatic recognize the meaning or importance of their symptoms. Thus many are treated for STIs they did not have and those who unknowingly have STIs go without being treated resulting in cases of under-treatment or overtreatment (Wilkinson et al., 1999, Wolday et al., 2004, Panchanadeswaran et al., 2006, Grosskurth et al., 2000, Malta et al., 2007).

Asymptomatic cases are patients who have been infected with STIs but have not yet manifested signs and symptoms of STIs. Those who are asymptomatic may continue transmitting the STIs unknowingly as they may not have been diagnosed and treated. Within this transmitting group, there are three subgroups of sexually active infected individuals: (1) those who have sought health care but have been inadequately diagnosed,

treated, and/or counselled; (2) those who are symptomatic but are delaying seeking health care; and (3) those who are asymptomatic (Abdool Karim, 1994). Effective management would need to be offered to all these groups to stem the tide of the infections.

Since syndromic diagnosis is being carried out within a research context, it is important to determine if it is a sufficient tool for diagnosing STIs or if it must be paired with laboratory testing.

1.3. Aim and Objectives

The aim of this study was to investigate the prevalence of, describe the risk factors associated with and to evaluate the performance syndromic diagnosis in the management of STIs within the Kisumu Incidence Cohort Study (KICoS) in Kisumu, Kenya.

The objectives of the study were as follows:

1. To estimate the prevalence of STIs within KICoS using both laboratory and syndromic diagnosis
2. To describe the risk factors associated with STIs within KICoS
3. To evaluate the performance of STI syndromic diagnosis against aetiological laboratory diagnosis within KICoS
4. To establish the performance of partner contact treatment in the management of STIs within KICoS

CHAPTER TWO

LITERATURE REVIEW

2. LITERATURE REVIEW

2.1. Prevalence of STIs

The prevalence and incidence of STIs has been on the rise over the years. The WHO estimated 340 million incident cases of syphilis, gonorrhoea, chlamydia and trichomoniasis in men and women aged 15-49 years in 1999 worldwide. This was an increase from approximately 250 million new cases in 1990 (WHO, 2001a). Sub Saharan Africa continues bearing the brunt of these infections with 69 million people being newly infected with these STIs in a population of 269 million adults aged 15–49 years (WHO, 2001a). HSV-2 is more prevalent with 30% to 80% of women and 10% to 50% of men in sub Saharan Africa being infected (Holmes et al., 1999).

With very few population-based prevalence and incidence studies, majority of studies have been based on sentinel surveillance of sentinel populations in STI clinics and antenatal clinics as well as commercial sex workers and other at risk populations. The populations at risk continues to grow dynamically due to the social, demographic and migratory trends (Holmes et al., 1999). Antenatal sentinel surveys in Central African Republic and Malaysia found the prevalence of Chlamydia to be 6.2% and 1.6% respectively while that of gonorrhoea was 3.1% and 0.2% respectively. The studies also found the prevalence of syphilis to be 6.7% and 0.3% respectively (Blankhart et al., 1999, WHO, 2001c).

Commercial sex workers (CSW) surveillance in Malaysia found the prevalence of STIs to be comparable to that of antenatal clinic attendees in Central African Republic save for syphilis which was very high at 30.8% (WHO, 2001c). Another CSW sentinel survey in Malawi that focused on syndromically diagnosed STIs found the prevalence to be high with GUD, PID and urethritis having prevalences of 21%, 24% and 53% respectively (Zachariah et al., 2003). Another sentinel survey among post abortal clinic attendees in Mozambique found higher prevalence of Chlamydia (42.5%), gonorrhoea (32.9%) and syphilis (7.9%) (Machungo et al., 2002).

A population-based prevalence and incidence study of syphilis and sexually transmitted disease syndromes in north-western Tanzania found the prevalence of syphilis to be 8.1% for males and 9.4% for females. It also found the prevalence of GUD to be 14.4% for men and 4.2% for women while 28.0% of males and 7.1% of females reported to be having urethral or abnormal vaginal discharge. The study also found the overall one year incidences of GUD to be 3.6% in men and 2.0% in women, and those of urethral or abnormal vaginal discharge as 6.8% and 4-4% for men and women respectively, again twice those of GUS (Mosha et al., 1993).

The four cities study in Cotonou, Yaounde, Kisumu, and Ndola reported the prevalence of HSV-2 to be over 50% among women and over 25% among men in Yaounde, Kisumu and Ndola, with notably high rates of infection among young women aged 15-19 years in Kisumu (39%) and Ndola (23%). The prevalence in Cotonou was lower with 30% of women and 12% of men being infected (Weiss et al., 2001).

Another population based prevalence study in Indonesia found the prevalence of Chlamydia (<1%,), gonorrhoea (1.7%) and syphilis (5.2%) (Sabin et al., 2003) to be lower than that of South Africa which found the prevalence of Chlamydia to be 6.1%, that of gonorrhoea to be 4.5% and that of syphilis to be 8.8% (Colvin et al., 1998). A seroprevalence study in Gabon found very high prevalence of Chlamydia (59.6%) and syphilis (8.6%) (Bertherat et al., 1998). A study among ANC attendees in 6 different clinics in Tanzania reported the prevalence of HSV-2 to be 20.7% and that of syphilis to be 1.6% (Yahya-Malima et al., 2008).

In a male cohort study in Rakai Uganda (Charvat et al., 2009), the prevalence of HSV-2 infection was 33.76%. A study in Malawi assessing the prevalence of HSV-2 among 4 cohorts found the prevalence to be higher ranging from 33.2% to 42.1% among the males and from 47.6% to 66.7% among females in the different cohorts (Glynn et al., 2008). In a high risk female cohort study in Tanzania, the prevalence of HSV-2 was found to be very high with 80% of the females being infected (Watson-Jones et al., 2007). This was close to a HSV-2 prevalence study in STD clinics in Tanzania which found the prevalence in males to be 35.5% and that for females to be 63% (Langeland et al., 1998).

Though there are not very many studies showing STI co-infection among study populations, some studies have documented this phenomenon with patients having two or more STIs concurrently. A study in china found co infection with gonorrhoea and Chlamydia to be prevalent amongst commercial sex workers (25%) and truck drivers (2%) with the highest prevalence of chlamydial or gonorrhoeal infection being observed among the 15-19 and the 19-24 age groups (WHO, 2001b). another study of genitourinary clinic attendees in Edinburg Scotland found that 7.3% of the study population had concurrent STI infection (Pakianathan et al., 1996).

2.2. Syndromic Management of STIs

The WHO recommends syndromic management as the first line management of uncomplicated STIs in resource-limited settings as well as in resource-rich settings dependent on circumstances (WHO, 2003, WHO, 2005). This approach involves the use of simple flowcharts to help health-care workers identify groups of symptoms and easily recognisable signs (syndromes) and guide treatment consisting of combination antibiotics likely to cover the most probable causes of the syndrome (Donovan, 2004, Low et al., 2006, WHO, 2003). The WHO further encourages countries or regions to adapt the algorithms and flow charts to fit their region or country-specific needs.

Though aetiological diagnosis and management is considered as the gold standard of STI treatment, laboratory testing for STIs is quite expensive with costs ranging from $6-89 for chlamydia trachomatis DNA, $1-89 for neisseria gonorrhoeae DNA, $12 for trichomonas vaginalis, $20-100 for bacterial vaginosis, $35-159 for HSV2 and $1-60 for syphilis (Peeling, 2006, Donovan, 2004). Also since most countries, especially developing countries, do not require regulatory approval for use of these tests in their regions, their validation in these regions becomes difficult with a resultant proliferation of even obsolete testing algorithms (Peeling, 2006).

It is on the back of this that the syndromic approach appears useful as it removes the need for laboratory testing and to an extent, even the need for physical examination (Donovan, 2004). This approach is seen as a practical strategy for use in resource-limited settings as it provides prompt treatment thus avoiding loss to follow up that could be witnessed in

STI management involving laboratory-based diagnosis (Low et al., 2006). In addition, this approach is sometimes necessary in resource-rich environments, such as in cases of upper genital tract infections where detection of the pathogen is difficult (Donovan, 2004).

Syndromic management is based on the ability of the health workers to remember the guidelines as well as the client's ability to recall and correctly describe the signs and symptoms which would fit into a specific syndrome. Those opposing the syndromic approach argue that it contributes to health workers being de-skilled as the procedures become routine to them thus they are reduced to robotic creatures (Garg et al., 2007). These opponents further point out that it does little to reduce the numerically dominant subclinical pool of STIs as patients in this category are still asymptomatic (Donovan, 2004, Mullick et al., 2005). In symptomatic patients, most symptoms are highly inconsistent in their positive predictive power for the STIs with expensive antibiotics being wasted at times with the risk of promoting resistance. The liberal use of antibiotics most of the time results in the development of resistance to the antibiotics with resultant treatment failure or change to more expensive antibiotics (Workowski et al., 2008).

Several studies (Chalamilla et al., 2006, Pépin et al., 2004, Low et al., 2006, Desai et al., 2003, Donovan, 2004, Kamali et al., 2003) have demonstrated syndromic management as being effective in the management of STIs in males, especially in the case of gonorrhoea and chlamydia infections. This on the other hand, is not true for females with only a minority receiving the correct syndromic management of both infections. These studies and others (Goh, 2005, Mosha et al., 1993) further found out that treatment guidelines for GUD against aetiological diagnosis was also poor with many patients being treated for syphilis and or chancroid which they did not have. The studies also found out that there were some cases of misreporting with patients reporting to have ulcers when actually they have discharge and vice versa.

Even though some studies have shown that reported symptoms of STIs in the past 12 months were high for both men and women, these same studies have also reported that the overall awareness level about STIs and their prevention was rather low with as many

as 70% of the study participants being unable to mention even one symptom of an STI (Garg et al., 2007, Hawken et al., 2002). These studies also observed poor treatment seeking behaviours among the participants and their partners.

2.3. Partner Contact Tracing

The one day treatment regimen allows for an opportunity for health promotion as well as prevention services with partner notification being a key factor (Low et al., 2006). Partner notification is an integral component of the syndromic approach and is aimed at preventing onward transmission of infection as well as re-infection (WHO, 2003, Low et al., 2006). It includes informing sexual partners of infected people of their exposure, administering presumptive treatment, and providing advice about the prevention of future infection. Studies have shown that the risk of re-infection or persistent infection in index cases can also be reduced with correct partner notification (Mullick et al., 2005, Low et al., 2006, Workowski et al., 2008).

A study in South Africa found that most female patients preferred to deliver medication to their partners as opposed to informing them to go for treatment to a clinic. This was mainly because they felt their partners would not have time or would not want to go to the clinic. In addition, they felt this was a way to ensure that partners received treatment (Young et al., 2007). Another study in Kenya (Wakasiaka et al., 2003) found that only 23% of their patients ever refereed their partners for STI management. They also found that patients with multiple sex partners were less likely to refer their partners and that counselling of STI patients on the importance of partner referral was more effective than issuing referral cards alone.

One of the major challenges in partner notification is the identification and provision of epidemiological treatment to sexual partners (Wilkinson et al., 1999, Goh, 2005). This has seen periodic presumptive treatment being provided in some risk group with better success (Steen et al., 2000). Even in centres that provide partner notification (Manavi et al., 2008), uptake has been low with a survey of 13 centres providing partner notification reporting an average of 32% partner notification.

A survey of physicians in the United States (St. Lawrence et al., 2002, St.Lawrence et al., 2002) found out that physicians would rather have the patients notify their partners than the physicians doing so. This actually negates the possibility of confirming whether the partner notification was done and subsequent treatment administered correctly. Another challenge has been the internet based STI treatment sites which offer information on products for STI treatment (Vivancos et al., 2007). These sites however seldom provided advice on treatment of sexual contacts or on preventive measures.

2.4. Risk Factors of STIs

STI infection has been associated with different risk factors and a change in these risk factors is almost always accompanied by a significant decrease in the incidence of STIs (Jackson et al., 1997). Several studies have demonstrated different risk factors to be associated with different STIs with some of them cutting across some infections.

Different studies have shown that HIV co-infection increases the chances of getting STIs and vice versa. A study in Addis Ababa found that HIV co-infection predisposes women to getting more ulcerative STIs as well as failing STI treatment especially HSV-2 (Wolday et al., 2004). This was also seen in another study in Tanzania that enrolled high risk females (Watson-Jones et al., 2007) and the four cities study in Cotonou, Yaounde, Kisumu and Ndola (Weiss et al., 2001). Another study in Malaysia also found HIV as a predisposing factor to syphilis among female and male sex workers (WHO, 2001c). A study in Malawi that followed four cohorts found that HSV-2 infection was not significantly affected by HIV infection (Glynn et al., 2008), and another male cohort study in Rakai found enrolment of HIV status not to significantly affect acquisition of HSV-2 (Charvat et al., 2009). The Rakai study also found that male circumcision reduced the risk of HSV-2 acquisition. Consistent condom use was also shown to be protective against the acquisition of HSV-2 (Watson-Jones et al., 2007, Yahya-Malima et al., 2008, Charvat et al., 2009)

Age has been shown to be a risk factor to the acquisition of STIs with different studies. Fenton et al., (2005) found that younger people were more at risk to acquire STIs than adults as was also seen in a study in Malawi (Glynn et al., 2008). This is also true in another study among antenatal women that found younger women to be more at risk of

having Chlamydia than their older counterparts (WHO, 2001c). On the other hand, a study in Tanzania (Newell et al., 1993) found very little to no association between age and STIs. Other studies in Edinburgh (Pakianathan et al., 1996), Cotonou, Yaunde, Kisumu and Ndola (Weiss et al., 2001) and Tanzania (Watson-Jones et al., 2007) found older age to be more associated with STI acquisition.

Several studies have looked at the effect of gender on STI acquisition with men being found to be more at risk of acquiring STIs as opposed to their female counterparts. Sabin et al., (2003) found men to be twice at risk of being infected with STIs compared to females. A study looking at risk factors to STIs in Western Tanzania not only found men to be more at risk of acquiring STIs, it also found that among the men, age, education, marital status, residence near brothels and exchanging money for sex were the factors putting them at a higher risk of STI acquisition (Newell et al., 1993). The study also found that divorced, separated or widowed men as well as those with higher educational status had an increased risk of STIs while this was not true to females. A Malawi study looking at HSV-2 prevalence among four cohorts found that HSV-2 prevalence was higher in females than in males with antenatal women having a lower prevalence than those in the general population (Glynn et al., 2008).

Education has been found to be a significant factor in STI transmission. A study in Tanzania found that educated women were less likely to be infected with syphilis while this was not true for men (Newell et al., 1993). On the other hand, educated men were more likely to have urethral discharge and genital ulcers compared to females. A CSW study also found that education had a protective effect in the acquisition of STIs with CSWs with lower education having more STIs and engage in more risky behaviours than their counterparts who are more educated (Solomon et al., 2008). This was also seen in a female high risk cohort study in Tanzania (Watson-Jones et al., 2007).

Separation, divorce or widowhood was found to put men at risk of acquiring STIs compared to those who were married or living as married while being single was found to be more protective. Women on the other hand had less marked differences based on marital status (Newell et al., 1993, Zachariah et al., 2003). The number of sexual partners

has also been found to be a risk factor with sexual concurrency (Drumright et al., 2004) and sexual networks (Doherty et al., 2005) showing that the more the number of sexual partners, the more the risk of STI acquisition (Newell et al., 1993, Colvin et al., 1998, Weiss et al., 2001, Fenton et al., 2005, Yahya-Malima et al., 2008, Charvat et al., 2009). These studies also showed that low condom use also increased the risk of having STIs.

Socio-economic class also plays a key role in the transmission of STIs with some studies (Fenton et al., 2005) showing no impact while others (Pakianathan et al., 1996, Watson-Jones et al., 2007) showing an impact on the transmission of STIs. Employment generally is protective against STI acquisition, but other occupations like being a house help or an immigrant worker predispose to higher chances of STI acquisition (Newell et al., 1993, Smith Fawzi et al., 2003).

Transactional sex and homosexuality have been shown to put people at risk of getting STIs with men living close to a brothel or bar also having a higher risk of acquiring STIs (Hughes et al., 2000, Noell et al., 2001, WHO, 2001c, Zachariah et al., 2003, Fenton et al., 2005). Other studies (Noell et al., 2001, Kraut-Becher and Aral, 2006) also found trans-generational sex to predispose people to acquire more STIs. Circumcision is protective especially from ulcerative STIs (Newell et al., 1993, Jansen et al., 2003), while it also predisposes the men to an increased risk of urethral discharge (Newell et al., 1993).

Injection drug use increases the risk of STI acquisition generally (Noell et al., 2001, Fenton et al., 2005). Different studies have also shown alcohol as a risk factor to the acquisition of STIs. In addition, alcohol intake was also associated with other risky sexual behaviours that also predispose to STI acquisition (Madhivanan et al., 2005, Kalichman et al., 2007, Chersich et al., 2007).

CHAPTER THREE

STUDY DESIGN AND METHODOLOGY

3. STUDY DESIGN AND METHODOLOGY

3.1. Study Design

This is a cross sectional descriptive study based on a retrospective review of STI data of study participants in KICoS.

3.2. Study Population

This study was set within KICoS which is a prospective cohort study to estimate incidence of HIV seroconversion and to identify determinants of successful recruitment and retention among adolescents and young adults in Kisumu, western Kenya (Chege et al., 2007). Participants in KICoS were young healthy adults aged 18-34 years. Other eligibility criteria for KICoS included being a resident of Kisumu, having had sexual intercourse at least once in the past three months and not being pregnant for females.

Participants in KICoS were screened for STIs including gonorrhoea, Chlamydia, syphilis and HSV-2. In addition, those presenting with signs and symptoms of any of the STIs receive syndromic management with definitive treatment offered as necessary two weeks later after laboratory results become available. Participants receiving syndromic or definitive treatment are given contact treatment cards to give their sexual partners to facilitate their coming to the clinic for anonymous STI treatment (Chege et al., 2007).

A non probability convenience sampling method was used to recruit study participants into KICoS. This approach did not provide a representative sample but ensured the identification of persons with a willingness to participate in a prospective study requiring multiple encounters with study staff. For KICoS, a sample size of 625 participants was calculated based on an estimated incidence 2.0 to 3.0 per 100 person-years and a retention rate of 80%.

3.3. Inclusion and Exclusion Criteria

To be included in this study, participants must have completed all the screening processes within KICoS, had STI testing and completed the behavioural questionnaire. Participants who did not have STI tests done or did not complete the behavioural questionnaire were excluded from this study.

3.4. Sampling

A total of 1,277 participants were pre-screened into KICoS of whom 68% were eligible to complete the screening procedures based on the inclusion and exclusion criteria for KICoS as explained in section 3.2 above. Of those completing screening procedures, 20 participants were excluded from this study because they were missing medical examination, pre screening, behavioural or laboratory data. This left a total of 847 participants who met the inclusion criteria and were thus included in this study. This is shown in figure 1 below. This sample size provides a good precision with confidence intervals around 0.0381 – 0.0697 to detect 5% STI prevalence or 0.0989 – 0.1445 to detect 12% prevalence.

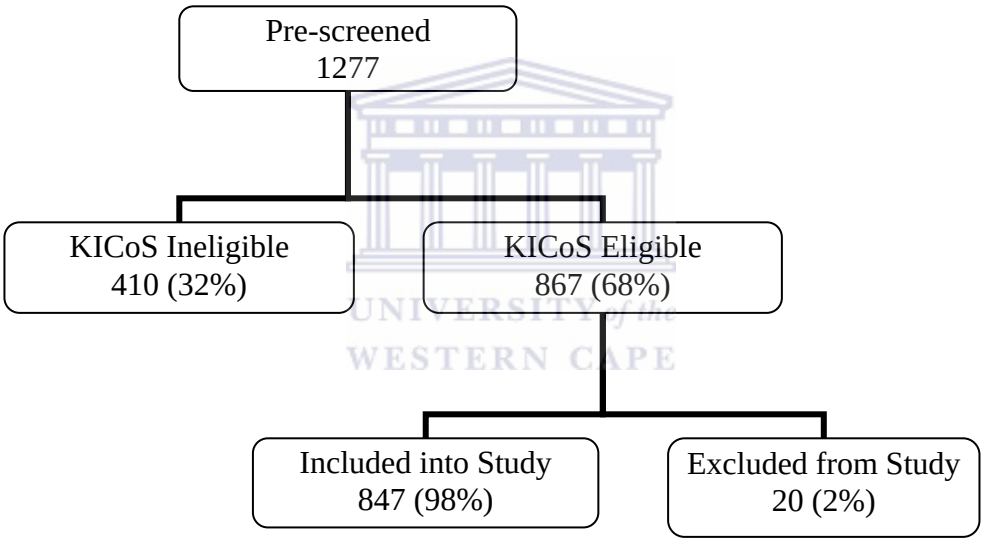

Figure I: Flow Chart Showing Participant Enrolled into the Study

3.5. Data Collection

In KICoS, participant information was obtained using Audio Computer Assisted Self Interviews (ACASI) and Computer Assisted Personal Interviews (CAPI). These two forms of questionnaire designs are paperless and allow for direct data entry into a computer thus reducing redundancy and risk of transcription errors. The data collected was then exported to a Questionnaire Development System® (QDS) (Nova, 2008) warehouse manager where it was stored for analysis.

Behavioural and demographic information was collected using ACASI which allowed the respondents to personally complete the study questionnaire by entering their responses directly into the computer via a touch screen. The behavioural questionnaire included questions on sexual debut, transactional sex, number of sexual partners, length of relationships, condom use, drug use during sex, anal or vaginal sex, circumcision status and symptoms and treatment history of STIs. Demographic information including education level, economic status as well as marital status was also collected on the ACASI questionnaire. Extracts from this questionnaire is included in Appendix A.

Other demographic information including age, gender and residence was collected on the CAPI pre-screening questionnaire in which the study staff entered the participant's responses directly to a computer in real time using the keyboard and mouse (Appendix B). Information on symptoms of STIs as well as diagnosis and treatment offered was collected using the CAPI medical history and physical examination questionnaire (Appendix C), after which the clinicians then fitted these responses within the syndromic classification as per the Kenya national guidelines for syndromic management of STIs (NASCOP, 1994).

Laboratory diagnosis was based on different assays. BD Micro-Vue RPR Card test (Becton Dickinson company®) and Serrodia- TPPA (Fujirebio Diagnostics,Inc®) for *Treponema Pallidum* and HSV-2 IgG ELISA (KALON BIOLOGICAL LTD®) for herpes simplex virus type 2. CT/NG PCR (Roche AMPLICOR®) was used for testing *Chlamydia trachomatis* and *Neisseriae gonorrhoeae.* All Positive results in the primary run for the HSV-2 IgG ELISA and CT/ NG PCR were repeated to confirm results. The results were then reported on the KICoS laboratory specimen collection and reporting form (Appendix D) which is a TeleForm® (Cardiff, 2008) paper form which were then scanned and stored in a Microsoft Access database for analysis. In addition, data on partner tracing was also collected on the KICoS partner treatment tracking form (Appendix E) which is also a TeleForm® paper form.

KICoS data extracted and reviewed in this study included the following:

- Information from the behavioural questionnaire completed at baseline screening

- Information from STI testing performed at baseline screening (STI panel inclusive of neisseria gonorrhoea, chlamydia trachomatis, syphilis and HSV-2)
- Information on HIV test results from testing performed at baseline
- Information from participant STI treatment forms
- Information from partner treatment forms
- Information from participant medical evaluation forms

The data extracted from the above sources and collected for this study was stored in MS Access 2007® as well as Excel 2007® and SAS 9.1® databases.

3.6. Validity and Reliability

KICoS data collection tools were designed electronically using QDS® software and Teleforms®. Internal checks for consistency and validity were programmed and embedded in the design of the questionnaires to ensure data quality. In addition, the study staff were trained and the data collection instruments pre-tested, in a one month pilot, prior to initiation of data collection. Data entry was automated thus eliminating the need for a separate data entry step. Participants were given a tutorial before they could start ACASI and also given trial questions to evaluate their competence with the programme before the start of the questionnaire. Study staff were also available all the time to assist the participant in case of any problems.

The study clinic and the laboratory adhered to standards of good clinical and laboratory practices (GCLP) and the local study-specific standard operating procedures (SOPs) manual for proper collection, processing, labelling, transport and storage of specimens. Specimen collection, testing, and storage were documented using a Laboratory Information Management System (LIMS). For quality assurance purposes, the laboratory retested 10% of all specimens tested as well as confirmation of all positive results. The laboratory is also enrolled in external quality assurance programmes where 20% of all specimens are shipped to external laboratories for validation.

All study procedures had SOPs detailing the procedures to be followed and regular competency tests were administered to staff. Study forms were linked through unique

study numbers assigned to study participants and personal identifier information was recorded on separate forms and kept separately to maintain confidentiality. Local databases are secured with password-protected access systems and access is limited. Computerized data records were electronically transferred to a secure password-protected network server on a daily basis.

3.7. Generalisability

Participants in this study were sampled from participants in KICoS. Since KICoS participants were sampled from the general community, the results of this study are therefore generalisable for the Kenyan population.

3.8. Data Analysis

Data analysis was done using statistical analysis software (SAS) for windows version 9.1 (SAS Institute, Cary, North Carolina, USA). To describe the baseline demographic characteristics of persons screened in the study, frequencies and percentages of participants in various socio-demographic groups was computed. The prevalence of STIs within KICoS at baseline was calculated for the overall study population at screening in order to describe the disease burden. This involved the calculation of overall STI prevalence, specific STI prevalence as well as the prevalence of syndromic and laboratory diagnosed STIs.

Bivariate and multivariate logistic regression was used to explore the association between risk factors and STI infection. Unadjusted and adjusted odds ratios with their 95% confidence intervals were calculated. Unadjusted odds ratios were used for bivariate analysis while adjusted odds ratios were used for the multivariate analysis that adjusted for the other risk factors that could act as confounders. Risk factors analysed included age group, gender, education, employment and marital status, number of spouses, inheritance status, type of sexual partners, transactional sex, alcohol and drug use, anal sex, time frame of last sex, condom use, circumcision status and STI treatment history and HIV status. The first model entailed a bivariate analysis of the presumed risk factors and those factors found to be having p values of <0.25 from the bivariate model were then included in the multivariate analysis. The cut off p value of <0.25 was chosen based on the works

of Bendel and Alfi (1977) and Mickey and Greenland (1989) which showed that this cut off point allows for the inclusion of all important variables even though it also has the disadvantage of including variables with questionable importance (Hosmer and Lemeshow, 2000).

To evaluate the performance of STI syndromic management against the aetiological laboratory diagnosis, a kappa coefficient (to assess agreement of the two methods) was computed as well as sensitivity and specificity analysis of the methods used. This was a two step process with the first step involving the correlation of the agreement between the two methods used to ask the syndromic questions namely the self administered ACASI questionnaire and the clinician administered CAPI questionnaire. This step used the clinician administered CAPI questionnaire as the gold standard. The second step entailed the correlation of the agreement between each of the two methods of syndromic questions administration and their corresponding laboratory diagnosed STI as well as the sensitivity and specificity of the same procedures. For this step the laboratory diagnosis was used as the gold standard.

To establish the success of partner contact treatment, the number of participants who were issued with contact tracing cards was computed against the number of partners who actually came for contact treatment. Since the partner treatment is anonymous, linking the partners to the index participants was however not done.

3.9. Ethical Considerations

KICoS was approved by both the KEMRI Scientific Steering Committee (SSC) and Ethical Review Committee (ERC) protocol # 1125 and the CDC Institutional Review Board (IRB) protocol #4938. In KICoS, informed consent was obtained from all participants. This study was further approved by the University of Western Cape higher degrees committee. Confidentiality was also assured for all participants with information collected being stored securely at the study clinic. All laboratory specimens, reports, data collection instruments, process logs, and administrative forms were identified by a coded study identification number to maintain participant confidentiality. All records that

contain personal identifiers were stored separately from study records identified by study ID and had limited access. All databases were password-protected for security of access.

3.10. Study Limitations

This study had the limitation of not including the mode of contact tracing as well as the reasons for partners not coming for treatment despite information. In addition the study could not link the contacts to the partners so knowing whose partner ever came for contact tracing was not possible. This was due to the design of KICoS which did not capture this information.

CHAPTER FOUR

RESULTS

4. RESULTS

4.1. Introduction

In this chapter, the results are presented based on data collected from 847 participants and the prevalence, risk factors associated with STIs, quality of syndromic diagnosis and contact tracing for participants in the study is shown. The results are presented thematically focusing on each of the four objectives of the study. The results are also summarised in tables and figures. In some tables and figures, the number of participants (N) does not total to 847. These are cases where there was no response and in such cases the number of participants whose data is analysed is indicated below the tables.

4.2. Socio-Demographics

In this section the frequency distributions of the main socio-demographic and socio-economic characteristics of the participants are presented. The socio-demographics of interest here include gender, age, religion, marital status, education and occupation.

Table I: Socio-Demographic Characteristics of Participants

Characteristic	Frequency	Percentage
Gender		
Males	422	49.8
Females	425	50.2
Age in Years		
18-19	106	12.5
20-24	530	62.6
25-29	149	17.6
30-34	62	7.3
Religion*		
Roman catholic	318	37.5
Protestant or other Christian	371	43.8
Muslim	27	3.2
Nomiya	45	5.3
Other	60	7.1
No religion	25	3.0
Marital Status[§]		
Single/Never married	516	60.9
Not married but living as married	72	8.5

Married	214	25.3
Divorced/Separated	28	3.3
Widowed	13	1.5
Education [¥]		
Ever attended school	576	68.0
Never attended school	40	4.7
Level of education*		
Primary	214	25.3
Secondary	312	36.8
Tertiary (technical + college)	263	31.1
University	14	1.6
Occupation		
Students	228	27.1
Farmer	29	3.4
Salaried worker	22	2.6
Casual worker	117	13.9
Self employed	146	17.3
Home maker	62	7.4
Unemployed	212	25.2
Other	26	3.1

*N=846 as 1 participant refused to respond to the question
[¥] N=844 as 3 participant refused to respond to the question
[§] N=843 as 4 participant refused to respond to the question

Table I above presents the socio-Demographic characteristics of the patients in the study. Of the total 847 participants included in this study, 422 (49.8%) were males. The average age of the participants was 22.9 years with majority (62.6%) of those in this study aged 20-24 years. Majority (81.3%) of the participant reported to be mainstream Christians of whose majority were protestant and other Christian. More than half (60.9%) of the participants have never been married with only one third (33.8%) of the participants being married or living as married. Majority of the participants (68.0%) reported having ever attended school with 589 (69.5%) of them having had more than primary education. Students comprised of 228 (27.1%) of the participants.

4.3. STI Prevalence

The first objective of this study was to estimate the prevalence of STIs within KICoS using laboratory and syndromic diagnosis. The STI prevalence calculated was both for syndromic diagnosed and specific laboratory diagnosed STIs.

4.3.1. Syndromic STI Prevalence

This section presents the prevalence of STIs based on syndromic diagnosis of participants. This prevalence is presented in Table II and figure II below. The syndromes diagnosed included vaginal and or urethral discharge, genital ulcers and lower abdominal and or scrotal pain.

Table II: Syndromic Prevalence of STIs

Syndromic Prevalence	Males N (%)	Females N (%)
Vaginal/Urethral discharge	1 (20.2)	33 (7.8)
Genital ulcers	5 (1.2)	0 (0.0)
Lower abdominal and scrotal pain	2 (0.5)	13 (3.1)
Overall	7 (1.7)	41 (9.8)

[1] N=812 as 35 participant refused to respond to the question
[2] N=812 as 35 participant refused to respond to the question
[3] N=839 as 8 participant refused to respond to the question

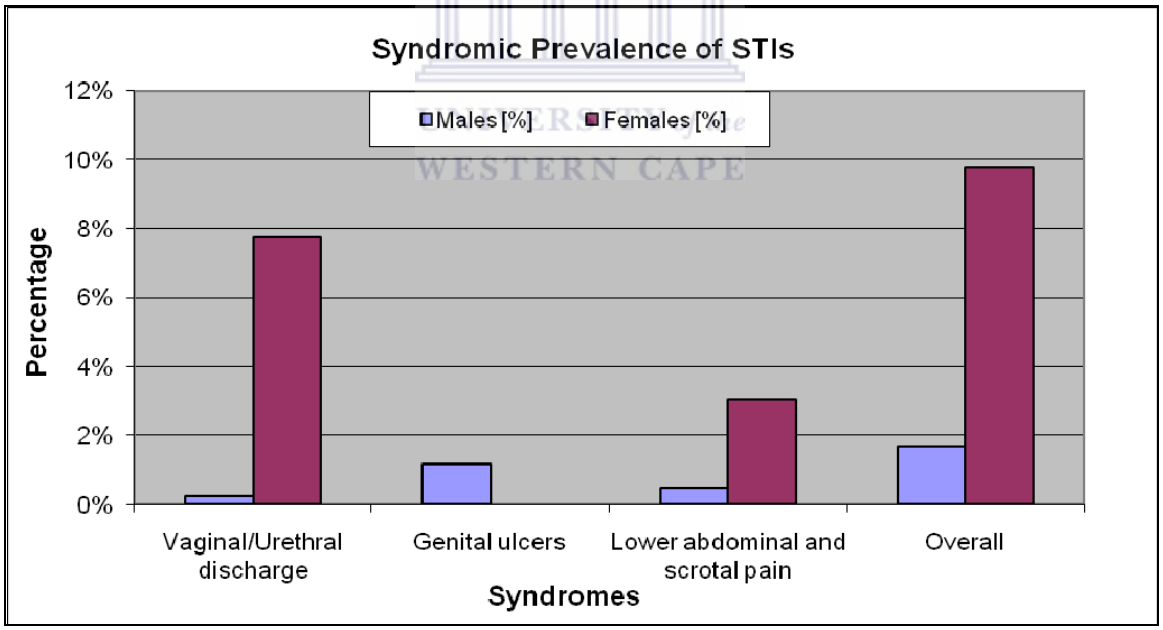

Figure II: Syndromic Prevalence of STIs

Table II and figure II above present data on the syndromic prevalence of STIs. Only 48 (5.7%) of the participants in this study were diagnosed with any STI by syndromic diagnosis with females accounting for 41 of those diagnosed. Of the 34 (4.0%)

participants diagnosed with vaginal and/or urethral discharge, 33 of them were females and all the 5 (1.2%) participants diagnosed with genital ulcers were males. Participants with lower abdominal and/or scrotal pain constituted 15 (1.8%) of the participants with 13 of them being females.

4.3.2. Aetiological STI Prevalence

This section presents the prevalence of STIs based on aetiological laboratory diagnosis of participants. The specific STIs diagnosed included gonorrhoea, Chlamydia, syphilis and HSV-2. Table III and figure III below presents the participants who were diagnosed with STIs aetiologically.

Table III: Aetiological Prevalence of STIs

Aetiological Prevalence	Males N (%)	Females N (%)
Gonorrhoea	0 (0.0)	20 (4.7)
Chlamydia	13 (3.1)	11 (2.6)
Syphilis	3 (0.7)	11 (2.6)
HSV-2	60 (14.2)	191 (44.9)
Overall	71 (16.8)	207 (48.7)

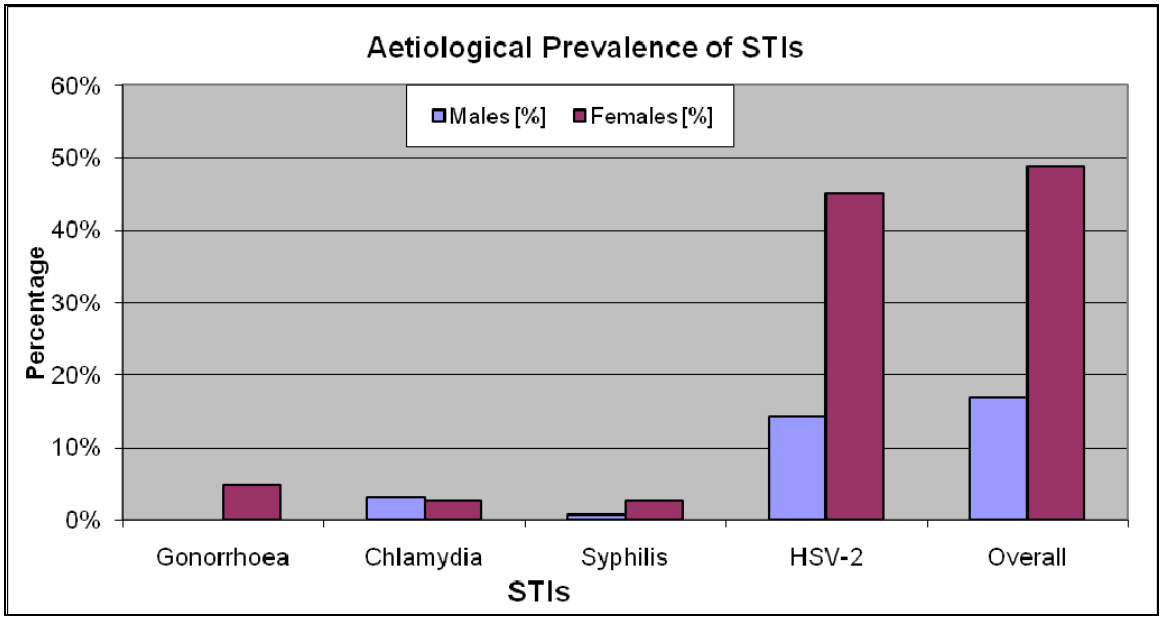

Figure III: Aetiological Prevalence of STIs

The laboratory diagnosed 32.8% (278) participants to be having an STI of whom 207 were females. All the 20 participants diagnosed with gonorrhoea were females with males constituting 13 of the 24 participants diagnosed with Chlamydia. HSV-2 accounted for 29.6% of the infections with 191 females being infected with HSV-2. Participants diagnosed with syphilis were only 1.7% (14) of who only 3 were males.

4.3.3. STI Co infection

Table IV and figure IV below presents the findings of participants who were infected with more than one STI at the same time. The range of STIs co infected is from 0 to 3.

Table IV: STI Co infection

Number of STIs	Males N (%)	Females N (%)
0	351 (83.2)	218 (51.3)
1	66 (15.6)	182 (42.8)
2	5 (1.2)	24 (5.7)
3	0 (0.0)	1 (0.2)

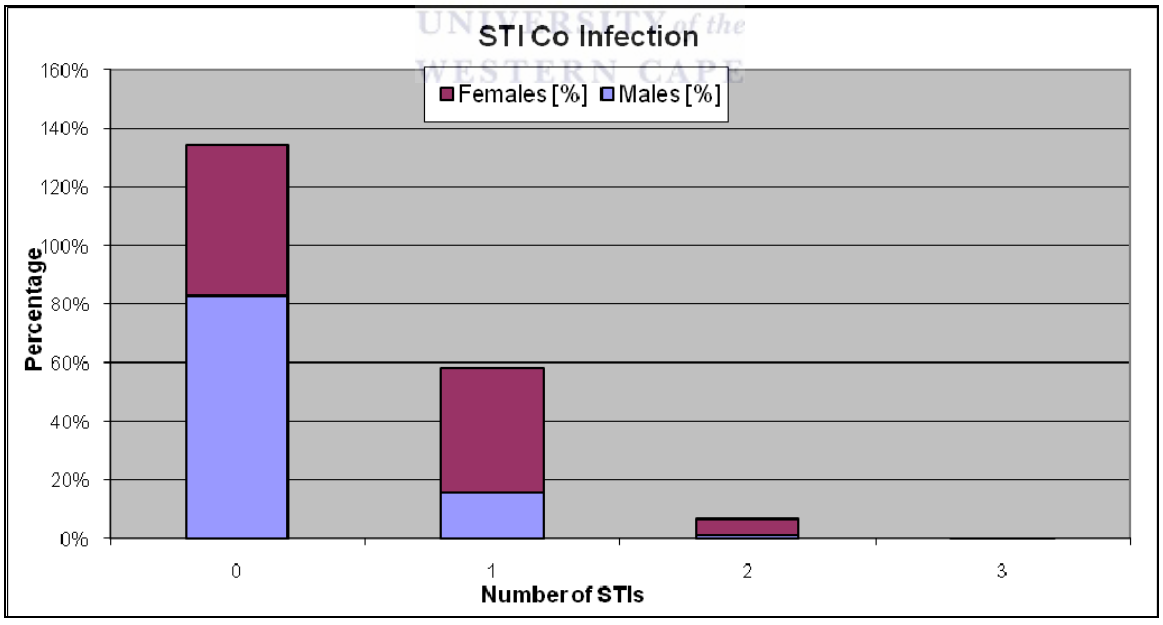

Figure IV: STI Co infection

Of all the participants in the study, 67.2% (569), of whom 351 were males, did not have any STI. Of the participants diagnosed with an STI, 248 (29.3%) had one STI with 182 of them being females. Participants found to be co infected with 2 STIs were 29 (3.4%), majority (24) of whom were females while 1 female had 3 STI co infections at the time of diagnosis.

Table V: Co Infected STIs

Co infected STIs	Frequency	Percentage
HSV-2 & Chlamydia	8	26.7
HSV-2 & Gonorrhoea	10	33.3
HSV-2 & Syphilis	11	36.7
HSV-2, Chlamydia & Gonorrhoea	1	3.3

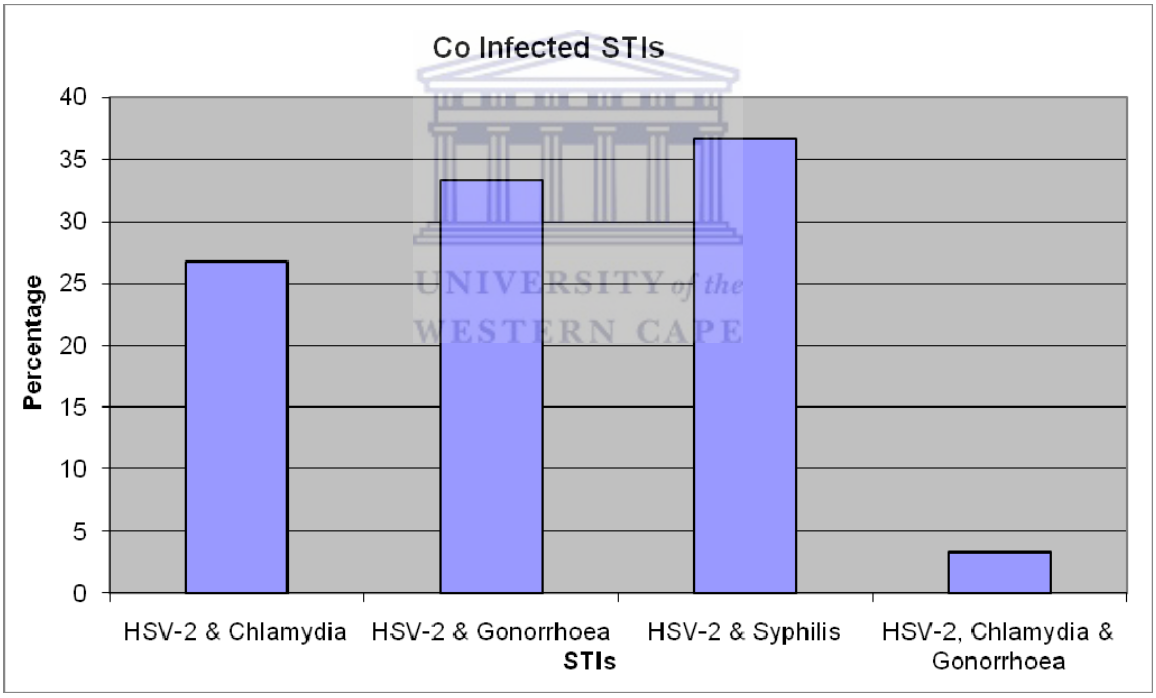

Figure V: Co Infected STIs

Of all the STI co infections, HSV-2 was predominant in all the participants co infected with any STI. Of all the participants co infected with STIs, 3.3% (1) of them were infected withHSV-2, Chlamydia and gonorrhoea and 26.7% (8) were co infected with HSV-2 and Chlamydia. A further 33.3% (10) were co infected with HSV-2 and

gonorrhoea while 36.7% (11) were co infected with HSV-2 and syphilis. Table V and figure V above summarises this data.

4.4. Risk Factors

The second objective of this study was to describe the socio-demographic, behavioural and health risk factors associated with STIs. Bivariate and multivariate logistic regression was used to explore the association between the factors and STI infection. This data is summarised in table VI below

Table VI: Risk Factors for STI Acquisition

Variable	Had STIs	Bivariate		Multivariate	
		OR[a]	p-value	AOR[b]	p-value
	N (%)	(95% CI)		(95% CI)	
Gender			<.0001		<.0001
Male (n=422)	71 (16.8)	0.22 (0.14, 0.35)		0.22 (0.11, 0.45)	
Female (n=425)	207 (48.7)	ref[c]		ref	
HIV positive			<.0001		0.0007
Yes (n=123)	85 (69.1)	6.44 (3.29, 12.63)		4.46 (1.89, 10.56)	
No (n=724)	193 (26.7)	ref		ref	
Highest level of education			<.0001		0.0289
Primary (n=214)	113 (52.8)	5.39 (2.92, 9.94)		2.85 (1.24, 6.54)	
Secondary (n=312)	98 (31.4)	2.41 (1.38, 4.23)		2.13 (1.08, 4.22)	
Tertiary (n=277)	47 (17.0)	ref		ref	
Marital status			<.0001		0.0343
Single (n=516)	108 (20.9)	0.07 (0.02, 0.27)		0.18 (0.03, 1.03)	
Married (n=286)	137 (47.9)	0.26 (0.07, 0.94)		0.39 (0.07, 2.24)	
Divorced/Widowed (n=41)	30 (73.2)	ref		ref	
Ever circumcised			0.0002		0.5236
Yes (n=184)	28 (15.2	ref		ref	
No (n=655)	247 (37.7)	3.48 (1.82, 6.63)		1.34 (0.55, 3.30)	
Last time of sex			0.0009		0.1955
Within three months (n=677)	200 (29.5)	0.35 (0.14, 0.88)		0.70 (0.22, 2.24)	
Four to six months (n=58)	26 (44.8)	2.17 (0.52, 9.09)		2.63 (0.42, 16.26)	
More than six months (n=72)	36 (50.0)	ref		ref	
Drug use			0.0013		0.0390
Yes (n=137)	23 (16.8)	ref		ref	

No (n=707)	254 (35.9)	3.67 (1.66, 8.09)		3.31 (1.06, 10.29)	
Alcohol use			0.0073		0.4324
Yes (n=363)	90 (24.8)	ref		ref	
No (n=483)	187 (38.7)	1.85 (1.18, 2.89)		0.77 (0.40, 1.48)	
Sex in exchange for gifts			0.0104		0.2276
Yes (n=103)	30 (29.2)	ref		ref	
No (n=737)	245 (33.2)	2.44 (1.23, 4.83)		1.86 (0.68, 5.09)	
Ever Inherited			0.0212		0.9329
Yes (n=45)	24 (53.3)	ref		ref	
No (n=796)	251 (31.7)	0.40 (0.19, 0.87)		1.05 (0.35, 3.18)	
Ever treated for STI			0.0850		0.0660
Yes (n=131)	58 (44.3)	ref		ref	
No (n=709)	216 (30.5)	0.61 (0.34, 1.07)		0.48 (0.22, 1.05)	
Condom use with main partner			0.0876		0.9000
All of the time (n=13)	7 (53.9)	1.31 (0.41, 4.22)		0.55 (0.11, 2.65)	
Most of the time (n=41)	15 (36.6)	0.68 (0.33, 1.42)		0.89 (0.34, 2.30)	
Sometimes (n=122)	36 (29.5)	0.55 (0.33, 0.90)		0.97 (0.49, 1.93)	
Never (n=211)	92 (43.6)	ref		ref	
Multiple spouses			0.1360		0.1585
Yes (n=21)	12 (57.1)	ref		ref	
No (n=824)	266 (32.3)	0.46 (0.17, 1.27)		2.50 (0.70, 8.97)	
Number of sexual partners			0.1494		0.0488
No sexual partners (n=59)	16 (27.1)	2.67 (0.63, 11.37)		2.57 (0.48, 13.83)	
Single sexual partner (n=91)	31 (34.1)	0.56 (0.24, 1.29)		0.35 (0.13, 0.94)	
Multiple sexual partners (n=696)	231 (33.2)	ref		ref	
Age			0.1819		0.7335
18 - 19 years old (n=106)	25 (23.6)	0.47 (0.18, 1.22)		0.50 (0.13, 1.85)	
20 - 24 years old (n=530)	163 (30.8)	0.50 (0.24, 1.05)		0.58 (0.20, 1.66)	

25 - 29 years old (n=149)	54 (36.2)	0.74 (0.33, 1.68)		0.68 (0.23, 2.00)	
30 - 34 years old (n=62)	36 (58.1)	ref		ref	
Age of sexual debut			0.2845		-
< 7 years old (n=17)	4 (23.5)	0.29 (0.02, 3.49)		-	
8 - 15 years old (n=314)	98 (31.2)	1.28 (0.32, 4.18)		-	
16 - 21 years old (n=459)	157 (34.2)	1.64 (0.41, 6.55)		-	
22 - 34 years old (n=26)	9 (34.6)	ref		-	
Currently Employed			0.3361		-
Yes (n=405)	144 (35.6)	ref		-	
No (n=440)	133 (30.2)	0.81 (0.53, 1.25)		-	
Had anal sex			0.3435		-
Yes (n=152)	38 (25.0)	ref		-	
No (n=685)	236 (34.5)	1.30 (0.75, 2.25)		-	
Has regular sex partner			0.4523		-
Yes (n=555)	178 (32.1)	ref		-	
No (n=284)	96 (33.8)	1.20 (0.75, 1.90)		-	
Has occasional sex partner			0.5307		-
Yes (n=485)	156 (32.2)	ref		-	
No (n=351)	120 (34.2)	1.15 (0.74, 1.80)		-	
Condom use in last sex			0.9859		-
Yes (n=265)	55 (20.8)	ref		-	
No (n=579)	221 (38.2)	<0.001 (<0.001, >999.99)		-	

[a] OR = Unadjusted odds ratios

[b] AOR = Adjusted odds ratios: adjusted for gender, HIV status, level of education, marital status, circumcision status, duration of last sex, drug use, alcohol use, sex in exchange for gifts, inheritance, previous STI treatment, condom use with main partner, multiple spouses, number of sexual partners and age

[c] ref = reference group

4.4.1. Bivariate Analysis

In the bivariate analysis, being male (OR 0.22; 95% CI, 0.14-0.35), being single (OR 0.07; 95% CI, 0.02-0.27) or married (OR 0.26; 95% CI, 0.07-0.94) as opposed to being widowed or divorced, not being inherited (OR 0.40; 95% CI, 0.19-0.87), having had sex within the last 3 months (OR 0.35; 95% CI, 0.14-0.88) as opposed to more than 6 months and sometimes using condoms with main partner (OR 0.55; 95% CI, 0.33-0.90) as opposed to never using condoms were protective to getting STIs.

On the other hand having secondary (OR 2.41; 95% CI, 1.38-4.23) or primary (OR 5.39; 95% CI, 2.92-9.94) education as opposed to tertiary education, taking alcohol (OR 1.85; 95% CI, 1.18-2.89), not taking drugs (OR 3.67; 95% CI, 1.66-8.09), being uncircumcised (OR 3.48; 95% CI, 1.82-6.63), not having sex in exchange for gifts (OR 2.44; 95% CI 1.23-4.83) and being HIV positive (OR 6.44; 95% CI, 3.28-12.63) were associated with getting STIs.

4.4.2. Multivariate Analysis

Multivariate analysis was performed on all the variables that had p values of <.25 from the bivariate analysis. These variables included gender, age, level of education, marital status, inheritance, having sex in exchange for gifts, alcohol use, drug use, time of last sex, condom use with main partner, having multiple spouses, number of sex partners, circumcision status, ever being treated for STIs and HIV status.

Being male (OR 0.22; 95% CI, 0.11-0.45) or having a single sexual partner (OR 0.35; 95% CI 0.13-0.94) was found to have a protective effect from getting STIs. On the other hand, having secondary (OR 2.85; 95% CI, 1.24-6.54) or primary (OR 2.13; 95% CI, 1.08-4.22) education, not using recreational drugs (OR 3.31; 95% CI, 1.06-10.29) and being HIV positive (OR 4.46; 95% CI, 1.89-10.56) was found to increase the risk of getting STIs.

4.5. Performance of Syndromic Management

The third objective of this study was to evaluate the performance of STI syndromic management against aetiological laboratory diagnosis. This was done in two steps which

included correlation of the agreement between the laboratory and syndromic diagnosis as well as the correlation of the two different syndromic questioning methods.

4.5.1. Correlation between CAPI and ACASI Methods of Interviewing

The first part of this analysis evaluated the correlation between the two methods of identifying the signs and symptoms of STIs based on the syndromic management guidelines. These were the clinician administered CAPI and the self administered ACASI. Table VII and figure VI summarises this information below.

Table VII: Kappa Analysis for agreement between ACASI and CAPI responses

STI	Kappa	95% Confidence Levels	
		Lower	Upper
Genital Ulcers	0.2642	0.1015	0.4268
Vagina/Urethral Discharge	0.3356	0.1994	0.4719
Scrotal/Lower abdominal pain	0.6454	0.5386	0.7521

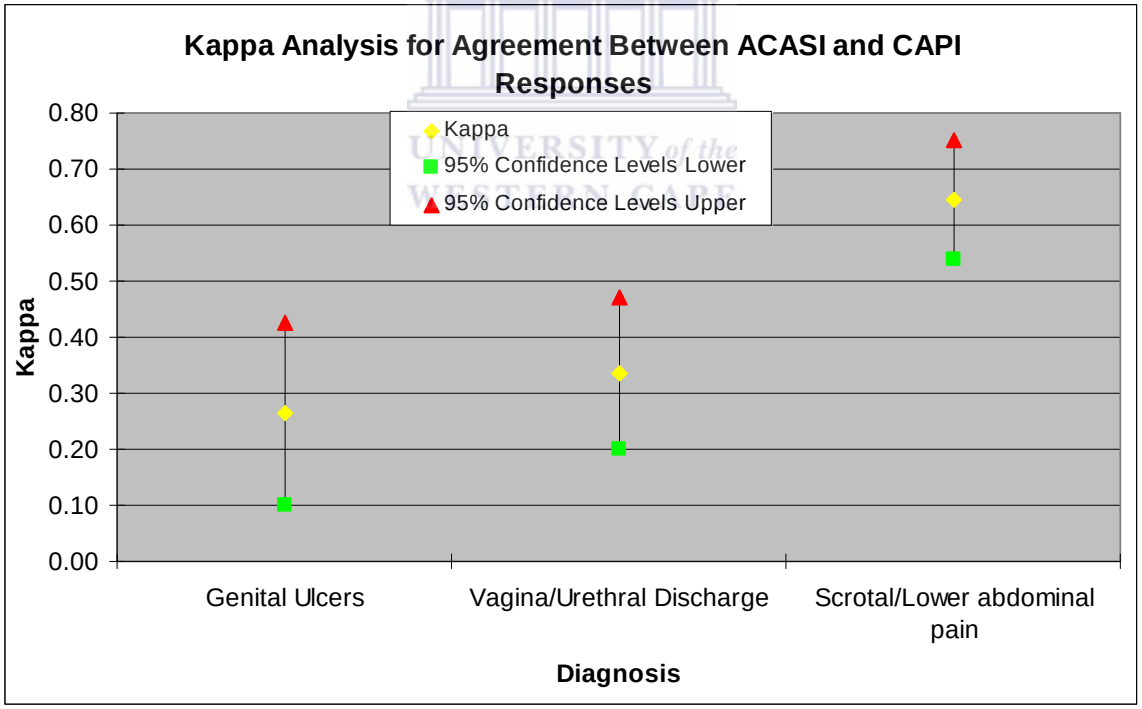

Figure VI: Kappa Analysis for agreement between ACASI and CAPI responses

The agreement between ACASI and CAPI methods of interviewing on the syndromic diagnosis of STIs ranged from fair to substantial agreement. Agreement on the diagnosis

of genital ulcers (0.26, CI: 0.10, 0.43) and vaginal/urethral discharge (0.34, CI: 0.20, 0.47) was fair, with that of scrotal/lower abdominal pain being substantial (0.65, CI: 0.54, 0.75).

4.5.2. Correlation between Syndromic and Laboratory Diagnosis

The second part of this analysis evaluated the correlation between the two methods STI diagnosis. These methods were the laboratory based aetiological diagnosis and the syndromic based CAPI and ACASI syndromic diagnosis. Table VIII and figures VII and VIII summarises this information below.

Table VIII: Kappa Analysis for agreement between ACASI and CAPI responses

STI	CAPI Kappa	95% Confidence Levels		ACASI Kappa	95% Confidence Levels	
		Lower	Upper		Lower	Upper
Syphilis	0.0002	0.0000	0.0004	-0.0009	-0.0057	0.0038
Gonorrhoea	-0.0023	-0.0079	0.0034	-0.0079	-0.0179	0.0021
Chlamydia	-0.0020	-0.0077	0.0037	-0.0032	-0.0114	0.0050
HSV 2	-0.0065	-0.0154	0.0025	-0.0018	-0.0216	0.0181
Overall	0.0567	0.0097	0.1038	0.0560	-0.0052	0.1172

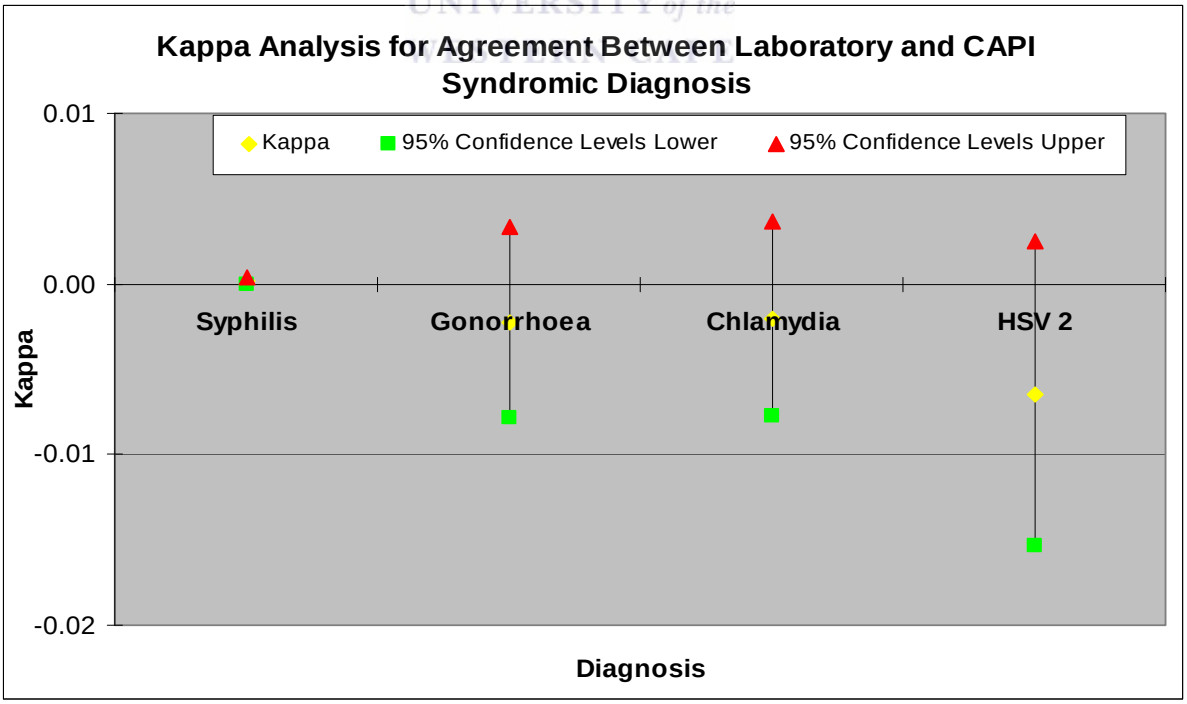

Figure VII: Kappa Analysis for agreement between Laboratory and CAPI responses

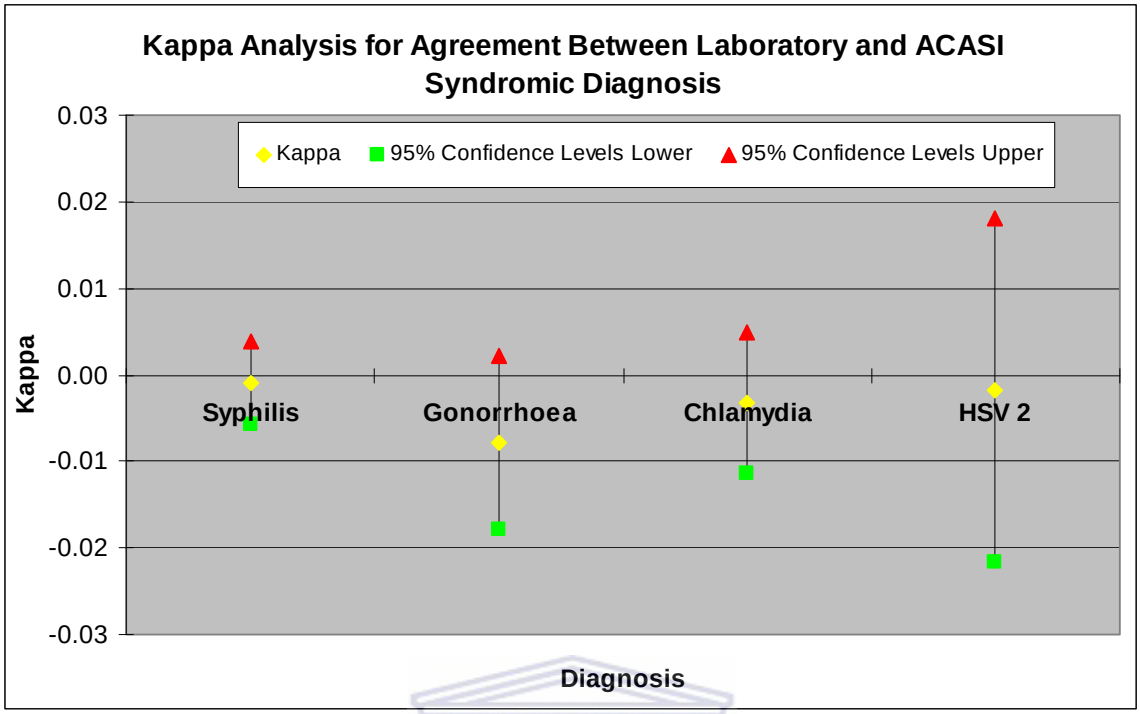

Figure VIII: Kappa Analysis for agreement between Laboratory and ACASI responses

Overall, there was no agreement between laboratory and CAPI (0.06, CI: 0.01, 0.10) as well as between the laboratory and ACASI (0.06, CI: -0.005, 0.12) diagnosis for STIs. There was also no agreement between the laboratory and CAPI as well as ACASI diagnosis for the specific STIs.

4.5.3. Sensitivity and Specificity of CAPI and ACASI Syndromic Diagnosis

The analysis also evaluated the sensitivity and specificity of the CAPI and ACASI syndromic diagnosis with the laboratory aetiological diagnosis being used as the gold standard. Overall as well as specific STI sensitivity and specificity was calculated.

Overall sensitivity was very low in CAPI (8.7%) and ACASI (17.7%) while specificity was very high in CAPI (95.8%) and ACASI (87.2%). STI specific sensitivity was generally very low across the different STIs with those diagnosed by CAPI being 0.0% (syphilis), 7.5% (gonorrhoea), 6.3% (Chlamydia) and 1.2% (HSV 2. ACASI diagnosis performed a little better than CAPI with syphilis (7.1%), gonorrhoea (22.5%), Chlamydia (12.5%) and HSV 2 (4.4%). STI specific specificity on the other hand performed very well with CAPI diagnosis specificity being 99.4% (syphilis), 98.3% (gonorrhoea), 97.2%

(Chlamydia) and 99.8% (HSV 2), while ACASI diagnosis specificity being syphilis (0.0%), gonorrhoea (7.5%), Chlamydia (6.3%) and HSV 2 (1.2%).

4.6. Partner Notification and Treatment

The last objective of this study was to establish the success of partner contact treatment. This was based on the tabulation of how many partners of participants actually came for STI contact treatment after the participants were issued with contact tracing cards.

4.6.1. STI Contact Cards Issued

The first part of this analysis tabulated the number of participants who were issued with STI contact tracing cards following them either being syndromic or aetiological diagnosed to have a STI.

Table IX: STI contact cards issued

STI Contact Cards Issued			
	Males N (%)	**Females N (%)**	**Total**
Syndromic Cards	7 (14.6)	41 (85.5)	48
Laboratory Cards	71 (25.5)	207 (74.5)	278

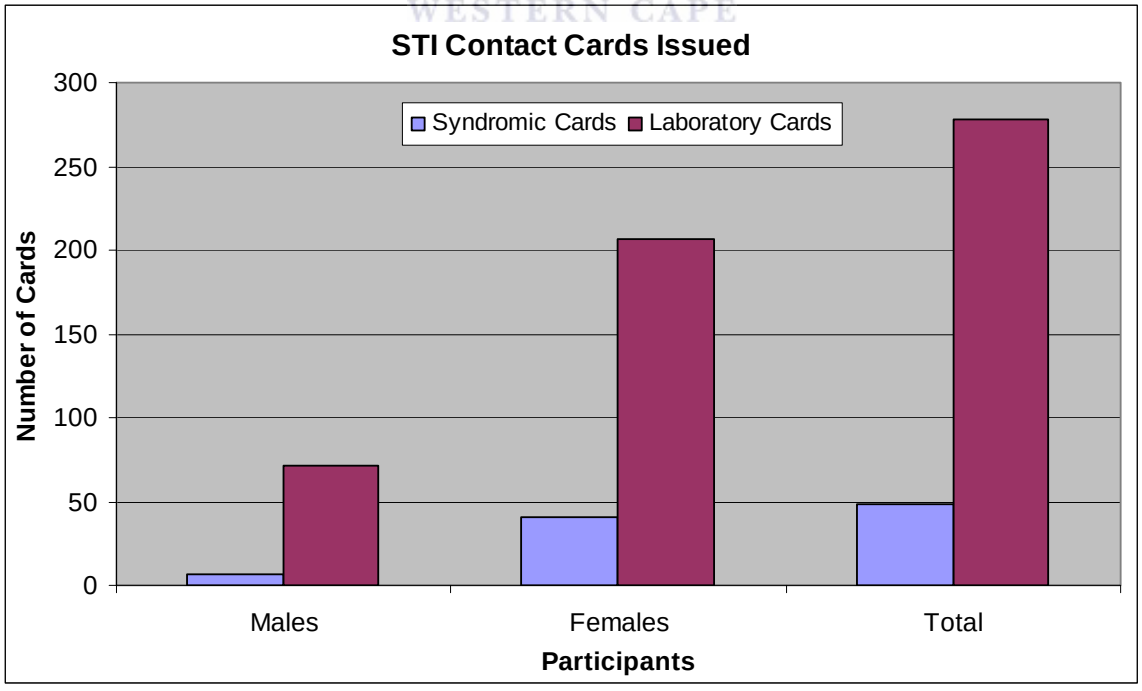

Figure IX: STI contact cards issued

Table IX and figure IX above presents the number of participants who were issued with STI contact tracing cards both at syndromic and aetiological diagnosis. A total of 48 participants (7 males and 41 females) were issued with contact tracing cards following syndromic management of STI while 278 (71 males and 207 females) were issued with cards following aetiological diagnosis.

4.6.2. STI Contact Treated

The second part of this analysis tabulated the number of contacts who came for contact treatment following their sexual partner being issued with STI contact tracing cards to hand over to them.

Table X: STI contacts treated

STI Contacts Treated			
	Males N (%)	**Females N (%)**	**Total N (%)**
Syndromic Contacts	0 (0.0)	1 (2.4)	1 (2.1)
Aetiological Contacts	1 (1.4)	0 (0.0)	1 (0.4)

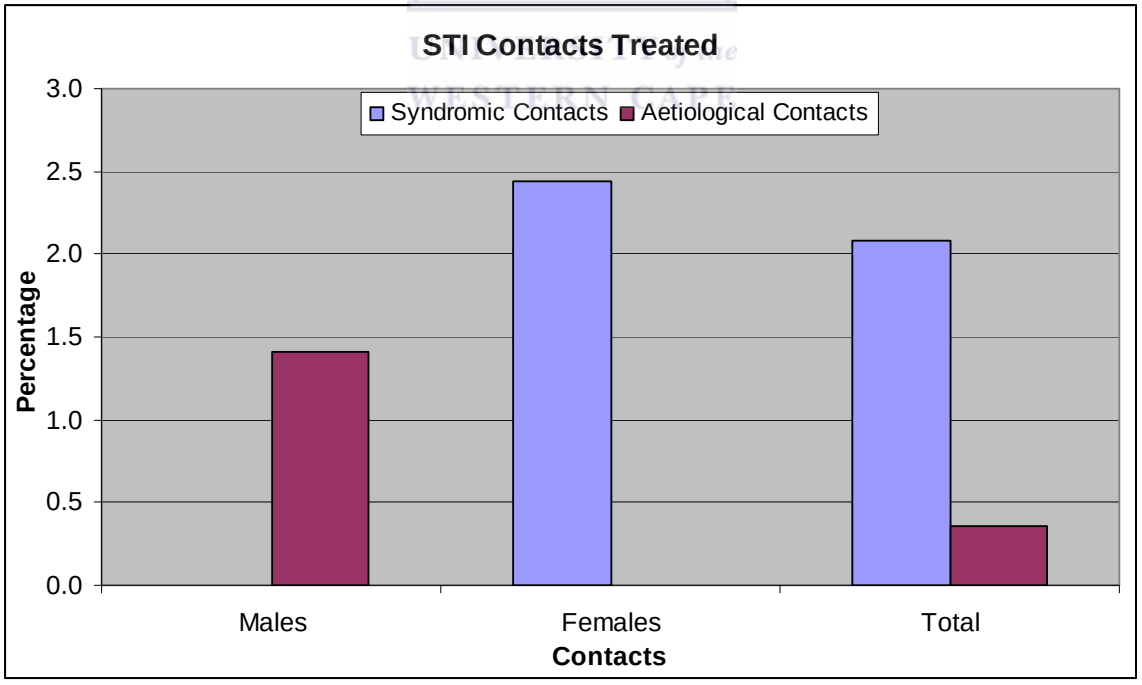

Figure X: STI contacts treated

Table X and figure X above presents the number of sexual contacts of participants who came for contact treatment at the clinic. Of the contacts of the participants who were syndromically diagnosed with STIs, only 1 (2.1%) contact came to the clinic for contact treatment. For the contacts of the participants who were aetiologically diagnosed with STIs, also just 1 (0.4%) contact came to the clinic for contact treatment.

CHAPTER FIVE

DISCUSSION

5. DISCUSSION

5.1. Introduction

This chapter discusses the key results of this study in relation to the objectives as well as to the findings of similar studies. The first section discusses the prevalence of STIs while the second section discusses the risk factors to acquisition of STIs. The third section discusses the performance of the methods used in the diagnosis of STIs in the study and the fourth section discusses the outcomes of partner contact tracing and treatment. The last section discusses the study limitations and their probable effect on the results.

5.2. STI Prevalence

The overall prevalence of STIs by syndromic diagnosis was found to be 5.7% which is lower than that of another population based study by Mosha et. al., (1993) in Tanzania as well as a CSW study in Malawi (Zachariah et al., 2003). The prevalence of aetiologically diagnosed STIs was found to be 32.8% with 16.8% males and 48.7% females being infected. These results are comparable to the Kenya AIDS indicator survey (KAIS) of 2007 (National AIDS and STI Control Programme, 2009). Specific STIs prevalence was also comparable with results being similar for syphilis and HSV-2 after adjusting for age since the age range in KAIS was 15-64 years. This prevalence is still high thus presenting a need for strengthening the screening and management capabilities of primary health facilities in the area.

Four percent of the participants were diagnosed with vaginal and/or urethral discharge. Males constituted only 0.2% of these participants which is lower than that seen in the Tanzania study of 28.0% (Mosha et al., 1993). The prevalence of vaginal and/or urethral discharge in females is however comparable to that seen in Tanzania at 7.8% but lower than that seen in the CSW study of 53% (Zachariah et al., 2003). This is most probably because the participants in the CSW study were more probably sexually active than those in this study and the Tanzania study.

The 1.2% prevalence of genital ulcers is lower than that found in the Tanzania study. All the participants diagnosed with genital ulcers were males showing that genital ulcers is

more prevalent among males which is comparable to the Tanzania study that found the prevalence of genital ulcers in males to be almost four fold that of females. Participants with lower abdominal and/or scrotal pain constituted 1.8% of the participants in this study which is seven times lower than that seen in the Tanzania study. Females had six times more lower abdominal and/or scrotal pain than males in this study. This prevalence was still lower than that seen in the CSW study in Malawi.

The prevalence of Chlamydia in this study was found to be 2.8% with that of females being 2.6% and males 3.1%. This is higher than the prevalence in the Indonesia study (Sabin et al., 2003) of <1%. The prevalence is however lower than that seen in a population survey in Gabon of 59.6% (Bertherat et al., 1998) and a rural community survey in South Africa of 6.1% (Colvin et al., 1998). This is despite the fact that all the 4 studies were population based. A sentinel survey among post abortal clinic attendees in Mozambique found prevalence of 42.5% which is very high compared to that seen in the females in this population (Machungo et al., 2002).

HSV-2 accounted for 29.6% of the infections with 14.2% being males and 44.9% being females in the study. Compared to the 4 cities study (Weiss et al., 2001), the prevalence of HSV-2 was comparable, even if we looked at the data for the same population in Kisumu. This is however not comparable to the prevalence seen in other studies in Malawi (Glynn et al., 2008), Uganda (Charvat et al., 2009) and Tanzania (Langeland et al., 1998, Yahya-Malima et al., 2008) which were higher ranging from 33.2% to 42.1% among the males and from 20.7% to 80% among females.

The prevalence of syphilis in this study was 1.7% of whom 2.6% were females and 0.7% being males. This is lower than what was seen in the literature reviewed with the prevalence being 5.2% in Indonesia (Sabin et al., 2003), 8.8% in South Africa (Colvin et al., 1998) and 8.6 in Gabon (Bertherat et al., 1998). A population-based study in Tanzania found the prevalence in males to be 8.1% and 9.4% for females (Mosha et al., 1993). This is despite the fact that all these studies were population based studies. A sentinel survey among post abortal clinic attendees in Mozambique reported a prevalence of 7.9%

(Machungo et al., 2002) which is most likely due to the high risk nature of the participants in this study.

STI co infection was generally low with HSV-2 infection being predominant in all the co infections. This is most probably due to the untreatable nature of HSV-2 and the lack of good diagnostic capabilities for its identification.

5.3. Risk Factors

Males and single individuals were found to be at a lower risk of STI acquisition compared to their counterparts, while those who had secondary or primary education, did not use recreational drugs and were HIV positive were at a higher risk of getting STIs. Females were most at risk for STI acquisition mostly probably because of biological predisposition since the signs and symptoms of STIs take longer to manifest in them and thus they take longer before they seek treatment (Newell et al., 1993, Sabin et al., 2003). Education as a risk factor has been found to be both protective and putting people at a higher risk of STI acquisition in different studies (Newell et al., 1993, Watson-Jones et al., 2007, Solomon et al., 2008). The studies that have higher education as a risk factor have demonstrated that with higher education comes associated with increased number of sexual partners, which might also be the case in this situation. HIV positivity as a risk factor is consistent with most studies (Weiss et al., 2001, WHO, 2001c, Wolday et al., 2004, Watson-Jones et al., 2007). Many studies that have looked at the use of recreational drugs, have shown it to be a risk factor to STI acquisition (Noell et al., 2001, Fenton et al., 2005) which is not consistent with data from this study.

5.4. Performance of Syndromic Management

There are not many studies that have compared the performance of syndromic diagnosis against aetiological diagnosis. This study evaluated a clinician administered syndromic evaluation as well as a self administered syndromic evaluation vis a vis the laboratory aetiological diagnosis. With the agreement between ACASI and CAPI methods of interviewing on the syndromic diagnosis of STIs ranging from fair to substantial agreement, it is probable that regardless of whether the syndromic questions were asked

by a clinician or the patients were given a self administered questionnaire, they would most of the time give almost similar to similar responses.

This study has failed to validate syndromic diagnosis with aetiological diagnosis. This is inconsistent with most studies that have shown syndromic diagnosis to be comparable to laboratory diagnosis (Mayaud et al., 1997, Mbofana et al., 2002, Wolday et al., 2004, Pickering et al., 2005). This is most probably because most of these studies focused on syndromic STI management within STI clinics as opposed to research studies. On the other hand, the study has shown the specificity of syndromic diagnosis to be very high which brings the advantage of the administration of the correct treatment once diagnosis is made. The two methods of syndromic diagnosis also performed relatively well against each other showing that volunteered as well as interrogated STI syndromic diagnosis would both work well.

5.5. Partner Notification and Treatment

The study found the uptake of contact tracing cards to be high with all patients diagnosed with STIs being issued with contact tracing cards. This was probably because of the protocol requirement to issue the cards and also for the intensive counselling that was part of the management. Uptake of contact treatment was however low with only 2.1% and 0.4% partners of the syndromicaly and aetiotiologicaly diagnosed participants coming for treatment. This was lower than other studies done in Kenya (Wakasiaka et al., 2003) and South Africa (Young et al., 2007). This is probably either due to participants not delivering the cards or the partners opting not to come for treatment or seeking treatment for them selves after developing signs and symptoms.

5.6. Limitations

Since the study did not include the mode of contact tracing as well as the reasons for partners not coming for treatment despite information, identification of the best mode of contact tracing was not possible especially since some of the recent studies have shown that partner delivered medication has been effective in the management of STIs (Kissinger et al., 1998, Kissinger et al., 2005, Kissinger, 2009). The inability of the study to link partners to index patients compromised the ability to link index patients with their

sexual partners. This made it impossible for the study to track which partners of index patients came for treatment so follow up could not be initiated.

CHAPTER SIX

CONCLUSION AND RECOMMENDATION

6. CONCLUSION AND RECOMMENDATIONS

6.1. Conclusions

This study describes the prevalence of, risk factors associated with and the performance syndromic diagnosis in the management of STIs within the Kisumu Incidence Cohort Study (KICoS) in Kisumu, Kenya. This was done through five objectives.

The prevalence of STIs by syndromic diagnosis was 5.7% while by laboratory diagnosis was 32.8%. In addition, 32.8% of the participants were co infected with 2 or 3 STIs with HSV-2 being predominant in all the participants co infected with any STI. This presents STIs as a problem in this population that needs addressing. Being female, being HIV positive, having lower than tertiary education, using recreational drugs and having multiple sexual partners were found to be risk factors to the acquisition of STIs in this population and thus should be mitigated.

The STI syndromic diagnosis generally performed very low against aetiological laboratory diagnosis. This was inconsistent with present data but most of this data is from studies done in STI clinics. The performance of partner contact tracing and treatment was very poor with very few partners coming for treatment even after their index was given contact tracing cards

6.2. Recommendations

Based on the description of the prevalence of, risk factors associated with and the performance syndromic diagnosis in the management of STIs within the Kisumu Incidence Cohort Study (KICoS) in Kisumu, Kenya, the following recommendations are made:

1. More emphasis needs to be put in risk reduction strategies to mitigate the spread of STIs.
2. The use of syndromic diagnosis of STIs in research settings need to be reviewed further.
3. There should be increase availability of laboratory services in the diagnosis of STIs
4. Efforts in partner contact tracing need to be intensified.

5. More research is still needed in this area to further understand and address the risk factors that predispose people to STI acquisition.

7. REFERENCES

ABDOOL KARIM, S. S. (1994) Challenges to the control of sexually transmitted diseases in Africa. *Am J Public Health,* 84**,** 1891-1893.

BERTHERAT, E., GEORGES-COURBOT, M. C., NABIAS, R., GEORGES, A. J. & RENAUT, A. (1998) Seroprevalence of four sexually transmitted diseases in a semi-urban population of Gabon. *Int J STD AIDS,* 9**,** 31-36.

BLANKHART, D., MULLER, O., GRESENGUET, G. & WEIS, P. (1999) Sexually transmitted infections in young pregnant women in Bangui, Central African Republic. *Int J STD AIDS,* 10**,** 609-614.

BUVE, A., LAGA, M. & PIOT, P. (1993) Sexually transmitted diseases; Where are we now? *Health Policy and Planning,* 8**,** 277-281.

CATCHPOLE, M. (2001) Sexually transmitted infections: control strategies. *British Medical Journal,* 322**,** 1135-1136.

CHALAMILLA, G., MBWANA, J., MHALU, F., MMARI, E., MAJIGO, M., SWAI, A., URASSA, W. & SANDSTROM, E. (2006) Patterns of sexually transmitted infections in adolescents and youth in Dar es Salaam, Tanzania. *BMC Infectious Diseases,* 6**,** 22-30.

CHARVAT, B., SSEMPIJJA, V., KIGOZI, G., SERWADDA, D., MAKUMBI, F., IGA, B., LAEYENDECKER, O., RIEDESEL, M., OLIVER, A., CHEN, MICHAEL Z., REYNOLDS, S. J., WAWER, M. J., GRAY, R. H. & QUINN, T. C. (2009) Factors Associated with the Prevalence and Incidence of Herpes Simplex Virus Type 2 Infection among Men in Rakai, Uganda. *The Journal of Infectious Diseases,* 199**,** 945-949.

CHEGE, W., THOMAS, T., OGENDO, A., OTIENO, F., MCLELLAN-LEMAL, E., PALS, S., ZEH, C., ACKERS, M., HART, C., LASERSON, K., CHEN, R., KILMARX, P. & VULULE, J. (2007) A prospective cohort study to estimate incidence of HIV seroconversion and to identify determinants of successful recruitment and retention in preparation for an HIV prevention trial among adolescents and young adults in Kisumu, western Kenya. KEMRI/CDC.

CHERSICH, M. F., LUCHTERS, S. M. F., MALONZA, I. M., MWAROGO, P., KING'OLA, N. & TEMMERMAN, M. (2007) Heavy episodic drinking among Kenyan female sex workers is associated with unsafe sex, sexual violence and sexually transmitted infections. *Int J STD AIDS,* 18**,** 764-769.

COHEN, M. S., HOFFMAN, I. F., ROYCE, R. A., KAZEMBE, P., DYER, J. R., DALY, C. C., ZIMBA, D., VERNAZZA, P. L., MAIDA, M., FISCUS, S. A., ERON JR, J. J. & MALAWI RESEARCH GROUP AIDSCAP (1997) Reduction of concentration of HIV-1 in semen after treatment of urethritis: implications for prevention of sexual transmission of HIV-1. *Lancet,* 349**,** 1867-1873.

COLVIN, M., KARIM, S. S. A., CONNOLLY, C., HOOSEN, A. A. & NTULI, N. (1998) HIV infection and asymptomatic sexually transmitted infections in a rural South African community. *Int J STD AIDS,* 9**,** 548-550.

DESAI, V., KOSAMBIYA, J., THAKOR, H., UMRIGAR, D., KHANDWALA, B. & BHUYAN, K. (2003) Prevalence of sexually transmitted infections and performance of STI syndromes against aetiological diagnosis, in female sex workers of red light area in Surat, India. *Sexually Transmitted Infections,* 79**,** 111-115.

DOHERTY, I. A., PADIAN, N. S., MARLOW, C. & ARAL, S. O. (2005) Determinants and Consequences of Sexual Networks as They Affect the Spread of Sexually Transmitted Infections. *The Journal of Infectious Diseases,* 191**,** S42-S54.

DONOVAN, B. (2004) Sexually transmissible infections other than HIV. *Lancet,* 363**,** 545-556.

DRUMRIGHT, L. N., GORBACH, P. M. & HOLMES, K. K. (2004) Do People Really Know Their Sex Partners?: Concurrency, Knowledge of Partner Behavior, and Sexually Transmitted Infections Within Partnerships. *Sexually Transmitted Diseases,* 31**,** 437-442.

FENTON, K. A., MERCER, C. H., JOHNSON, A. M., BYRON, C. L., MCMANUS, S., ERENS, B., COPAS, A. J., NANCHAHAL, K., MACDOWALL, W. & WELLINGS, K. (2005) Reported Sexually Transmitted Disease Clinic Attendance and Sexually Transmitted Infections in Britain: Prevalence, Risk Factors, and Proportionate Population Burden. *The Journal of Infectious Diseases,* 191**,** S127-S138.

GARG, S., SINGH, M., NATH, A., BHALLA, P., GARG, V., GUPTA, V. & UPPAL, Y. (2007) Prevalence and awareness about sexually transmitted infections among males in urban slums of Delhi. *Indian Journal of Medical Sciences,* 61**,** 269-277.

GILSON, L., MKANJE, R., GROSSKURTH, H., MOSHA, F., PICARD, J., GAVYOLE, A., TODD, J., MAYAUD, P., SWAI, R., FRANSEN, L., MABEY, D., MILLS, A. & HAYES, R. (1997) Cost-effectiveness of improved treatment services for sexually transmitted diseases in preventing HIV-1 infection in Mwanza Region, Tanzania. *Lancet,* 350**,** 1805-1809.

GLYNN, J. R., CRAMPIN, A. C., NGWIRA, B. M. M., NDHLOVU, R., MWANYONGO, O. & FINE, P. E. M. (2008) Herpes simplex type 2 (HSV-2) trends in relation to the HIV epidemic in northern Malawi. *Sex Transm Infect***,** sti.2008.030056.

GOH, B. T. (2005) Syphilis in adults. *Sexually Transmitted Infections,* 81**,** 448-452.

GROSSKURTH, H., GRAY, R., HAYES, R., MABEY, D. & WAWER, M. (2000) Control of sexually transmitted diseases for HIV-1 prevention: understanding the implications of the Mwanza and Rakai trials. *Lancet,* 355**,** 1981-1987.

HAWKEN, M., MELIS, R., NGOMBO, D., MANDALIYA, K., NG'ANG'A, L., PRICE, J., DALLABETTA, G. & TEMMERMAN, M. (2002) Opportunity for prevention of HIV and sexually transmitted infections in Kenyan youth: results of a population-based survey. *Journal of Acquired Immune Deficiency Syndromes & Human Retrovirology.,* 31**,** 529-535.

HOLMES, K. K., F.SPARLING, P., MÅRDH, P. A., LEMON, S. M., STAMM, W. E., PIOT, P. & WASSERHEIT, J. N. (1999) *Sexually Transmitted Diseases,* New York, McGraw/Hill.

HOSMER, D. W. & LEMESHOW, S. (2000) *Applied Logistic Regression,* New York, John Wiley & Sons.

HUGHES, G., CATCHPOLE, M., ROGERS, P. A., BRADY, A. R., KINGHORN, G., MERCEY, D. & THIN, N. (2000) Comparison of risk factors for four sexually transmitted infections: results from a study of attenders at three genitourinary medicine clinics in England. *Sexually Transmitted Infections,* 76**,** 262-267.

JACKSON, D. J., RAKWAR, J. P., RICHARDSON, B. A., MANDALIYA, K., CHOHAN, B. H., BWAYO, J. J., NDINYA-ACHOLA, J. O., MARTIN, H. L., JR., MOSES, S. & KREISS, J. K. (1997) Decreased incidence of sexually transmitted diseases among trucking company workers in Kenya: results of a behavioural risk-reduction programme. *AIDS,* 11**,** 903-909.

JANSEN, H. A. F. M., MORISON, L., MOSHA, F., CHANGALUCHA, J., TODD, J., OBASI, A., RUSIZOKA, M., MAYAUD, P., MUNGUTI, K., MABEY, D., GROSSKURTH, H. & HAYES, R. (2003) Geographical variations in the prevalence of HIV and other sexually transmitted infections in rural Tanzania. *Int J STD AIDS,* 14**,** 274-280.

KALICHMAN, S. C., SIMBAYI, L. C., KAUFMAN, M., CAIN, D. & JOOSTE, S. (2007) Alcohol Use and Sexual Risks for HIV/AIDS in Sub-Saharan Africa: Systematic Review of Empirical Findings *Prevention Science,* 8**,** 141-151.

KAMALI, A., QUIGLEY, M., NAKIYINGI, J., KINSMAN, J., KENGEYA-KAYONDO, J., GOPAL, R., OJWIYA, A., HUGHES, P., CARPENTER, L. M. & WHITWORTH, J. (2003) Syndromic management of sexually-transmitted infections and behaviour change interventions on transmission of HIV-1 in rural Uganda: a community randomised trial. *Lancet,* 361**,** 645-652.

KISSINGER, P. (2009) Considering the patient in patient-delivered partner therapy. *Sexually Transmitted Infections,* 85**,** 80-81.

KISSINGER, P., BROWN, R., REED, K., SALIFOU, J., DRAKE, A., FARLEY, T. A. & MARTIN, D. H. (1998) Effectiveness of patient delivered partner medication for preventing recurrent Chlamydia trachomatis. *Sexually Transmitted Infections,* 74**,** 331-333.

KISSINGER, P., MOHAMMED, H., RICHARDSON ALSTON, G., LEICHLITER, J. S., TAYLOR, S. N., MARTIN, D. H. & FARLEY, T. A. (2005) Patient Delivered Partner Treatment for Male Urethritis: A Randomized, Controlled Trial. *Clinical Infectious Diseases,* 41**,** 623-629.

KRAUT-BECHER, J. R. & ARAL, S. O. (2006) Patterns of age mixing and sexually transmitted infections. *Int J STD AIDS,* 17**,** 378-383.

LAGA, M., MANOKA, A., KIVUVU, M., MALELE, B., TULIZA, M., NZILA, N., GOEMAN, J., BEHETS, F., BATTER, B. & ALARY, M. (1993) Non-ulcerative sexually transmitted diseases as risk factors for HIV-1 transmission in women: results from a cohort study. *Acquired Immunodeficiency Syndrome,* 7**,** 95-102.

LANGELAND, N., HAARR, L. & MHALU, F. (1998) Prevalence of HSV-2 antibodies among STD clinic patients in Tanzania. *Int J STD AIDS,* 9**,** 104-107.

LOW, N., BROUTET, N., ADU-SARKODIE, Y., BARTON, P., HOSSAIN, M. & HAWKES, S. (2006) Global control of sexually transmitted infections. *Lancet,* 368**,** 2001-2016.

MACHUNGO, F., ZANCONATO, G., PERSSON, K., LIND, I., JORGENSEN, B., HERRMANN, B. & BERGSTROM, S. (2002) Syphilis, gonorrhoea and chlamydial infection among women undergoing legal or illegal abortion in Maputo. *Int J STD AIDS,* 13**,** 326-330.

MADHIVANAN, P., HERNANDEZ, A., GOGATE, A., STEIN, E., GREGORICH, S., SETIA, M., KUMTA, S., EKSTRAND, M., MATHUR, M., JERAJANI, H. & LINDAN, C. P. (2005) Alcohol Use by Men Is a Risk Factor for the Acquisition of Sexually Transmitted Infections and Human Immunodeficiency Virus From Female Sex Workers in Mumbai, India. *Sexually Transmitted Diseases,* 32**,** 685-690.

MALTA, M., BASTOS, F. I., STRATHDEE, S. A., CUNNIGHAM, S. D., PILOTTO, J. H. & KERRIGAN, D. (2007) Knowledge, perceived stigma, and care-seeking experiences for sexually transmitted infections: a qualitative study from the perspective of public clinic attendees in Rio de Janeiro, Brazil. *BMC Public Health,* 7**,** 1-8.

MANAVI, K., BHADURI, S., TARIQ, A. & ON BEHALF OF THE WEST MIDLANDS BASHH AUDIT GROUP (2008) Audit on the success of partner notification for sexually transmitted infections in the West Midlands. *Int J STD AIDS,* 19**,** 856-858.

MAYAUD, P., MOSHA, F., TODD, J., BALIRA, R., MGARA, J., WEST, B., RUSIZOKA, M., MWIJARUBI, E., GABONE, R., GAVYOLE, A., GROSSKURTH, H., HAYES, R. & MABEY, D. (1997) Improved treatment services significantly reduce the prevalence of sexually transmitted diseases in rural Tanzania: results of a randomized controlled trial. *Acquired Immune Deficiency Syndrome,* 11**,** 1873-1880.

MBOFANA, F. S., BRITO, F. J., SAIFODINE, A. & CLIFF, J. L. (2002) Syndromic management of sexually transmitted diseases at primary care level, Mozambique. *Sexually Transmitted Infections,* 78**,** 1-2.

MOSHA, F., NICOLL, A., BARONGO, L., BORGDORFF, M., NEWELL, J., SENKORO, K., GROSSKURTH, H., CHANGALUCHA, J., KLOKKE, A. & KILLEWO, J. (1993) A population-based study of syphilis and sexually transmitted disease syndromes in north-western Tanzania. 1. Prevalence and incidence. *Genitourin Med,* 69**,** 415-420.

MULLICK, S., WATSON-JONES, D., BEKSINSKA, M. & MABEY, D. (2005) Sexually transmitted infections in pregnancy: prevalence, impact on pregnancy outcomes, and approach to treatment in developing countries. *Sexually Transmitted Infections,* 81**,** 294-302.

NASCOP (1994) Kenya National Guidelines for Syndromic Management of Sexually Transmitted Infections. Nairobi, National AIDS and STD Control Programme.

NATIONAL AIDS AND STI CONTROL PROGRAMME (2009) Kenya AIDS Indicator Survey 2007: Final Report. Nairobi, Ministry of Health, Kenya.

NEWELL, J., SENKORO, K., MOSHA, F., GROSSKURTH, H., NICOLL, A., BARONGO, L., BORGDORFF, M., KLOKKE, A., CHANGALUCHA, J. & KILLEWO, J. (1993) A population-based study of syphilis and sexually transmitted disease syndromes in north-western Tanzania. 2. Risk factors and health seeking behaviour. *Sexually Transmitted Infections,* 69**,** 421-426.

NOELL, J., ROHDE, P., OCHS, L., YOVANOFF, P., ALTER, M. J., SCHMID, S., BULLARD, J. & BLACK, C. (2001) Incidence and Prevalence of Chlamydia, Herpes, and Viral Hepatitis in a Homeless Adolescent Population. *Sexually Transmitted Diseases,* 28**,** 4-10.

PAKIANATHAN, M. R., ROSS, J. D. C. & MCMILLAN, A. (1996) Characterizing patients with multiple sexually acquired infections: a multivariate analysis. *Int J STD AIDS,* 7**,** 359-360.

PANCHANADESWARAN, S., JOHNSON, S. C., MAYER, K. H., SRIKRISHNAN, A. K., SIVARAM, S., ZELAYA, C. E., GO, V. F., SOLOMON, S., BENTLEY, M. E. & CELENTANO, D. D. (2006) Gender differences in the prevalence of sexually transmitted infections and genital symptoms in an urban setting in southern India. *Sexually Transmitted Infections,* 82**,** 491-495.

PEELING, R. W. (2006) Testing for sexually transmitted infections: a brave new world? *Sexually Transmitted Infections,* 82**,** 425-430.

PÉPIN, J., DESLANDES, S., KHONDE, N., KINTIN, D., DIAKITÉ, S., SYLLA, M., MÉDA, H., SOBÉLA, F., ASAMOAH-ADU, C., AGYARKO-POKU, T. & FROST, E. (2004) Low prevalence of cervical infections in women with vaginal discharge in West Africa: implications for syndromic management. *Sexually Transmitted Infections,* 80**,** 230-235.

PICKERING, J. M., WHITWORTH, J. A. G., HUGHES, P., KASSE, M., MORGAN, D., MAYANJA, B., VAN DER PAAL, L. & MAYAUD, P. (2005) Aetiology of sexually transmitted infections and response to syndromic treatment in southwest Uganda. *Sexually Transmitted Infections,* 81**,** 488–493.

SABIN, K. M., RAHMAN, M., HAWKES, S., AHSAN, K., BEGUM, L., BLACK, R. E. & BAQUI, A. H. (2003) Sexually transmitted infections prevalence rates in slum communities of Dhaka, Bangladesh. *Int J STD AIDS,* 14**,** 614-621.

SMITH FAWZI, M. C., LAMBERT, W., SINGLER, J. M., KOENIG, S. P., LEANDRE, F., NEVIL, P., BERTRAND, D., CLAUDE, M. S., BERTRAND, J., SALAZAR, J. J., LOUISSAINT, M., JOANIS, L. & FARMER, P. E. (2003) Prevalence and risk factors of STDs in rural Haiti: implications for policy and programming in resource-poor settings. *Int J STD AIDS,* 14**,** 848-853.

SOLOMON, M. M., SMITH, M. J. & RIO, C. D. (2008) Low educational level: a risk factor for sexually transmitted infections among commercial sex workers in Quito, Ecuador. *Int J STD AIDS,* 19**,** 264-267.

ST. LAWRENCE, J. S., MONTAÑO, D. E., KASPRZYK, D., PHILLIPS, W. R., ARMSTRONG, K. & LEICHLITER, J. S. (2002) STD Screening, Testing, Case

Reporting, and Clinical and Partner Notification Practices: A National Survey of US Physicians. *American Journal of Public Health,* 92**,** 1784-1788.

ST.LAWRENCE, J. S., MONTAÑO, D. E., KASPRZYK, D., PHILLIPS, W. R., ARMSTRONG, K. & LEICHLITER, J. S. (2002) STD Screening, Testing, Case Reporting, and Clinical and Partner Notification Practices: A National Survey of US Physicians. *American Journal of Public Health,* 92**,** 1784-1788.

STEEN, R., VUYLSTEKE, B., DECOITO, T., RALEPELI, S., FEHLER, G., CONLEY, J., BRUCKERS, L., DALLABETTA, G. & BALLARD, R. (2000) Evidence of Declining STD Prevalence in a South African Mining Community Following a Core-Group Intervention. *Sexually Transmitted Diseases,* 27**,** 1-8.

VIVANCOS, R., SCHELENZ, S. & LOKE, Y. K. (2007) Internet treatment of sexually transmitted infections – a public health hazard? *BMC Public Health,* 7**,** 1-5.

WAKASIAKA, S. N., BWAYO, J. J., WESTON, K., MBITHI, J. & OGOL, C. (2003) Partner Notification in the Management of Sexually Transmitted Infections in Nairobi, Kenya. *East African Medical Journal,* 80**,** 646-651.

WATSON-JONES, D., WEISS, H. A., RUSIZOKA, M., BAISLEY, K., MUGEYE, K., CHANGALUCHA, J., EVERETT, D., BALIRA, R., KNIGHT, L., ROSS, D. & HAYES, R. J. (2007) Risk Factors for Herpes Simplex Virus Type 2 and HIV Among Women at High Risk in Northwestern Tanzania: Preparing for an HSV-2 Intervention Trial. *JAIDS Journal of Acquired Immune Deficiency Syndromes,* 46**,** 631-642 10.1097/QAI.0b013e31815b2d9c.

WAWER, M. J., SEWANKAMBO, N. K., SERWADDA, D., QUINN, T. C., PAXTON, L. A., KIWANUKA, N., WABWIRE-MANGEN, F., LI, C., LUTALO, T., NALUGODA, F., GAYDOS, C. A., MOULTON, L. H., MEEHAN, M. O., AHMED, S., GRAY, R. H. & PROJECT STUDY GROUP RAKAI (1999) Control of sexually transmitted diseases for AIDS prevention in Uganda: a randomised community trial. *Lancet,* 353**,** 535-535.

WEISS, H. A., BUVE, A., ROBINSON, N. J., VAN DYCK, E., KAHINDO, M., ANAGONOU, S., MUSONDA, R., ZEKENG, L., MORISON, L., CARAL, M., LAGA, M., HAYES, R. J. & FOR THE STUDY GROUP ON HETEROGENEITY OF HIV EPIDEMICS IN AFRICAN CITIES (2001) The epidemiology of HSV-2 infection and its association with HIV infection in four urban African populations. *AIDS,* 15**,** S97-S108.

WHO (1999) *Sexually transmitted infections prevalence study methodology: guidelines for the implementation of STI prevalence surveys.,* Switzerland, World Health Organisation.

WHO (2001a) *Global prevalence and incidence of selected curable sexually transmitted infections,* Geneva, World Health Organisation.

WHO (2001b) Prevalence survey of sexually transmitted infections among female sex workers and Truck drivers in china 1999-2000. Geneva, World Health Organisation.

WHO (2001c) Prevalence survey of sexually transmitted infections among female sex workers and women attending ante natal clinics in Malaysia 1999-2000. Geneva, World Health Organisation.

WHO (2003) *Guidelines for the management of sexually transmitted infections,* Geneva, World Health Organisation.

WHO (2005) *Sexually transmitted and other reproductive tract infections: A guide to essential practice,* Geneva, World Health Organisation.

WHO (2007) *Global strategy for the prevention and control of sexually transmitted infections : 2006 - 2015 : breaking the chain of transmission,* Switzerland, World Health Organisation.

WHO (2008) *Periodic presumptive treatment for sexually transmitted infections : experience from the field and recommendations for research.,* Switzerland, World Health Organisation.

WILKINSON, D., ABDOOL-KARIM, S. S., HARRISON, A., LURIE, M., COLVIN, M., CONNOLLY, C. & STURM, A. W. (1999) Unrecognized sexually transmitted infections in rural South African women: a hidden epidemic. *Bulletin of the World Health Organization,* `77**,** 22-28.

WOLDAY, D., G-MARIAM, Z., MOHAMMED, Z., MELES, H., MESSELE, T., SEME, W., GEYID, A. & MAAYAN, S. (2004) Risk factors associated with failure of syndromic treatment of sexually transmitted diseases among women seeking primary care in Addis Ababa. *Sexually Transmitted Infections,* 80**,** 393-394.

WORKOWSKI, K. A., BERMAN, S. M. & DOUGLAS-JR, J. M. (2008) Emerging Antimicrobial Resistance in Neisseria gonorrhoeae: Urgent Need to Strengthen Prevention Strategies. *Annals of Internal Medicine,* 148**,** 606-613.

WORKOWSKI, K. A., LEVINE, W. C. & WASSERHEIT, J. N. (2002) U.S. Centers for Disease Control and Prevention Guidelines for the Treatment of Sexually Transmitted Diseases: An Opportunity To Unify Clinical and Public Health Practice. *Annals of Internal Medicine,* 137**,** 255-262.

YAHYA-MALIMA, K., EVJEN-OLSEN, B., MATEE, M., FYLKESNES, K. & HAARR, L. (2008) HIV-1, HSV-2 and syphilis among pregnant women in a rural area of Tanzania: Prevalence and risk factors. *BMC Infectious Diseases,* 8**,** 75.

YOUNG, T., DE KOCK, A., JONES, H., ALTINI, L., FERGUSON, T. & VAN DE WIJGERT, J. (2007) A comparison of two methods of partner notification for sexually transmitted infections in South Africa: patient-delivered partner medication and patient-based partner referral. *Int J STD AIDS,* 18**,** 338-340.

ZACHARIAH, R., SPIELMANN, M. P., HARRIES, A. D., NKHOMA, W., CHANTULO, A. & ARENDT, V. (2003) Sexually transmitted infections and sexual behaviour among commercial sex workers in a rural district of Malawi. *Int J STD AIDS,* 14**,** 185-188.

APPENDICES

Appendix A: Questionnaire extract from ACASI behavioural questionnaire
Appendix B: CAPI pre-screening for basic eligibility
Appendix C: CAPI medical history and physical examination
Appendix D: Extract from KICoS laboratory specimen collection and reporting form K411B
Appendix E: Partner tracking form K318

7.1. Appendix A: Questionnaire Extract from ACASI Behavioural Questionnaire

Participant ID: |__|__|__|__|__|__|__|__|

Date: |__|__|/|__|__|/|__|__|__|__|

dd / mm / yyyy

Language:

01 English

02 Swahili

03 Luo

Residence ID

01 **Rural**

02 **Urban**

Gender (Dem_1):

01 Male

02 Female

DEMOGRAPHICS

Education

1. **Have you ever attended school?**
   - 01 Yes
   - 00 No
2. **If [Q1=01] What is the highest level of school you attended?**
   - 01 Primary
   - 02 Post-primary/vocational
   - 03 Secondary
   - 04 College (Middle level)
   - 05 University
3. **If [Q1=01] What is the highest *[standard/form/year]* you completed at that level?**

[standard/form/year] _____

Employment

4. Are you currently working?

01 Yes

00 No

5. What kind of work do you do most of the time?

01 Farmer

02 Salaried worker (e.g. teacher, nurse)

03 Casual worker

04 Self-employed

05 Homemaker

06 Student

07 Other **(specify: _____)**

6. How many shillings (KES) did you earn in the last 30 days?

KES earned_____

Partnerships/Marriage

Now, we would like to ask you questions about your marital status.

24. What is your current marital status?

01 Single/ Never married

02 Not married, but living as married

03 Married

04 Separated/ Divorced

05 Widowed

25. [If Q24 = 01, 04, or 05] Do you currently have a person that you consider a… (choose all that apply)

01 Regular sex partner

02 Occasional sex partner

03 One-time sex partner

04 Someone you get/give money or other gifts for sex

26. [If Q24 = 03 and Dem_01 = 01] Do you have more than one wife?

[If Q24 = 03 and Dem_01 = 02] Does your husband have other wives?

01 Yes

00 No

27. [If Q24 = 01 and Dem_01 = 01] How many total wives do you have right now?

[If Q24 = 01 and Dem_02 = 01] Including yourself, how many total wives does your husband have right now?

Number of spouses /_ /_ /

Sexual History (Q47-Q66 only asked at baseline)

The next set of questions focus on sexual intercourse. By sexual intercourse, we mean, times that a penis is inside the vagina or anus. We would like you to think about all the people that you have had sexual intercourse with. This includes times that you did want to have sexual intercourse and times that you did not want to have sexual intercourse.

Your answers are very important to us. We would like you to be honest and truthful. It may make you feel uncomfortable to answer these questions. Please remember that no one will know your answers.

47. When you were a child or teenager, did someone who was older than you or someone more powerful than you, ever force you to have sexual intercourse with him/her?

01 Yes

00 No

48. [Q47=01] How old were you when this happened?

Age in years _ _

49. [Q47=01] What was the sex of the person(s) who forced you?

01 Male

00 Female

50. [Q47=01] How was this person related to you?

01 Relative living in the same house

02 Relative not living in the same house

03 Neighbour

04 Friend

05 Teacher

06 Somebody else known to you

07 Stranger

51. How old were you the first time that you had sexual intercourse? Please think about the very first time, even if it was with someone who had sex with you only once, including sexual intercourse during special occasions, or sex with someone that you did not want to have sexual intercourse.

Age |__|__|

52. When you had sex for the first time, how long had you known each other ?

01 More than a year

02 Months

03 Days

04 1 day or less

53. What best describes the first time you had sex. (choose only one)

01 You wanted to have sexual intercourse

02 You did not plan on having sexual intercourse, but it happened anyway

03 You wanted to delay sexual intercourse but felt pressured

04 You did not want to have sexual intercourse, but you were physically forced

05 You did not want to have sexual intercourse, but you were tricked into doing so

54. Did you have sexual intercourse with this person again?

01 Yes, but less than 5 times

02 Yes, 5 times or more

00 No

55. What was this person's relationship to you?

01 Spouse

02 Boyfriend/girlfriend

03 Some other type of friend

04 Brother/sister in-law

05 A relative, living in the same house

06 A relative, not living in the house

07 A neighbour

08 Somebody with authority in the community

09 Non-relative, but person that you know

10 Non-relative and a person you never met before

56. Did this person give you something like money, gifts, or other favours for having sexual intercourse with him/her?

01 Yes, every time

02 Yes, sometimes or occasionally

00 No, never

57. [If Q56 = 01] What did you receive for having sexual intercourse with him/her? (choose all that apply)

01 Food/non-alcoholic drink

02 Alcohol

03 Clothing

04 School items

05 Money

06 Soap, lotion, or hair/beauty products

07 Other(specify)

58. Did you use condoms during the first time you had sexual intercourse?

01 Yes

00 No

59. [Q58=00] What was the main reason why you did not use a condom?

01 Did not know how to use a condom

02 Did not have a condom available

03 Trusted my partner

04 Partner refused to use a condom

05 Wanted to have a child

06 Fear using condom

07 Other

60. The first time you had sexual intercourse, was any type of alcohol involved?

01 Yes

00 No

61. The first time you had sexual intercourse, were any drugs involved?

01 Yes

00 No

62. Was the person you had sexual intercourse with for the first time, male or female?

01 Male

02 Female

63. What was the age of the person with whom you first had sexual intercourse?

01 About your age

02 5 or more years older

03 5 or less years younger

For the next questions, please think of all the persons that you have had sexual intercourse.

64. With how many different people have you ever had sexual intercourse?

Number of sex partners/_ /_ /

65. Please think of all the times that you have had sexual intercourse. Has a man ever put his penis to your anus?

01 Yes

00 No

66. Please think of all the times that you have had sexual intercourse. Did you ever have oral sex? By oral sex we mean when a woman puts the penis in her mouth or the man put his tongue in the vagina.

01 Yes

00 No

Recent Sexual Behaviour

Thank you for the information you have given us about your sexual history. Please remember that to help us find out what puts people at greater risk for HIV infection, we need to ask very personal questions. Remember, that your name is not linked to the answers you give us and that what you enter into the computer will not be shared with anyone.

The next set of questions will ask you about your sexual behaviour in the past 3 months. Please answer these questions honestly.

67. In the past 3 months, with how many different persons have you had sexual intercourse?

Number of recent sex partners/_ /_ /

68. In the past 3 months, with how many men or boys have you had sexual intercourse?

Number of male partners/_ /_ /

69. In the past 3 months, with how many girls or women have you ever had sexual intercourse?

Number of female partners/_ /_ /

70. Of this/these X person(s) [from Q67], how many do you know or think might have HIV?

Number of HIV+ partners/_ /_ /

If Q67 = 0, skip to Q83.

71. How did you find out that this/these person(s) were HIV infected? (choose all that apply)

01 They told me on their own
02 I asked and they told me
03 I guessed and they confirmed it
04 Someone else told me
05 They looked sick
06 We got tested together
07 I went with them to get their test results
08 Someone from the testing site came looking for them

72. In the past 3 months, when you had sexual intercourse with person(s) you know or think might have HIV, how often did you use a condom?

01 Always

02 Most of the time

03 Sometimes

04 Once

05 Never

73. If **[Q72=05] What was the main reason why you did not use a condom?**

01 Did not know how to use a condom

02 Did not have a condom available

03 Trusted my partner

04 Partner refused to use a condom

05 Wanted to have a child

06 Fear using condom

07 Other

116. Have you been circumcised? *(only asked at baseline)*

Alternative question wording for 3, 6, 9, and 12 month visits: **Since your last visit, have you been circumcised?**

117. [If Q116 = 00 and Dem_1 = 01] Would you be interested in getting circumcised?

01 Yes

00 No

118. [If Q116 = 01] How old were you when you were circumcised? *(only asked at baseline)*

Age |__|__|

119. Have you ever been treated for a sexually transmitted disease? *(only asked at baseline)*

01 Yes

00 No

120. [If Q119 = 01] During the past 3 months, have you been treated for a sexually transmitted disease?

01 Yes

00 No

121. [If Dem_1 = 01] Do you currently have ulcers anywhere on your penis and/or scrotum?

[If Dem_1 = 02] Do you currently have ulcers anywhere on your vagina and/or labia?

01 Yes

00 No

122. [If Dem_1 = 01] Do you currently have any pus dripping from your penis and/or a burning pain when passing urine?

[If Dem_1 = 02] Do you currently have any abnormal or smelly discharge from your vagina?

01 Yes

00 No

123. [If Dem_1 = 01] Do you currently have pain in your scrotum?

[If Dem_1 = 02]Do you currently have pain during sexual intercourse?

01 Yes

00 No

124. Do you clean your genitals after each time you have sexual intercourse?

01 Yes

00 No

If "Yes" to Q.124: How soon after sexual intercourse do you clean your genitals?

01 Right away

02 Within 5 min

03 Within 10 min

04 After 10 min

If "Yes" to Q.124: What do you use to clean your genitals?

01 Dry cloth

02 Wet cloth without soap

03 Wet cloth with soap

04 Other

If "Yes" to Q.124: [for females only] how did you clean your genitals? Do you say you …

01 Cleaned inside the genitals only

02 Cleaned outside the genitals only

03 Cleaned both inside and outside the genitals

7.2. Appendix B: CAPI Pre-Screening for Basic Eligibility

Participant ID: |__|__|__|__|__|__|__|__|

Date: |__|__|/|__|__|/|__|__|__|__

dd / mm / yyyy

Language:

01 English

02 Swahili

03 Luo

Visit ID: 01 (Baseline)

Gender (Dem_1):

01 Male

02 Female

Staff ID: |__|__|__|

Thank you for your interest in this study. Before we begin, we would like to explain that there are many reasons why a person may not be included in the study. Not everyone who wishes to get into the study will do so. To help us figure out if you might be included, we will need you to answer some basic questions. If the information you give us shows that you might be suitable for the study, we will ask you more questions, get a medical history from you, and run some medical tests. If your answers to our questions show that you should be included and your medical tests show that you are healthy, you will then be invited to take part.

Do you have any questions?

1. **Are you male or female? (Dem_01)**

   01 Male

   02 Female

2. **In what day, month and year were you born? *[Check National Identification or other form of age verification]***

   __ __Day

   __ __Month

   __ __Year

3. **How old were you at your last birthday?**

   ___ ___ years

4. **Are you currently a resident of:**

   01 Kisumu District

   02 Siaya District

   03 Nandi District

   04 Rachuonyo District

   05 Bondo District

   06 Vihiga District

   07 Nyando District

   08 Other District (specify)

5. **In which village/estate do you live? Living in a village/estate is defined as having a home that you can go to eat and to sleep everyday. _____**

   [Classify as urban or peri-urban/rural according to map]

6. **Within the past two years, has there ever been a time when you moved out of [Insert District from Q4] for at least 3 consecutive months?**

   01 Yes

   00 No

7. **[If Q6 = 01] What are the reasons that you left [Insert District from Q4]?**

   01 Not enough land

   02 Build a new home

   03 Attend boarding school

   04 To look for a job

   05 To start own household elsewhere

   06 To join husband's family

   07 To join spouse

   08 To further education

   09 Was asked to leave

   10 Personal or community conflict

   11 Committed a crime or harmed someone

   12 Other reason **(specify:_____)**

8. **[If Q6 = 01] When you moved out of [Insert District from Q4], where did you move to?**

    01 Another District in Nyanza Province **(specify: _____)**

    02 Another District in Kenya outside of Nyanza Province **(specify: _____)**

    03 Outside Kenya **(specify: _____)**

Questions 9-13 must be answered YES to take part in screening interview.

9. **If you are found to be suitable to take part in the study, are you willing to come in for study visits every 3 months for one year?**

    01 Yes

    00 No

10. **If you are found to be suitable to take part in the study, are you willing to give study staff detailed information about how they can reach you?**

    01 Yes

    00 No

11. **During the past 3 months, have you had sexual intercourse one or more times? By sexual intercourse, we mean that the penis enters the vagina or anus.**

    01 Yes

    00 No

12. **Are you willing to get an HIV test to take part in this study?**

    01 Yes

    00 No

13. **[If Q12 = 01] Are you willing to get the results of your HIV test?**

    01 Yes

    00 No

Questions 14-18 must be answered NO to take part in screening interview.

14. **Do you plan to move away from Kisumu within the next 12 months?**

    01 Yes

    00 No

    If [Q14=01] will it be for 3 months or more?

    01 Yes

    00 No

15. **Are you currently taking part in HIV research where you are receiving an intervention?**

    01 Yes

    00 No

16. **Do you have any health problems that require ongoing attention by a doctor?**

    01 Yes **(specify)**

    00 No

17. **Have you ever been told by a doctor, nurse, or VCT site that your blood test results show that you are infected with HIV, the virus that causes AIDS?**

    01 Yes

    00 No

18. **For females: Are you currently pregnant?**

    01 Yes

    00 No

19. **For females: [Q17=00] Do you intend to become pregnant within the next 12 months?**

    01 Yes

    00 No

7.3. Appendix C: CAPI Medical History and Physical Examination

SECTION Bf: GENITOURINARY

Bf1. **Do you currently have ulcers anywhere on your genitals?**

1 Yes

0 No

8 Refuse to Answer

Bf2. **Do you currently have any discharge in your penis (males) or vagina (females)?**

1 Yes

0 No

8 Refuse to Answer

Bf3. **Do you currently have lower abdominal pain (females) or pain in your scrotum (males)?**

1 Yes

0 No

8 Refuse to Answer

SECTION D: PHYSICAL EXAMINATION

Da10. (Applicable to Women Only) *[Instruction to the Clinician]* **Enter pregnancy test results** (Choose one)

1 Positive

2 Negative

9 Not Applicable

If VISITID is greater than 1, then skip to Dg1.

SECTION Dg: GENITOURINARY

Dg1. *[Instruction to the Clinician]* **Are genital ulcers present?**

1 Yes

0 No

8 Refuse to Answer

Dg2. *[Instruction to the Clinician]* **Is vaginal or urethral discharge present?**

1 Yes

0 No

8 Refuse to Answer

Dg3. *[Instruction to the Clinician]* **Is tenderness in the lower abdomen or scrotum present?**

1 Yes

0 No

8 Refuse to Answer

Dg4. (Ask of Men Only) [*Instruction to the Clinician]* **Circumcision present?**

1 Yes

0 No

8 Refuse to Answer

If VISITID is greater than 1, then skip to E1.

SECTION E: CLINICIAN'S NOTES

E1. *[Instruction to the Clinician]* **Is there a diagnosis made?**

1 Yes

0 No

If E1 is equal to 0, then skip to E116.

E2. *[Instructions to the Clinician]* **What is the diagnosis?**

__ __

E3. *[Instruction to the Clinician]* **Please enter the diagnosis code for** [Response to E2]. __ __ __ __ __

99999 Not Applicable ***Skip to instruction before Q2***

E4. *[Instruction to the Clinician]* **Are you giving a prescription for** [Response to E2]?

1 Yes

0 No

If E4 is equal to 0, then skip to E24.

E5. *[Instruction to the Clinician]* **Enter the medication prescribed for** [Response to E2]. __

E6. *[Instruction to the Clinician]* **Enter the prescription medication code for [Response to E5].** __ __ __ __ __

99999 Not Applicable ***Skip to instruction before Q2***

E7. *[Instructions to the Clinician]* **What is the expiration date?**

__ __ / __ __ / __ __ __ __ mm / dd / yyyy

2099 Not Applicable (Year)

E8. *Instructions to the Clinician]* **What is the medication start date?**

__ __ / __ __ / __ __ __ __ mm / dd / yyyy

2099 Not Applicable (Year)

E9. *[Instruction to the Clinician]* **Are you giving another prescription for [Response to E2]?**

1 Yes

0 No

If E9 is equal to 0, then skip to E24.

E10. *[Instruction to the Clinician]* **Enter the medication prescribed for [Response to E2].**__ __

E11. *[Instruction to the Clinician]* **Enter the prescription medication code for [Response to E10].**

__ __ __ __ __

99999 Not Applicable ***Skip to instruction before Q2***

E12. *[Instructions to the Clinician]* **What is the expiration date?**

__ __ / __ __ / __ __ __ __ mm / dd / yyyy

2099 Not Applicable (Year)

E13. *Instructions to the Clinician]* **What is the medication start date?**

__ __ / __ __ / __ __ __ __ mm / dd / yyyy

2099 Not Applicable (Year)

7.4. Appendix D: Extract From KICoS Laboratory Specimen Collection and Reporting Form K411B

1328294537

Kisumu Incidence Cohort Study
Laboratory Specimen Collection and Reporting Form
Form K411B

Stick Participant ID here

When: Any time a lab request or lab test(s) that does not generate lab report has been done.
By Whom: Nurse counselor or designee and laboratory technician/technologist.
Instructions: Participant ID, visit code, visit date and gender is filled in by Nurse counselor or designee. The laboratory technician/technologist transcribes the results of the test on the **test results section**. This form is reviewed and signed by the laboratory supervisor and field supervisor or designee.

Participant ID

Visit Code

Visit Date

dd / mm / 2007

Gender ○ Male ○ Female

Leave blank if it does not apply.

Test Results Section

HIV EIA ○ Positive ○ Negative ○ Indeterminate ○ Test not done

Date processed dd / mm / yyyy Time processed : ○ am ○ pm

Processed by Staff code

HIV PCR ○ Positive ○ Negative ○ Indeterminate ○ Test not done

Date processed dd / mm / yyyy Time processed : ○ am ○ pm

Processed by Staff code

KICoS Laboratory Specimen Collection and Reporting Form - K411B - Final Version 2
Revised 18-12-07

Page 1 of 6

5620294536

Syphilis ○ Positive ○ Negative

Date processed □□ / □□ / □□□□ dd / mm / yyyy

Time processed □□ : □□ ○ am ○ pm

Processed by □□□ Staff code

CT/NG PCR

CT ○ Positive ○ Negative

NG ○ Positive ○ Negative

Date processed □□ / □□ / □□□□ dd / mm / yyyy

Time processed □□ : □□ ○ am ○ pm

Processed by □□□ Staff code

HSV 2 ○ Positive ○ Negative ○ Indeterminate ○ Test not done

Date processed □□ / □□ / □□□□ dd / mm / yyyy

Time processed □□ : □□ ○ am ○ pm

Processed by □□□ Staff code

Ad 5 ○ Positive ○ Negative

Date processed □□ / □□ / □□□□ dd / mm / yyyy

Time processed □□ : □□ ○ am ○ pm

Processed by □□□ Staff code

ESR □□□ mm/hr

Date processed □□ / □□ / □□□□ dd / mm / yyyy

Time processed □□ : □□ ○ am ○ pm

Processed by □□□ Staff code

7.5. Appendix E: Partner Tracking Form K318

Kisumu Incidence Cohort Study

Partner Treatment Tracking Form

Form K318

Instructions: - For Partners bringing an STI code card. Indicate the partner's sex and age (in years).Indicate the date of visit and mark the first letter of the colour indicated on the STI card.

O Male OFemale Age_._

Date: _____

(dd/mm/yyyy) Colour ☐

O Male OFemale Age_._

Date: _____

(dd/mm/yyyy) Colour ☐

O Male OFemale Age_._

Date: _____

(dd/mm/yyyy) Colour ☐

Completed by: Date Completed

Staff Code: ☐☐☐ Signature _____ ☐☐☐☐☐☐☐☐

dd/ mm/ yyyy

Reviewed by: Date Reviewed

Staff Code: ☐☐☐☐☐☐☐ Signature _____ ☐☐☐☐

dd/ mm/ yyyy