PREVALENCE OF AND RISK FACTORS FOR SEXUALLY TRANSMITTED INFECTIONS AMONG WOMEN ATTENDING FAMILY PLANNING CLINIC AT KENYATTA NATIONAL HOSPITAL, NAIROBI

A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF **MASTER OF SCIENCE IN MEDICAL MICROBIOLOGY**

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DECLARATION

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ACKNOWLEDGEMENT

I wish to express my heartfelt and sincere gratitude to my Supervisors Professor Omu Anzala and Dr. Joshua Kimani for their guidance since the start to the completion of my work. Their guidance, comments, critiques, encouragements and patience have made this work possible.

I thank the head of the Department of Reproductive Health, Kenyatta National Hospital Dr. J. Ong'ech for allowing me to conduct the study at Clinic 66. I would also like to thank the nurses in clinic 66 for their cooperation during the entire study.

I would like to thank Mr. Jonathan Oloo of the University of Nairobi, Department of Medical Microbiology and Mr. Christopher Wainaina of Hain Lifescience East Africa Ltd for their assistance during laboratory procedures.

I appreciate the assistance of Mr.Gichuki for his professional advice during data analysis.

To the entire Sirkoi family for making this a worthwhile venture and for providing the much needed comic relief.

Finally, I would like to glorify the name of the Almighty God, for giving me health, power and the ability to accomplish this work.

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LIST OF ABBREVIATIONS

ANC	-	Antenatal clinic
CDC	-	Centres for Disease Control
CGI	-	Complicated gonococcal infection
CT	-	*Chlamydia trachomatis*
DGI	-	Disseminated gonococcal infection
DNA	-	Deoxyrinonucleic acid
EB	-	Elementary body
FP	-	Family planning
FSW	-	Female sex worker
FVU	-	First void urine
GC	-	*Neisseria gonorrhoeae*
HIV	-	Human Immunodeficiency Virus
KAIS	-	Kenya AIDS Indicator Survey
KDHS	-	Kenya Demographic and Health Survey
KNH/UON ERC-		Kenyatta National Hospital/University of Nairobi Ethics Review Committee
KNH	-	Kenyatta National Hospital
LGV	-	Lymphogranuloma venereum
LPS	-	Lipopolysaccharide
MomP	-	Major outer membrane protein
MSM	-	Men who have sex with men

MSW	-	Male sex worker
NAAT	-	Nucleic acid amplification test
NASCOP	-	National AIDS and STI Control Programme
PCR	-	Polymerase chain reaction
RB	-	Reticulate body
RNA	-	Ribonucleic acid
STI	-	Sexually Transmitted Infection
TV	-	*Trichomonas vaginalis*
UGI	-	Uncomplicated gonococcal infection
UoN	-	University of Nairobi
WHO	-	World Health Organization

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ABSTRACT

Background

Sexually Transmitted Infections (STIs) are a major public health problem, especially in developing countries. The complications of untreated STIs in the female genital tract and their role in adverse pregnancy and perinatal outcomes have been well documented. However, most infections are asymptomatic and screening, especially for women in the reproductive age group is recommended. The prevalence of STIs in Kenya among women in the general population has not been extensively studied and there is a lack of guidelines for screening of nonpregnant women. Knowledge of the prevalence of curable STIs among this population can provide a basis for integrating STI screening in family planning clinics.

Objective: To determine the prevalence and the risk factors for three curable sexually transmitted infections among women attending family planning clinic at Kenyatta National Hospital.

Methodology: A cross-sectional study was conducted between May and September 2013 at the Family Planning (FP) clinic at Kenyatta National Hospital. A total of 261 participants were enrolled with data from 249 participants being analysed. An interviewer-administered questionnaire was used to gather socio-demographic data and assess for risk factors. Two endocervical swabs were collected from each participant and used to screen for *Trichomonas vaginalis* using the wet mount procedure; to culture for *Neisseria gonorrhoeae* and to conduct PCR for *Chlamydia trachomatis*.

Results: A total of 249 women aged between 20 – 49 years were tested. The prevalence of *Chlamydia trachomatis* was 13.3%, *Trichomonas vaginalis* 0.4% and *Neisseria gonorrhoeae* 0%. All the infected women reported having had only one partner in the previous year. The

age group prevalence for *Chlamydia trachomatis* was highest in the 35 – 39 years age group (30.3%). Married participants were associated with higher infection rate (91%) than single participants (3.03%) and an age of coitarche of less than 20 years was associated with increased risk of Chlamydia infection.

Conclusion: A high prevalence of *Chlamydia trachomatis* was identified among women, majority of whom were married, attending the Family Planning Clinic at Kenyatta National Hospital. The prevalence of *Neisseria gonorrhoeae* and *Trichomonas trachomatis* was however found to be low. The study reinforces the need to implement regular screening for STIs among FP clinic attendants. It also reveals the need to review the usage of the syndromic approach for the management of STIs as it showed a low specificity and positive predictive value when symptoms were compared to the gold standard of CT PCR.

1.0 BACKGROUND

According to the World Health Organisation (WHO), over 30 bacterial, viral and parasitic pathogens have been identified to date that can be transmitted sexually. Four curable sexually transmitted infections (STIs) (gonorrhoea, chlamydial infection, syphilis and trichomoniasis) were responsible for 498.9 million new cases of STIs in 2008. In the prevalence estimates, the African region had the highest prevalence for gonorrhoeae and syphilis at 4.3% and 7.4% respectively. Females had a higher prevalence for chlamydial infection (2.6%), gonorrhoea (2.3%) and trichomoniasis (20.2%) (WHO, 2012). Untreated STIs can have critical implications for reproductive, maternal and newborn health.

The most accurate method of diagnosing STIs is by laboratory tests, but these are often unavailable or too expensive, especially in developing countries. Because of this, since 1990 WHO has recommended a syndromic approach to diagnosis and management of STIs in patients presenting with consistently recognized signs and symptoms of particular STIs (WHO, 2013).

In the Kenyan public health sector, the syndromic approach for the management of STIs, as recommended by the WHO is utilised (Ministry of Health, 2002). However, several studies have shown that a majority of STIs, especially in women, are asymptomatic. In a study done in five countries, a range of 31.2% to 100% of participants reported no symptoms (Detels R. , et al., 2011) while another study done in the United States estimated that 86 to 98% of untreated cases were untreated because they were never symptomatic (Farley, Cohen, & Elkins, 2003).

The complications of untreated STIs in the female genital tract and their role in adverse pregnancy and perinatal outcomes have been well documented. These include pelvic inflammatory disease (PID), infertility, ectopic pregnancy, premature delivery, low-birth-

weight babies, and infection of the foetus leading to congenital malformations and infections which can have negative outcomes like blindness (Palafox SKV, 2011).STIs have also been recognised as increasing the risk for HIV acquisition (McClelland Scott, et al., 2007).

In Kenya, no guidelines exist for the screening of non-pregnant women for the four curable STIs, while in pregnant women; syphilis is the only curable STI that is screened for. In the Kenya Demographic and Health Survey (KDHS) of 2008/2009, the self-reported prevalence of STIs and STI symptoms was higher among women than among men. 57.3% of respondents reported their source of modern contraceptive methods as public government-sponsored facilities (KNBS & Macro, 2010). Family planning clinics in public government-sponsored facilities therefore have the potential as access points for STIs' work for the general population.

This study therefore intended to assess the prevalence and risk factors for three curable STIs (gonorrhoea, trichomoniasis and Chlamydia) among women attending the Kenyatta National Hospital's family planning (FP) clinic. The data obtained will be useful in informing policy on STI screening among women from the general population and the potential of FP clinics integrating STIs diagnostics as part of their services in our settings going forward.

2.0 LITERATURE REVIEW

2.1 Introduction

Sexually transmitted infections (STIs) are infections generally acquired by sexual contact. Some of these infections can also be transmitted nonsexually through mother to child transmission during pregnancy or childbirth; or through blood transfusions; or shared needles. STIs have a great impact on health, potentially causing severe health outcomes like infertility, ectopic pregnancy, pelvic inflammatory disease(PID) and gynaecologic cancers such as cervical, vulvar and vaginal (Idahl, et al., 2011). They also have adverse outcomes during pregnancy and the neonatal period (Schulz, Cates, & O'Mara, 1987).

Sexually transmitted infections (STIs) caused by *Trichomonas vaginalis*, *Chlamydia trachomatis* and *Neisseria gonorrhoeae* were responsible for 437 million new cases of STIs that occurred globally in 2005 (WHO, Prevalence and Incidence of Selected Sexually Transmitted Infections, 2011).

2.2 *Trichomonas vaginalis*

Trichomonas vaginalis (TV) is the causative agent of trichomoniasis. It is the most common non-viral STI and was estimated to cause 276.4 million new infections in 2008 (WHO, 2012). Humans are the only known hosts of TV and transmission occurs predominantly through sexual intercourse though some studies have linked transmission in sexually inactive people to sharing of bathing elements (Crucitti, et al., 2011).

TV is $\simeq$ 10-20μm long and 2-1μm wide and has four flagella projecting from the anterior portion of the cell and one flagellum extending backward to the middle of the organism,

forming an undulating membrane. An axostyle, a rigid structure extends from the posterior aspect of the organism. It is anaerobic, can only exist as a trophozoite and lacks a cystic stage, replicating by longitudinal binary fission.

In women, TV is isolated from the vagina, cervix, urethra, bladder and Bartholin and Skene glands while in men, it is isolated from the urethra and the prostate gland.

2.2.1 Epidemiology of *Trichomonas vaginalis*

Prevalence estimates of TV vary depending on the population studied and diagnostic methods used. Generally, trichomoniasis is more common in women than in men. Several studies have shown that trichomoniasis is more common in older women compared to other STIs which are more common in younger women (Helms, et al., 2008; Freeman, et al., 2010). Higher TV prevalence in women older than 40 years is probably attributed to the reason for testing i.e. symptomatic versus routine screening in younger women in countries where routine screening is carried out (Ginocchio, et al., 2012).The prevalence rate ranges from 0.4% among low risk women (Uddin, Ryder, McNutty, Wray, & Donovan, 2011) to 17% among high-risk women (Vandepitte, et al., 2011). In pregnancy, a prevalence of 20% was found in Nigeria (Olusola, et al., 2010)while a rate of 1.4% was found in urban Bangladesh (Begum, et al., 2003). In a study done among HIV-1 infected pregnant women in Nairobi, a prevalence of 16% for TV was found (Marx, et al., 2010).

Some of the risk factors that have been found to increase the risk for the acquisition of trichomoniasis include: having an infected partner; low socioeconomic background; substance abuse; a history of bacterial vaginosis and high-risk sexual practices (unprotected sex, multiple partners) (Olakolu, Abioye-Kuteyi, & Oyegbade, 2011).

2.2.2Clinical Presentation

Women with trichomoniasis report a wide range of symptoms. When clinically apparent, symptoms include vaginal pruritus, dysuria, dyspareunia and a malodorous discharge. More severe infections may occasionally be associated with vulvitis and vaginitis. The vaginal discharge is usually green-yellow and frothy. Colpitus macularis (strawberry cervix) occurs in severe infections and is a sign of cervical inflammation.

However, several studies have shown that the rate of asymptomatic *Trichomonas vaginalis* infection can be as high as 60%. In a study done among HIV-uninfected high-risk women, only 12.3% of the study participants who had a laboratory-diagnosed discharge -causing STI had clinically evident discharge (Mlisana, et al., 2012).The health consequences of trichomoniasis in women include: increased risk for HIV acquisition (McClelland Scott, et al., 2007); pelvic inflammatory disease(PID) (Moodley, Wilkinson, Connolly, Moodley, & Sturm, 2002); infertility, cervical neoplasia and preterm birth (Cotch, et al., 1997).

2.2.3Diagnosis of *Trichomonas vaginalis*

The specimens collected for diagnosis of TV in women include: urine, vaginal swabs, and cervical swabs. Diagnostic tests for TV include:

1. **Microscopy**- in which microscopic observation of motile protozoa from vaginal, cervical samples or urethral secretions is done. The sensitivity of the test varies from 38% to 83.3% (Madhivanan, et al., 2013) (Nathan, et al., 2013). The need for the specimen to remain moist and the experience of the observer are important variables. At room temperature and in phosphate-buffered saline, the organism remains alive for 6 hours. Since the viability of the organism is required, delay in

transport and evaporation of moisture from the specimen reduces motility and consequently the diagnostic sensitivity (Stoner, Rabe, Meyn, & Hillier, 2013).

2. **Culture**- Culture using a variety of liquid and semi-solid media remains the reference standard for diagnosis of trichomoniasis in women. After inoculation with vaginal swab specimen or urine sediment, cultures are incubated for 3 to 5 days at $37^{o}C$ in a 5% CO_2 atmosphere and examined daily using microscopy for motile trichomonads. Broth culture technique has been the gold standard for TV culture and the growth of the organism is easy to interpret. The standard broth is Diamond's TYI medium in glass tubes. The sensitivity of culture ranges from 88% to 94.4% (Madhivanan, et al., 2013) (Nathan, et al., 2013).
3. **Nucleic acid detection.**
4. **Rapid diagnostic tests**: These include the Affirm^{TM} VP111 Microbial Identification Test which is an oligonucleotide probe test with a sensitivity of 80-90% and a specificity of 95% compared with wet mount and culture using vaginal swabs. The OSOM Trichomonas Rapid Test is an immunochromatographic capillary-flow enzyme immunoassay dipstick test. It is performed on vaginal secretions with results available within 10 minutes. It has a sensitivity of 83-92% and a specificity of 99-100% (Madhivanan, et al., 2013) (Nathan, et al., 2013).

2.2.4 Treatment of trichomoniasis

5-nitroimidazole drugs are used for the treatment of trichomoniasis e.g. metronidazole and tinidazole. Treating the patient's sexual partners to prevent reinfection further improves the cure rate.

2.3 *Chlamydia trachomatis*

Chlamydia trachomatis(CT) is an obligate intracellular bacterium with a Gram negative cell wall and is an obligate human pathogen. The reproductive cycle of the chlamydiae comprises two developmental stages: (i) Elementary bodies (EB) which are optimally adapted to survive outside of host cells. (ii)Reticulate bodies (RB) which are intracellular and reproduce inside host cells by transverse fission. The infectious form is the EB which lies outside cells. After attachment, EBs penetrate into their host cells where they reorganize into metabolically active and replicative RBs that accumulate by division in a large cytoplasmic inclusion.

Chlamydia trachomatis can be differentiated into 18 serovars (serologically variant strains) on the basis of monoclonal antibody–based typing assays. These serovars are associated with different medical conditions, as follows:

- Serovars A, B, Ba, and C cause trachoma, a serious eye disease endemic in Africa and Asia that is characterized by chronic conjunctivitis and can lead to blindness,
- Serovars D-K – Genital tract infections,
- Serovars L1-L3 – Lymphogranuloma venereum (LGV), which is associated with genital ulcer disease in tropical countries

2.3.1 Epidemiology of *Chlamydia trachomatis*

More cases of STIs are caused by *Chlamydia trachomatis* than by any other bacterial pathogen, making chlamydial infections an enormous public health problem throughout the world. In the 2008 WHO estimates, CT was responsible for 105.7 million new cases of STIs in adults between the ages of 15 and 49 years; with the prevalence of infection being generally higher among females than males. In the African region, the prevalence of infection among females was 2.6% against a prevalence of 2.1% among males (WHO, 2012)

Chlamydia trachomatis is the most frequently reported sexually transmitted infection in the United States with 1,307,893 cases of Chlamydia being reported in 2010 (CDC, 2012).

Chlamydial infection is more common among women and young people. In a study done in France, increased prevalence rates were found in subjects aged 18 to 29 years with 2.5% for men and 3.2% for women against a prevalence of 1.4% in people aged 18-44 years (Goulet, de Barbeyrac, Prudhomme, Semaille, & Warszawski, 2010). In Australia, pooled prevalence for women <25 years in studies conducted post-2005 was 5.0%and for men <30 years over the entire review period was 3.9% (Lewis, et al., 2012). In Rwanda, a prevalence of 3.8% among infertile women was found while a rate of 3.3% was found among fertile controls, a difference that was not statistically significant. The same study found that women <25 years were more likely to have genital infections (Murunyi, et al., 2012).

In pregnancy, a prevalence rate of 19% was found among pregnant urban adolescents in the United States (Berggren & Patchen, 2010) while a different study in Brazil conducted among pregnant women aged 15 to 24 years found a prevalence of 9.8% (Pinto, et al., 2011).

In Kenya, the prevalence rates vary depending on the population studied. Among MSM, a prevalence estimate of 12% was found (Sanders, et al., 2010) while a rate of 3.2% was found among fishermen working along Lake Victoria in Kisumu (Kwen, et al., 2010).

Transmission of *Chlamydia trachomatis* is through sexual intercourse which could be vaginal or anal. Mother to child transmission can also occur during birth through an infected vaginal canal.

The risk factors for the acquisition of chlamydial infection include: young age of sexual debut; low income; unprotected sex; history of drug or alcohol use (Deogan, Cnattingius, &

Mansdotter, 2012); young age (≤24 years) and number of new partners over the preceding 12 months prior to being tested (Paul, Garcia, Giesel, Holmes, & Hitti, 2009).

2.3.2 Clinical Presentation

The majority of infected persons are asymptomatic, and thus provide an ongoing reservoir for infection. In a study done in five countries, a range of 66.7% and 100% of participants reported no symptoms (Detels R. , et al., 2011). In infants born to mothers through an infected birth canal, conjunctivitis and pneumonia can occur (Rours, et al., 2008). Moreover, both men and women can experience clinical syndromes due to infection at common epithelial sites, including the rectum and conjunctivae. Other types of *C. trachomatis* infection, including lymphogranuloma venereum and endemic trachoma, an ocular infection spread by direct contact and seen commonly in the developing world, may occur in both men and women.

In women, the cervix is the most commonly infected anatomic site although a proportion may also have infection of the urethra. The incubation period ranges from seven to fourteen days. Untreated cervical infection can ascend to cause pelvic inflammatory disease (PID) and its sequelae of infertility and chronic pain. Majority of infected women are asymptomatic and when symptoms do occur, they tend to be non-specific: a change in vaginal discharge, inter-menstrual vaginal bleeding and post-coital bleeding. The classic signs of cervicitis may occur: mucopurulent endocervical discharge, easily induced endocervical bleeding or oedematous ectopy.

PID due to CT is associated with higher rates of subsequent tubal infertility, ectopic pregnancy and chronic pelvic pain. Perihepatitis (Fitzhugh-Curtis syndrome) which is the

inflammation of the liver capsule and adjacent peritoneal surfaces may occur although it is most commonly seen in the setting of actual PID (De Seta, et al., 2012).

Infection during pregnancy can increase the risk for ectopic pregnancy, premature rupture of membranes and preterm delivery (Rours, et al., 2011).

2.3.3 Diagnosis of *Chlamydia trachomatis*

The specimens used for diagnosis *of C.trachomatis* include: first void urine(FVU); vaginal swabs; rectal swabs; endocervical swabs; conjuctival swabs; urethral swabs; fallopian tube aspirates in the case of salpingitis; for LGV strains, bubo pus or biopsy samples may be used.

Chlamydial specimens should be refrigerated on receipt in the laboratory; if specimens cannot be processed within 24 h after collection, they should be frozen at -70°C. Diagnostic tests for CT include:

1. **Direct cytological examination-** useful in diagnosing acute inclusion conjunctivitis of the newborn.
2. **Isolation in cell culture-** McCoy, Hep-2 and HeLa cells are the most commonly used for CT. The cells are incubated at 35°C in 5% CO_2 for 48 h to 72 h, and the cover slip is examined for inclusions by immunofluorescence, iodine staining or Giemsa staining.
3. **Antigen detection-** available products use either monoclonal or polyclonal antibodies to detect chlamydial lipopolysaccharide (LPS), which is more soluble than the major outer membrane protein (MOMP).
4. **Nucleic acid amplification tests(NAATs)-** Several Nucleic acid amplification methods are currently used:
    i. Polymerase chain reaction(PCR)

ii. Ligase chain reaction

iii. Transcription-mediated amplification

iv. Strand displacement amplification.

The PCR, ligase chain reaction and strand displacement amplification assays amplify nucleotide sequences of the cryptic plasmid, which is present in multiple copies in each CT EB. The transcription-mediated amplification is directed against ribosomal RNA, which is also present in multiple copies.

The estimated sensitivities and specificities for diagnostic tests for CT include:

i. Tissue culture: 70-85%(sensitivity); 100%(specificity) (Black, 2013).

ii. Direct fluorescent antibody:80-85%(sensitivity); >99%(specificity) (Black, 2013).

iii. Enzyme immunoassay: 53-76%(sensitivity); 95%(specificity) (Black, 2013).

iv. Direct hybridization: 65-83%(sensitivity); 99%(specificity) (Black, 2013).

v. PCR: 89.7%-90.3% (sensitivity); 98.4%-99.4 %(specificity) depending on the specimen used (Black, 2013).

vi. Strand displacement amplification: 80.5%-94.6%(sensitivity); 91.4%-98.4%(specificity) depending on the specimen used (Black, 2013).

vii. Transcription mediated amplification: 94.2%-97.0%(sensitivity); 97.6%-99.1%(specificity) depending on the specimen used (Black, 2013).

viii. Real-time PCR: 80.9%-93.3% (sensitivity); 98.3%-99.1% (specificity) depending on the specimen used (Black, 2013).

In the Kenyan situation however, these tests are not standard of care as they are expensive and require highly trained personnel. The symptomatic approach is used instead.

2.3.4 New variant *Chlamydia trachomatis*(nvCT)

In 2006, a variant strain of CT was discovered in Sweden. This was after a 25% decrease in diagnosed infections in some areas of the country was detected in the beginning of 2006. This raised a suspicion of impairment of the kit quality or a change in the target area in the microbe. DNA sequencing of the area in the cryptic plasmid containing the target region for the assays that had previously been used for diagnosis revealed a 377-bp deletion (Ripa & Nilsson, 2007). Dual target NAATs that target both the genomic DNA and cryptic plasmid are therefore recommended.

2.3.5 Treatment of chlamydial infections

i. Recommended regimen: Azithromycin 1g orally in a single dose

OR

Doxycycline 100mg orally twice a day for 7 days.

ii. Alternative regimen: Erythromycin base 500mg orally four times a day for 7 days

OR

Erythromycin ethylsuccinate 800mg orally four times a day for 7 days

OR

Levofloxacin 500mg orally once daily for 7 days.

OR

Ofloxacin 300mg orally twice a day for 7 days (CDC, 2011).

2.4 Neisseria gonorrhoeae

Neisseria gonorrhoeae, also known as the gonococcus or GC, is a Gram-negative coccus 0.6-1.0μm in diameter, usually seen in pairs with adjacent flattened sides. It is an obligate human

pathogen, which colonises primarily the mucosa of the lower anogenital tract resulting in uncomplicated gonococcal infection (UGI). The organism can ascend to the normally sterile upper genital tract and cause complicated gonococcal infection (CGI) or it can invade the bloodstream to cause disseminated gonococcal infection (DGI). Gonorrhoea facilitates HIV transmission (Klotman, et al., 2008) and therefore effective treatment plays an important role in HIV prevention strategies.

The DNA of *Neisseria gonorrhoeae* is a circular double stranded molecule≃ 2.11Mb that aggregates to form a visible mass called the nucleoid. Extrachromosomal circular DNA can also be found in plasmids which typically contain genes that confer special properties such as antimicrobial resistance (Mehta, et al., 2011).

2.4.1 Epidemiology of gonorrhoea infection

Gonorrhoea represents 88 million of the estimated 448 million new cases of curable STIs which occur globally every year (WHO, 2011). In the United States, gonorrhoea is the second most commonly reported notifiable infection, with >300,000 cases reported during 2011 (del Rio, et al., 2012). In Europe, an increase in the cases reported has been attributed in part to increased risk behaviour among both MSM and young adults (Van de Laar & Spitera, 2012).

In sub-Saharan Africa, gonorrhoea prevalence in the adult population is estimated at 2 to 3%, with incidence rates estimated at 58 cases per 1,000 males and 65 per 1,000 females, the highest among developing countries (Tapsall, 2001). In Kenya, Mehta et al (2011) showed a decreased prevalence from 3.8% in 2002 to 2.7% in 2009 from a cohort of young men in Kisumu. In South Africa, a prevalence of 5.4% was found among asymptomatic HIV-Infected patients (Lewis, et al., 2012).

The prevalence among high-risk groups varies in different regions of the world. In China, a GC prevalence of 8.3% was found among FSW in Yunnan Province (Wang, et al., 2009).In

Côte d'Ivoire, Vuylsteke et al (2012) found a GC prevalence of 12.8% for all participants and 15.6% among first time attendees in a study done among MSW; in Uganda a prevalence of 13% in a cohort of FSW was reported (Vandepitte, et al., 2011); while in

Kenya a study done among HIV-negative MSM showed a prevalence of 2% for urethral gonorrhoea and 11% for rectal gonorrhoeae (Sanders, et al., 2010).

Among pregnant women, 3.5% prevalence was found in HIV-infected pregnant women attending ANC in Tanga, northeastern Tanzania (Chidio, et al., 2012); while among pregnant urban adolescents in Washington DC, USA, a prevalence of 10% was found, with a reinfection rate of 3% (Berggren & Patchen, 2011).

Gonococcal ophthalmia neonatorum was found in 43% of cases of ophthalmia neonatorum in a study done in Nairobi, Kenya (Fransen, et al., 1985).

2.4.2 Transmission of *Neisseria gonorrhoeae*

Gonorrhoea is transmitted by contact with exudates from mucous membranes of infected persons primarily through sexual activity. This can occur during vaginal, oral or anal sexual activity. Gonococcal ophthalmia neonatorum can occur in neonates who have had contact with the mother's infected birth canal during birth.

Risk factors for gonorrhoea include unprotected sex especially unprotected anal intercourse (Jin, et al., 2007), multiple sexual partners (Risbud, Deshpande, Narayanan, Parimi, & Das, 2011), male homosexuality, low socioeconomic status, transactional sex, history of concurrent or past STDs, early age of onset of sexual activity and illegal drug use (Loza, et al., 2010).

2.4.3 Gonococcal infections

Gonorrhoea is a set of clinical conditions resulting from infection with GC. It is generally limited to superficial mucosal surfaces lined with columnar epithelium and is usually

characterized by a purulent discharge. The most frequently involved areas are the urethra, cervix, rectum, pharynx, and conjunctiva.

2.4.3.1 Uncomplicated Gonococcal Infections (UGI)

Uncomplicated gonorrhoea in the adult male is an inflammatory and pyogenic infection of the mucous membranes of the anterior urethra. The most common symptom is a discharge that may range from a scanty, clear or cloudy fluid to one that is copious and purulent. Dysuria is often present. Inflammation of the urethral tissues results in the characteristic redness, swelling, heat, and pain in the region.

Endocervical infection is the most common form of uncomplicated gonorrhoea in women. Such infections are usually characterized by vaginal discharge and sometimes by dysuria. A high prevalence and incidence of asymptomatic gonorrhoea was identified among men and women in a wide variety of settings by a study done by Detels et al (Detels R. , et al., 2011).Rectal infections (proctitis) with *N. gonorrhoeae* occur in about one-third of women with cervical infection. They most often result from autoinoculation with cervical discharge and are rarely symptomatic. Rectal infections in homosexual men usually result from anal intercourse and are more often symptomatic.

2.4.3.2 Complicated Gonococcal Infections (CGI)

In men, the organism may invade the prostate causing prostatitis, or extend to the testes resulting in orchitis. In women, cervical involvement may extend through the uterus to the fallopian tubes resulting in **s**alpingitis, or to the ovaries resulting in oophoritis. In a study done among female adolescents in Texas, USA, 13% were found to have pelvic inflammatory disease (PID) after initially being diagnosed with GC (Risser & Risser, 2011). The involvement of the testes, fallopian tubes or ovaries may result in sterility.

2.4.3.3 Disseminated Gonococcal Infections (DGI)

Occasionally, disseminated infections occur. The most common forms of disseminated infection are a dermatitis-arthritis syndrome (Bleich, Sheffield, Wendel, Sigman, & Cunningham, 2012), endocarditis and meningitis. Disseminated gonococcal infection is a rare but important complication of mucosal infection with *Neisseria gonorrhoeae*. Classic DGI typically manifests as a combination of dermatitis, tenosynovitis and migratory polyarthralgia, or as purulent arthritis without skin lesions (O'Brien, Goldenberg, & Rice, 1983).

2.4.3.4 Gonococcal Ophthalmia Neonatorum

Ocular infections by *Neisseria gonorrhoeae* can have serious consequences of corneal scarring or perforation. Ocular infections (ophthalmia neonatorum) occur most commonly in newborns exposed to infected secretions in the birth canal (Bhuiyan, Rokon, Farzana, Tania, & Baker, 2011). Gonococcal conjunctivitis tends to be more severe than other causes of ophthalmia neonatorum; there is a classic presentation of bilateral purulent conjunctivitis. Corneal involvement, including diffuse epithelial edema and ulceration, may progress to perforation of the cornea and endophthalmitis. Patients also may have systemic manifestations (e.g., rhinitis, stomatitis, arthritis, meningitis, anorectal infection, and septicemia).

2.4.4 Diagnosis of *Neisseria gonorrhoeae*

The specimens used for diagnosis of *Neisseria gonorrhoeae* include: FVU; vaginal swabs; rectal swabs; endocervical swabs; conjuctival swabs; urethral swabs; or pharyngeal swabs and aspirates from joint fluid. Transportation must be as rapid as possible for the optimal recovery of the organism.

Diagnostic tests include:

1. **Microscopy**- A direct smear for Gram staining may be performed as soon as the swab specimen is collected from the urethra, cervix, vagina or rectum. Because of its high specificity (>99%) and sensitivity (>95%), a Gram stain of a male urethral specimen that demonstrates polymorphonuclear leukocytes with intracellular Gram-negative diplococci can be considered diagnostic for infection with *N. gonorrhoeae* in symptomatic men. However, it is relatively insensitive for specimens collected from women and for specimens from extragenital sites where the specificity of gram stain may also be affected by the presence of commensal *Neisseria* species.
2. **Culture**- Primary specimens should be inoculated onto nonselective chocolate blood agar and also on selective agar containing antimicrobial agents that inhibit the growth of commensal bacteria and fungi. The antibacterial agents in the selective agar which include modified Thayer-Martin, Martin Lewis and New York City medium are vancomycin, colistin, trimethoprim lactate and the antifungal agents nystatin and anisomycin or amphotericin B. The inoculated plates should be incubated at 35°C to 37°C in a moist atmosphere enriched with CO_2 (3% to 7%). Gonoccocal culture ranges in sensitivity from 85 to 95% for acute infections and may fall as low as 50% for females with chronic infection. It however remains the gold standard for definitive diagnosis (Kousmans, Johnson, Knapp, & St. Louis, 1998).
3. **Nucleic acid amplification assays (NAATs)** -these include PCR, ligase chain reaction and strand displacement amplification system. There are several advantages of GC NAATs: first, they offer improved sensitivity compared with

bacterial culture. The increases sensitivity makes them particularly suitable for screening, enabling accurate diagnosis of both symptomatic and asymptomatic gonococcal infections. Secondly, specimens collected for NAAT assays do not require the organism to be viable for detection and therefore require less stringent transport conditions compared with those collected for bacterial culture. The limitations include high cost, carryover contamination, inhibition of the reaction, high quality control requirements and the absence of antibiotic resistance data.

The nucleic acid detection methods are however expensive as they require expensive reagents and equipment which require constant power supply which may not be available in all public health facilities. Microscopy and culture are the most feasible methods for diagnosis of GC in the Kenyan public health sector.

2.4.5 Treatment of Gonococcal Infections

Currently, the CDC recommends dual therapy with ceftriaxone 250mg intramuscularly as a single dose plus either azithromycin 1 gram orally as a single dose or doxycycline 100 mg orally twice a day for 7 days as the most effective treatment for uncomplicated gonorrhoea (del Rio, et al., 2012). Patients infected with *N. gonorrhoeae* frequently are coinfected with *C. trachomatis*; this finding has led to the recommendation that patients treated for gonococcal infection also be treated routinely with a regimen that is effective against uncomplicated genital *C. trachomatis* infection (CDC, 2011).

According to the 2010 CDC guidelines, the initial treatment of choice for gonococcal arthritis or disseminated gonococcal infection (DGI) in adults is ceftriaxone 1 g intramuscularly (IM) or intravenously (IV) every 24 hours (CDC, 2010). Alternatives include cefuroxime 1 g IV every 8 hours and cefotaxime 1 g IV every 8 hours.

Pregnant patients with gonococcal infections should be treated with a recommended cephalosporin or, if they cannot tolerate a cephalosporin, azithromycin 2 g orally (CDC,

2010). Children can be treated with ceftriaxone 25-50 mg/kg/day IV or IM or cefotaxime25 mg/kg IV or IM every 12 hours.

Third-generation cephalosporins such as cefixime and ceftriaxone show negligible cross-allergy with penicillins (Pichichero & Casey, 2007). Recommended treatments for patients giving a history of such hypersensitivity are: Spectinomycin 2g IM as a single dose with Azithromycin 1g oral as a single dose or Azithromycin 2.0g oral as a single dose or Ciprofloxacin 500mg orally as a single dose when the infection is known or anticipated to be quinolone sensitive.

Test-of-cure is the reculturing or isolation and identification of *Neisseria gonorrhoeae* from a site of initial infection to determine whether the patient has been cured following treatment. Post-treatment infections result from reinfection caused by failure of sexual partners to receive treatment, or a new infection due to initiation of sexual activity with a new infected partner.

The treatment should also include the 4C's of STI management: compliance to the full drug course and follow-up; counselling on safer sexual behaviour; proper condom use and contact tracing, partner treatment and notification.

High levels of flouroquinolone resistance among high risk groups have been shown in Kenya. Despite this, fluoroquinolones are still being used as first line therapy for the management of *Neisseria gonorrhoeae* in public health facilities (Lagace-Wiens, et al., 2012).

3.0 STUDY JUSTIFICATION

Sexually transmitted infections (STIs) are a major global cause of acute illness, infertility, long-term disability and death with serious medical and psychological consequences of millions of men, women and infants. Although STIs remain one of the leading causes of the disease burden in Kenya, the focus on HIV/AIDS in the last 10-15 years has overshadowed the predominance of STIs (NASCOP, 2009). The emergence of multiple drug resistant *Neisseria gonorrhoeae* is a major cause of concern especially because of the asymptomatic nature of most cases of the disease. In Kenya, health care facilities use the syndromic management of STIs recommended by the WHO. However, aetiologic surveillance of STIs has not been implemented (NASCOP, 2009). Most of the available data on the prevalence of sexually transmitted infections among women in Kenya have been obtained from studies done among high risk populations like female sex workers and special populations like pregnant women.

Recent baseline data available on the current burden of curable STIs among women in the general population in Kenya is limited. With the KDHS 2008/2009 report showing that 57.3% of female respondents reported their source of modern contraception as public government-sponsored facilities and with the self-reported prevalence of STIs and STI symptoms higher among women than among men, FP clinics are excellent entry points for STI screening and interventions.

This study therefore sought to establish the prevalence of *Trichomonas vaginalis, Chlamydia trachomatis* and *Neisseria gonorrhoeae* among women attending FP clinic and the risk factors for their acquisition.

4.0 RESEARCH QUESTION

What is the prevalence of and risk factors for three (3) curable sexually transmitted infections among women attending the family planning clinic at Kenyatta National Hospital?

5.0 OBJECTIVES

5.1 BROAD OBJECTIVE

To determine the prevalence of and risk factors for three(3) curable sexually transmitted infections among women attending the family planning clinic at Kenyatta National Hospital.

5.2 SPECIFIC OBJECTIVES

1. To determine the prevalence of *Trichomonas vaginalis, Chlamydia trachomatis* and *Neisseria gonorrhoeae* among women attending the family planning clinic at Kenyatta National Hospital.
2. To assess the risk factors associated with acquisition of the three curable STIs.

6.0 METHODOLOGY

6.1 Study Period:

This study was carried out between May and September 2013.

6.2 Study design:

This was a cross-sectional descriptive study involving women attending the FP clinic at KNH.

6.3 Study site

The FP clinic at Kenyatta National Hospital (clinic 66) is open from Monday to Friday between 9.00 A.M and 4.00PM except on public holidays. It has an average attendance of 5 female clients (both new and old clients) per clinic day.

6.4 Study population:

All women between the ages of 18 and 49 years who attended the FP clinic during the study period:-

Inclusion criteria

- Women attending the family planning clinic and were between the ages of 18 and 49 years and who gave their written informed consent to participate in the study.

Exclusion criteria

- Women between the ages of 18 and 49 years but who declined to give a written informed consent to participate in the study.
- Women who may have been treated for an STI in the preceding three (3) weeks.
- Women who may have been on a broad spectrum antimicrobial agent in the preceding three (3) weeks.

6.5 Sampling procedure:

Clients were recruited consecutively until the required number was obtained. All the women who met the inclusion criteria were identified from those attending the FP clinic. After

identification, the potential study participants were taken through the informed consent process whereby the study objectives, risks, benefits and study procedures were explained in English (Appendix 1) or *Kiswahili* (Appendix 3) or translated into a language of the participant's preference by the clinic nurses who were also the research assistants. Only those who agreed to participate by signing the consent form were included in the study.

6.6 Sample size calculation:

The sample size had been estimated using the Fisher's formula (Fisher, 1921).

$$n = \frac{Z^2PQ}{L^2}$$

Where:

n= sample size required for this study

Z= Critical value from standard normal table. For a 95% Confidence Interval, z=1.96

P= expected prevalence or proportion or estimated proportion of *Trichomonas vaginalis, Chlamydia trachomatis* and *Neisseria gonorrhoeae* among women in the general population. This is the prevalence that will be estimated by the study.

According to the WHO estimates of 2008, the prevalence of TV, GC and CT in Africa for women was 20.2%, 2.3% and 2.6% respectively (WHO, 2012). Since each of the three organisms was being screened in each client, the highest prevalence of 20.2% for *Trichomonas vaginalis* was used to calculate the sample size.

Q= 1-P (probability of no event)

L= Error margin or α.

For this study, a specified level of significance of 95%, and an error margin of ±5% was considered acceptable, based on similar studies elsewhere.

Substituting:

$$n = \frac{1.96^2 \times 0.202 \times 0.798}{0.05^2}$$

$$= \mathbf{248}$$

Therefore, **248** was the minimum number of respondents that was required for this cross-sectional study.

6.7 Procedure:

6.7.1 Recruitment and Sample Collection

All women between the ages of 18 and 49 attending the FP clinic during the study period were informed about the study and a written informed consent (Appendix 2) was sought from those who met the inclusion criteria. A trained interviewer then administered a structured questionnaire (Appendix 5) to capture the socio-demographic characteristics, any symptoms of the three curable STIs and risk factors for their acquisition.

Two endocervical samples were then collected from each study participant using sterile swabs by qualified study assistants. The endocervical sample for wet mount microscopy for *Trichomonas vaginalis* and culture for *Neisseria gonorrhoeae* was collected on a dry cotton swab while a second sample for PCR for *Chlamydia trachomatis* was collected and placed in Amies transport media and taken to the microbiology laboratory of the Department of Medical Microbiology, UoN within 15 minutes. The cervical specimen for GC was taken before that of CT since GC is found in the cervical mucus while CT is found in the cervical epithelial cells.

6.7.2 Laboratory procedures

6.7.2.1 *Neisseria gonorrhoeae* culture

The endocervical specimen collected using the dry sterile swab was immediately inoculated onto the selective Thayer Martin Medium (TMM). Inoculation onto Chocolate Blood Agar (CBA) was used as nonselective control for all organisms. These were then incubated at 35^0C in 3-5% CO_2 for 48 hours. The media was then examined at 18-24 hours and at 48 hours for the characteristic colonies of *Neisseria gonorrhoeae* which are pinkish-brown in colour.

6.7.2.2 Wet mount for *Trichomonas vaginalis*

Wet mounts of all swab samples were made in sterile normal saline on clean slides and examined under the low power (10x) and high power (40x) magnifications for *Trichomonas vaginalis*. The slide was then visually examined for trichomonads which were differentiated on the basis of their characteristic jerky movements. This was done not more than 20 minutes after the collection of the sample in the parasitology laboratory, Department of Medical Microbiology, University of Nairobi. The slides were first viewed by the principal investigator and were then reviewed by at least one senior technologist in the parasitology laboratory.

6.7.2.3 PCR for *Chlamydia trachomatis*

DNA extraction was carried out on the endocervical specimen collected in Amies medium according to manufacturer's instructions. The DNA extracts were then frozen at -80^0C until PCR was carried out.

The samples were analyzed by PCR using the GenoQuick© CT PCR kit (Hain Lifescience, Nehren Germany) according to the manufacturer's instructions. This was carried out in the

Molecular Microbiology Laboratory in the Department of Medical Microbiology, University of Nairobi.

An internal control was used in each amplification reaction, such as the positive and negative controls for *Chlamydia trachomatis* included in the kit.

6.8 Quality Assurance Plan

Research assistants were hired and trained among nurses working at the FP clinic. This ensured continuity of care and familiarity.

Specimen collection, labelling, storage and transportation to the laboratory were carried out in accordance to existing standard operating procedures.

Internal and external quality controls of the laboratory procedures were done according to manufacturers' specifications where relevant.

The Principal Investigator in collaboration with trained and highly experienced laboratory technologists handled the entire specimen testing throughout the study period to ensure consistency.

Data quality and safety was ensured at all stages of data collection, entry and analysis.

6.9 Data Management and Analysis

Data collected was entered into an Excel spreadsheet in a password- protected computer. Data analysis was done using Statistical Package for Social Sciences Programme (SPSS) version 17.0. Categorical variables were summarized as frequencies and proportions and continuous discrete variables were summarized as means and medians where appropriate with their measures of dispersion. Chi-squared and Fisher's exact tests were used to determine univariate associations with prevalent *Chlamydia trachomatis* infection.

7.0 Ethical considerations

The study was conducted after approval from the KNH/UON ERC (Appendix 8). Permission to carry out the study in the FP clinic at KNH was also obtained from the Department of Reproductive Health at KNH (Appendix 9). Informed consent was obtained from all the study participants. The participants who were found to be infected were contacted confidentially and were asked to report to the FP clinic where appropriate medication was prescribed. They were also advised to inform their sexual partner(s) about the infection, encouraged to use condoms and to seek screening and treatment at a health institution of their choice.

8.0 RESULTS

261 participants were enrolled in the study during the May to September 2013 study period. Data from 12 participants was excluded from analysis: 2 had not been sexually active for more than 4 years, while 10 were discovered to have used broad-spectrum antimicrobial agents at least 2 weeks prior to the study.

Therefore, data from 249 participants was analysed.

8.1 Demographic characteristics

The mean age of the participants was 36.5 years with majority aged between 35 to 39 years. Only 5.2% of the participants were aged less than 25 years. Majority of the participants were married (84.7%) and 73% had a level of education of secondary school and above. 51% were in self employment while 29.3% were in salaried employment although a majority (44.8%) had a monthly income of less than 10000 shillings.

Table 1: Summary of demographic characteristics

Characteristics	Frequency(%)
Mean age(Mean(SD))	36.5(6.8)
Visit type	
First visit	117(49.2)
Revisit	121(50.8)
Marital status	
Single	28(11.3)
Married	211(84.7)
Widowed	4(1.6)
Separated/divorced	6(2.4)
Level of education	
None	5(2.1)
Primary	62(24.9)
Secondary	93(37.3)

College/University	89(35.7)
Occupation	
Student	6(2.4)
Housewife	31(12.5)
Casual labourer	10(4)
Self employed	127(51)
Salaried	73(29.3)
Unemployed	2(0.8)
Monthly income	
<10,000	111(44.8)
10,000-20,000	69(27.8)
20,001-30,000	22(8.9)
30,001-40,000	25(10.1)
>40,000	21(840

8.2 History of Symptoms

The most commonly reported symptoms were lower abdominal pain and vaginal discharge with a 59.30% and 53.10% positive response rate respectively. Although a significant number of participants (8.6%) reported having had genital ulcers in the preceding three weeks, there was no evidence of this during sample collection. The ulcers could therefore have been caused by Herpes simplex virus-2 which has been reported to be the commonest cause of genital ulcer disease and the symptoms of which resolve in two to three weeks. In the KAIS 2007 report, the prevalence of HSV-2 in women in Kenya was 41.7% (NACC, 2009). The symptoms usually resolve in two to three weeks

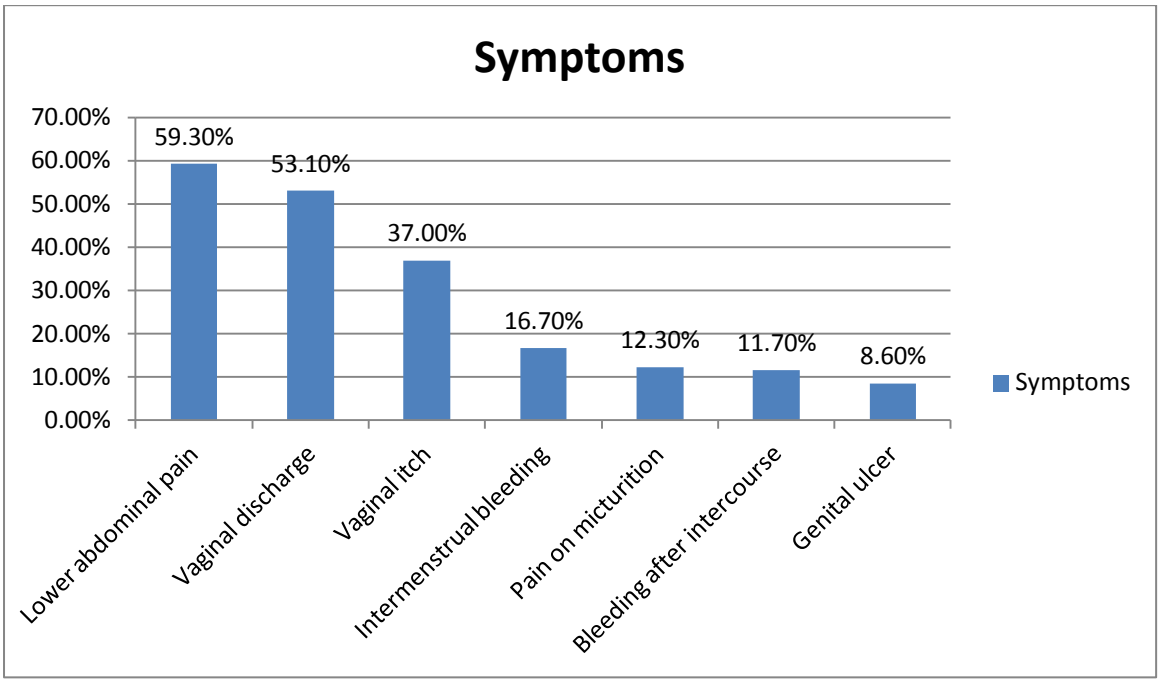

Figure 1: History of symptoms in the preceding three (3) weeks.

8.3 Sexual History

The median age of first sexual intercourse was 20 years with the minimum age being 5 years and the maximum age being 33 years.

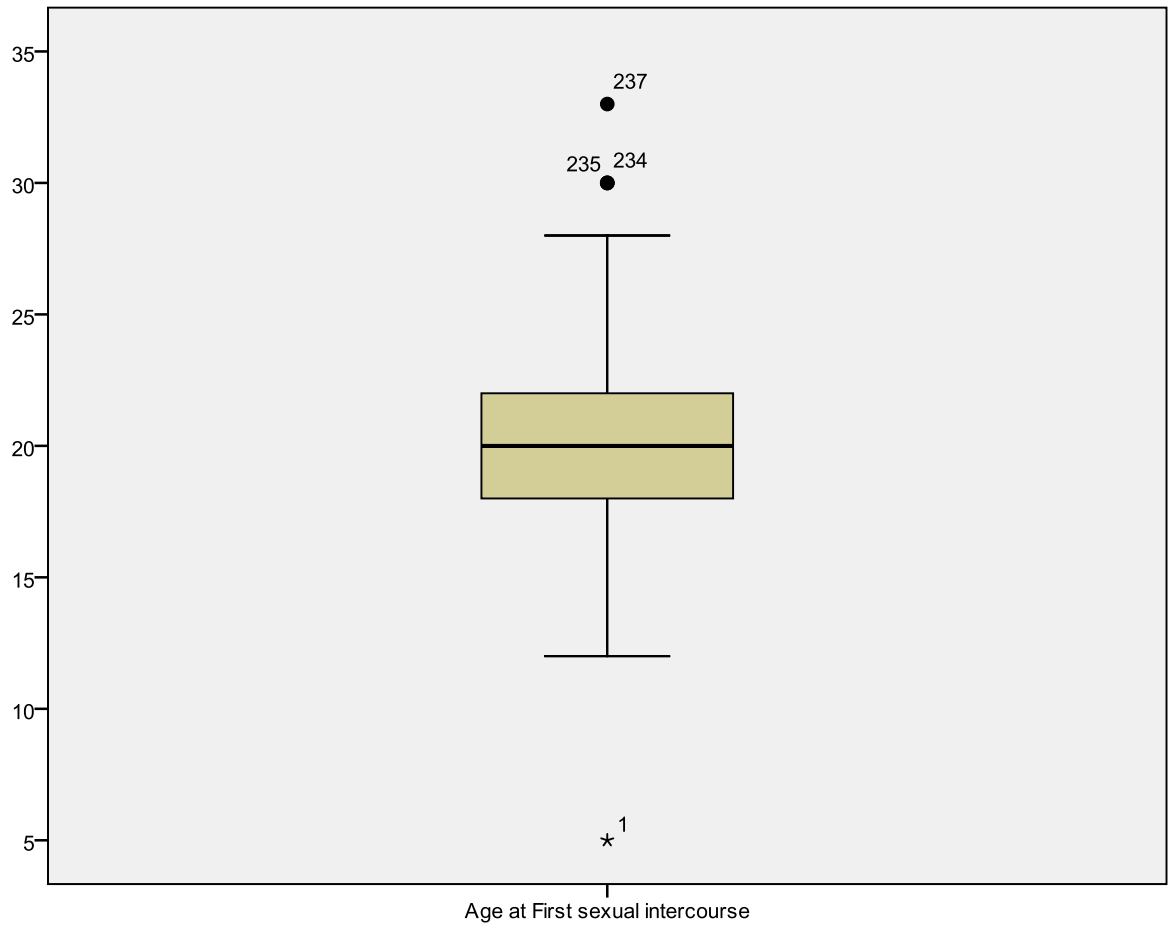

Figure 2: Box plot on the age of coitarche

A majority of the participants (90.8%) had only 1 sexual partner in the preceding 1 year while 4.4% and 0.4% had 2 and 3 sexual partners respectively in the preceding 1 year.

15.3% of participants reported using a condom during their last sex act. Only 10% of participants reported having been treated for STIs in the previous three (3) months.

8.4 Prevalence and Risk Factors for STIs

Of the 249 participants, a total of 33 participants were found to have STIs. *Trichomonas vaginalis* was found in 1/249(0.4%), while *Chlamydia trachomatis* was found in 33/249(13.3%) participants. A coinfection of CT and TV was found in 1/249(0.4%) participant. No participants (0%) were found to have *Neisseria gonorrhoeae.*

A majority 30/33(91%) of *Chlamydia trachomatis* positive participants were married although on further analysis of those currently married and those not currently married, no statistical significance was found(p= 0.59).

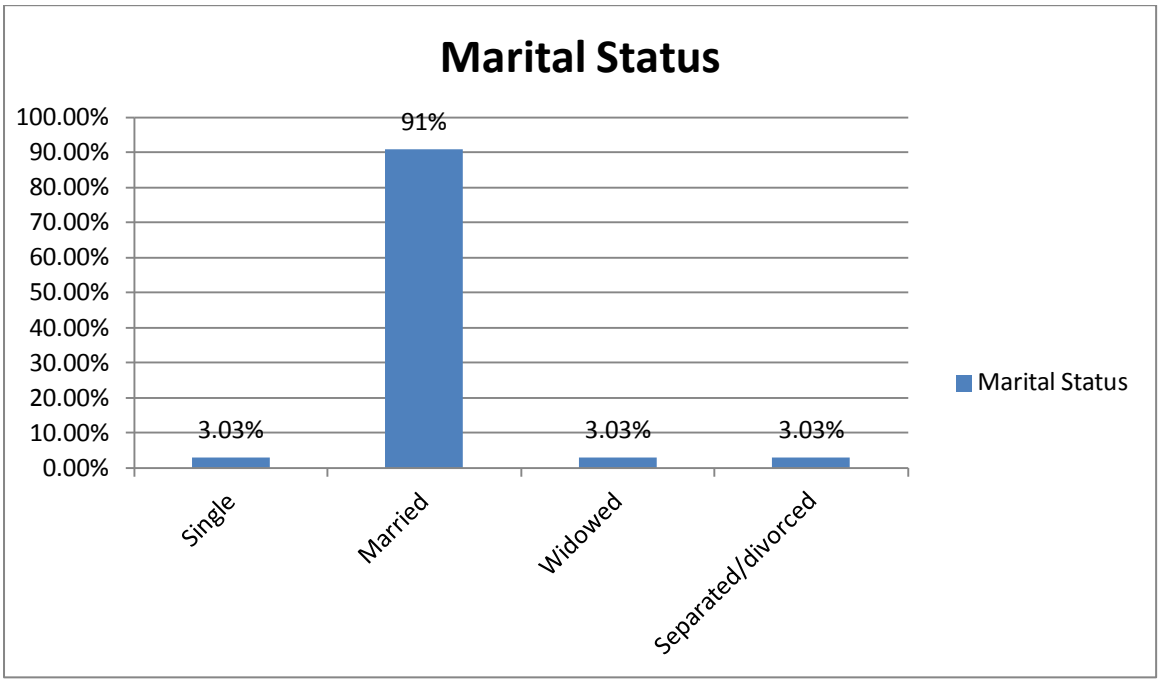

Figure 3: Distribution of *Chlamydia trachomatis* infection by marital status

The frequency of *Chlamydia trachomatis* was highest amongst women aged 35-39 years, 10/33(30.3%), followed by those aged 40-44, 8/33(24.2%) years.

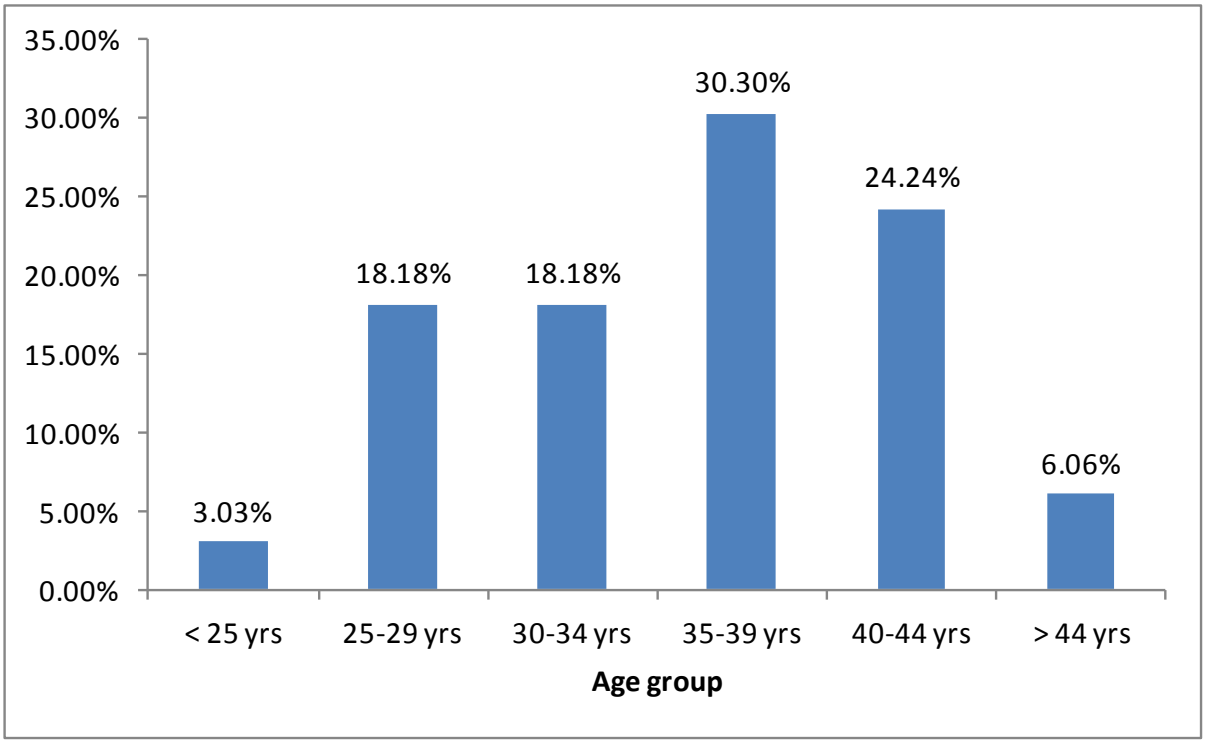

Figure 4: Distribution of *Chlamydia trachomatis* infection by age group

Of those who tested positive for *Chlamydia trachomatis*, a majority (56.3%) were on their initial visit to the FP clinic although this was not statistically significant (p=0.388).

Table 2: Summary of social and demographic characteristics in CT positive participants

	Chlamydia trachomatis		
Characteristics	**Positive**	**Negative**	**P-Value**
Currently Married			
No	4(12.1)	34(15.7)	0.59
Yes	29(87.9)	182(84.3)	
Education			
Primary and below	11(33.3)	56(25.9)	0.371
Above Primary	22(66.7)	160(74.1)	
Occupation			
Paid employment	11(33.3)	72(33.3)	0.904
Self employed	16(48.5)	111(51.4)	
.Unemployed	6(18.2)	33(15.3)	
Monthly income			
<10,000	16(48.5)	95(44.2)	0.176
10,000-20,000	7(21.2)	62(28.8)	
20,001-30,000	6(18.2)	16(7.4)	
30,001-40,000	1(3)	24(11.2)	
>40,000	3(9.1)	18(8.4)	

The most commonly reported symptoms among the participants who tested positive for *Chlamydia trachomatis* were vaginal discharge (36.4%) and lower abdominal pain (33.3%) although none of these was statistically significant. There was however a large proportion of asymptomatic participants who tested positive for CT. 21/33(63.6%) of those who tested positive for CT did not report any vaginal discharge; 22/33(66.7%) had no lower abdominal pain while (25/33)75.8% did not report any vaginal itch.

Table 3: History of symptoms in CT positive participants

	Chlamydia Trachomatis		
Characteristics	**Positive(n=33)**	**Negative(n=216)**	**P-Value**
Vaginal discharge			
No	21(63.6)	142(65.7)	0.813
Yes	12(36.4)	74(34.3)	
Pain on micturition			
No	32(97.0)	197(91.2)	0.488
Yes	1(3.0)	19(8.8)	
Vaginal Itch			
No	25(75.8)	164(75.9)	0.983
Yes	8(24.2)	52(24.1)	
Intermenstrual vaginal bleeding			
No	32(97.0)	190(88.0)	0.223
Yes	1(3.0)	26(12.0)	
Bleeding after Sexual Intercourse			
No	29(87.9)	201(93.1)	0.293
Yes	4(12.1)	15(6.9)	
Genital ulcer			
No	32(97.0)	203(94.0)	0.701
Yes	1(3.0)	13(6.0)	
Lower abdominal pain			
No	22(66.7)	131(60.6)	0.508
Yes	11(33.3)	85(39.4)	

Using the CT PCR used in the current study as the standard, the sensitivity, specificity and positive predictive values (PPV) for the different symptoms was calculated.

Table 4: Sensitivity, specificity and positive predictive value (PPV) of symptoms using CT PCR as the standard

	Sensitivity %	**Specificity %**	**PPV %**
Vaginal discharge	36.40	65.70	14.00
Lower abdominal pain	33.33	60.64	11.50
Vaginal itch	24.24	75.92	13.30
Pain on micturition	3.03	82.87	5
Intermenstrual bleeding	3.03	87.96	3.7
Bleeding after sexual intercourse	12.12	93.05	21.10
Genital ulcer	3.03	93.98	7.10

67.7% had an age of sexual debut of 20 years or less; while 97% had not been treated for STIs in the previous three (3) months. None of these characteristics was statistically significant.

Table 5: Risk factors in CT positive participants

	Chlamydia Trachomatis		
Characteristics	**Positive**	**Negative**	**P-Value**
Age at coitarche			
<= 20 yrs	21(67.7)	139(67.1)	0.948
> 20 yrs	10(32.3)	68(32.9)	
Index or partner treated for STI			
No	32(97.0)	192(88.9)	0.217
Yes	1(3.0)	24(11.1)	
New sexual partner last 3 months			
No	32(97.0)	208(96.3)	0.847
Yes	1(3.0)	8(4.7)	
Number of sexual partners in last 1 year			
No Partner	0	11(5.1)	0.144
1 partner	33(100)	193(89.4)	
2 or more partners	0	12(5.5)	

9.0 DISCUSSION

The prevalence of *Chlamydia trachomatis* (13.3%) found in this study is comparable with that which has been reported in previous published studies from Kenya involving women. A CT prevalence of 12% was found among women using intrauterine contraceptive devices at the KNH FP clinic between 1984 and 1986 (Sinei, et al., 1988); 9% was found among women with complaints of vaginal discharge (Fonck K. , et al., 2000); Kohli *et al*(2013) found a prevalence of 6% among women attending outpatient clinics in Nairobi; 4% was found among HIV-1 infected pregnant women and among women attending an STD referral clinic (Marx, et al., 2010) and (Fonck J. , et al., 2000) respectively. This indicates that the prevalence of *Chlamydia trachomatis* is still significant in the female population and introduction of routine screening procedures at FP clinics would reduce the burden of the disease.

However, the prevalence of 0% and 0.4% for *Neisseria gonorrhoeae* and *Trichomonas vaginalis* respectively is lower than what has been previously published in studies in which similar laboratory procedures were used. Marx *et al*(2010) found a TV prevalence of 16% and a GC prevalence of 2% among HIV-1 infected pregnant women in Nairobi; Fonck *et al*(2000) found a high prevalence of 23% for TV and 7% for GC among women with complaints of vaginal discharge attending an STD referral clinic in Nairobi while Daly *et al*(1994) found a GC prevalence of 3.2% and a TV prevalence of 5.2% among women attending FP clinic in Nairobi. It was not clear why the prevalence of TV in this study was low as most studies have shown that a higher prevalence of TV is found in women above the age of 30 years, which was the age for a majority of participants in this study. The mode of transmission of GC is similar to that of CT and it is not known why no infections were detected. The low GC and TV prevalence could be explained by the fact that molecular methods were used for the detection of CT while GC was detected by culture while TV was

detected by wet mount whose sensitivity varies from 38% to 82% (Madhivanan, et al., 2013) (Nathan, et al., 2013).

All the women that were diagnosed with CT and TV had had only one sexual partner in the preceding one year and only 1/33(3%) had a new sexual partner in the three months prior to the study. These findings therefore suggest that the women were likely to have been infected by their regular partner. This finding further stresses the importance of partner notification, testing and treatment as well as addressing the significant impact of the transmission between partners and the importance of directing prevention campaigns towards reducing this.

The high proportion of asymptomatic participants who tested positive for *Chlamydia trachomatis*(63.6% for vaginal discharge and 66.7% for lower abdominal pain) corroborates findings in other studies and further stresses the importance of the aetiologic approach as opposed to the syndromic approach of managing STIs. However, due to lack of adequate laboratory infrastructure in the country, the WHO syndromic approach for the management of STIs is utilised (Ministry of Health, 2002). The syndromic management approach is based on the identification of consistent groups of symptoms and easily recognised signs and syndromes and the provision of treatment that will deal with the majority of or the most serious organisms responsible for producing a syndrome (WHO, 2003). In the current study, evaluation of the diagnosis accuracy of the most commonly used symptoms in the syndromic approach using the CT PCR as the gold standard was done. The evaluation showed a sensitivity of 36.40% and 33.33%, a specificity of 65.70% and 60.64% and a positive predictive value of 14.00% and 11.50% for vaginal discharge and lower abdominal pain respectively which are the most commonly used symptoms in the syndromic approach of managing STIs. This is comparable with what has been found in other studies: Detels R(2011) found that over 80% of the participants, who were drawn from five countries, were asymptomatic and that the positive predictive value of urethral or vaginal discharge was 58%;

Fonck K. (2000) found that the algorithm in use in Kenya as national policy had a sensitivity of 42% and a specificity of 63% for the detection of *N gonorrhoeae* or *C trachomatis* and thus failed to discriminate between infected and uninfected women. This complicates identification and treatment of infected individuals and it also provides a large pool of asymptomatic transmitters since individuals who have no symptoms are unlikely to seek testing and treatment. The findings from this study therefore lead to the conclusion that the syndromic approach to the management of STIs leads to an underestimation of the proportion of infected individuals, as a large majority tend to be asymptomatic. The aetiologic approach to management for symptomatic patients is therefore recommended in addition to screening in order to detect asymptomatic individuals.

Only 13/249(5.2%) participants were aged between 18 and 24 years. This could be explained by the fact the KNH FP clinic charges for its FP services which could put them out of reach for women in this age group. The study therefore could have missed an age group with a higher burden of infection or more risk factors. The findings therefore cannot easily be generalized to women in Kenya who may have different sociodemographic characteristics and risk factors. A study involving women in the adolescent age group is therefore recommended.

The CDC recommendations for the treatment of *Trichomonas vaginalis* and *Chlamydia trachomatis* were used in treating the infected participants (CDC, 2011). All the infected participants were informed of their results and requested to come to the FP clinic where prescriptions were given to them. They were also advised to disclose to their partners and to help them get screened and treated at a health institution of their choice. Thirty one out of the thirty three infected participants showed up at the clinic for treatment. Two participants showed up with their partners where free screening was offered by the principal investigator.

One participant had received syndromic management before the CT PCR results were released to her. One participant declined medication.

10.0 CONCLUSION

The prevalence of CT is high among women attending the FP clinic at KNH with women between 35 and 39 years being mostly affected. The GC and TV prevalence was however found to be low. Majority of the participants found to have CT were married (30/33, 91%). Only 5.2% of the participants were aged below 25 years and accounted for 3.03% of CT infections. A large proportion of asymptomatic participants (63.6% for vaginal discharge and 66.7% for lower abdominal pain) were CT positive.

11.0 RECOMMENDATIONS

1. There is need for appropriate STI screening services to be introduced in FP clinics.
2. Transmission between regular sexual partners should be addressed when developing STI control programs.
3. Studies to determine the prevalence and the risk factors for STIs among adolescent women (15-24 years) are highly recommended.
4. The syndromic approach to the management of STIs needs to be reviewed as it may no longer be relevant in the face of a large proportion of asymptomatic individuals.

12.0 STUDY LIMITATIONS

The assessment of potential risk factors for acquisition of *Trichomonas vaginalis, Chlamydia trachomatis* and *Neisseria gonorrhoeae* involved asking very confidential information like the number of sexual partners, age at sexual debut and history of STIs. This may have elicited insincere responses from the study participants. Confidentiality was however emphasized during the interviews and these questions were asked last after rapport had been established between the interviewer and the participant.

The fee for service at the KNH FP clinic means that not all women have access to its services especially those in the lower socioeconomic status and this could have introduced some selection bias.

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APPENDIX 1: INFORMATION TO PARTICIPANTS AND CONSENT FORM

CODE OF THE PARTICIPANT: _____

TITLE OF STUDY: Prevalence and risk factors for sexually transmitted diseases among women attending family planning clinic at Kenyatta National Hospital.

Investigator: Dr Anne Njeri Maina

Supervisors: Prof Omu Anzala

: Dr Joshua Kimani

My name is Dr. Anne Njeri Maina and I am a post-graduate student from the University of Nairobi, Kenya. I wish to invite you to take part in this research. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns.

Purpose of the study

In this study we are interested in knowing how many women attending the family planning clinic at Kenyatta National Hospital may be having some sexually transmitted infections and

if there are some things that put one at risk. The sexually transmitted infections that we are interested in are those caused by the bacteria *Neisseria gonorrhoeae* and *Chlamydia trachomatis* and by the protozoan *Trichomonas vaginalis*. These infections are spread through sexual contact, and can also be transmitted from a mother to her baby. This can occur during pregnancy, during delivery and after delivery. The infections in most people especially women, do not show any symptoms but can still be transmitted to others. In women, the infections can lead to consequences such as infertility, chronic lower abdominal pain and infections to newborn babies such as inflammation of the inner lining of the eye.

You are therefore being requested to take part in this study because you are attending the family planning clinic. We have obtained written permission from the National Ethics Committee to conduct this study.

Study procedures

If you agree to take part in this research study, the interviewer will fill a form that will capture your personal details like your age, marital status, and education level. You will be asked further questions to assess if you have had any risk-related events in the past.

Two vaginal swabs will be collected from you. This procedure may cause slight discomfort. Both swabs will be taken to the University of Nairobi department of medical microbiology laboratory for testing for *Trichomonas vaginalis*, *Neisseria gonorrhoeae* and *Chlamydia trachomatis*. In case of a positive result of any of the above, you will be contacted and will be advised on how to get treated for the infection.

Confidentiality

We will not record your name or any identification anywhere in the questionnaire or laboratory form so no one will be able to tell who you are. It will be very confidential. Your form will only show a code that is assigned each participant.

Benefits and Risks

By choosing to participate in this study, you will not have any direct benefits from it other than that of a free test to know your health status. However the information obtained from the study will be useful to the country in general by giving information on the disease status of the people and can be used in planning for screening and management of sexually transmitted infections. Other than the discomfort and pain in obtaining the vaginal swabs, there are no other foreseeable risks that will arise from participating in the study.

Costs and Compensation

By choosing to participate in the study, you will not incur any extra monetary cost. You will however take about thirty minutes longer than your usual clinic visits to go through the study procedures. You will not be paid for taking part in the study.

Voluntary participation.

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you decline to participate you will not be denied any services from this hospital.

Questions

If you have any questions about this study now or later, you may contact the Principal Investigator, Dr Anne Maina on the following phone number **0727490540.**If you have any

questions about your rights as a study participant, you can contact the UON/KNH ethics committee on these contacts:020 2726300 or uonknh_erc@uonbi.ac.ke

APPENDIX 2 **CERTIFICATE OF CONSENT**

* *

I……(participant's name) have had the information on this form read and explained to me. I was free to ask any questions and they have been answered. I am exercising my free power of choice, and hereby give my consent to be included as a participant in this study of '**The prevalence and risk factors for sexually transmitted infections among women attending family planning clinic at Kenyatta National Hospital'.**

Participant

(Name)_____(Signature)_____Date:___/___/2013

Research assistant

(Name)_____(Signature)_____Date:___/___/2013

APPENDIX 3: HABARI KWA WASHIRIKI NA FOMU YA KIBALI

CODE OF THE PARTICIPANT: _____

TITLE OF STUDY: Prevalence and risk factors for sexually transmitted diseases among women attending family planning clinic at Kenyatta National Hospital.

Mpelelezi: Dr Maina Anne Njeri

Wasimamizi: Prof OmuAnzala

: Dr Joshua Kimani

Jina langu ni Dr. Anne Njeri Maina kutoka chuo kikuu cha Nairobi, na ningependa kuuliza ushiriki wako katika utafiti nitakaoufanya. Maelezo katika karatasi hii ni ya kukusaidia kukata shauri kama utashiriki au la. Unao uhuru wa kuuliza swali lolote kuhusu utafiti huu.

Katika utafiti huu, tungependa kujua ni akina mama wangapi wanao hudhuria hii kliniki ya upangaji wa uzazi kwa mara ya kwanza wana magonjwa ya zinaa na kama kuna tabia ambazo zinaweza kuongeza hatari ya kuambukizwa magonjwa haya.

Yale magonjwa ya zinaa ambayo tutaangalia ni pamoja na kisonono(gonorrhoea), ugonjwa wa Chlamydia na ugonjwa wa trichomoniasis. Haya magonjwa yanaambukizanwa wakati wa kushiriki ngono na pia kutoka kwa mama mjamzito kwa mtoto ambaye hajazaliwa wakati wa mimba, kuzaliwa au baada ya kuzaliwa.

Haya magonjwa ya zinaa, zaidi katika wanawake, hayaonyeshi dalili zozote, lakini bado yanaweza kuambukiza wengine. Katika wanawake, yanaweza leta madhara kama utasa, uchungu katika sehemu ya chini ya tumbo na pia magonjwa katika watoto waliozaliwa kama magonjwa ya macho.

Tungependa kukualika kushiriki katika utafiti huu kwa sababu unahudhuria hii kliniki. Kibali cha kufanya utafiti huu kimepeanwa na shirika la University of Nairobi/Kenyatta National Hospital Ethics Committee.

Taratibu ya utafiti

Kama utakubali kushiriki katika huu utafiti, mtafiti atajaza fomu ambayo itaelezea maelezo binafsi kama vile umri, hadhi ya ndoa, kiwango cha elimu na vinginevyo. Vilevile, utaulizwa maswali mengine ili kutathmini kama umekuwa na matukio ambayo yanaweza ongeza hatari ya kuambukizwa magonjwa ya zinaa.

'Swabs' mbili zitachukuliwa kutoka kwa njia ya uzazi. Hii inaweza leta usumbufu kidogo. 'Swab'zote zitapelekwa katika maabara ya chuo kikuu cha Nairobi kufanyiwa uchunguzi wa *Trichomonas vaginalis, Neisseria gonorrhoeae* na *Chlamydia trachomatis*. Ikiwa utapatikana na mmoja ya haya magonjwa, tutawasiliana na wewe na utapewa ushauri kuhusu jinsi unaweza pata matibabu.

USIRI

Jina lako ama jinsi yoyote ya kukutambulisha hazitatumika kokote katika dodoso/fomu, kwa hivyo hakuna mtu yeyote ambaye ataweza kukutambua. Taarifa zote ambazo utatupatia ni siri. Fomu yako itaonyesha tu nambari ambayo kila mshiriki anapatiwa.

Faida na Hatari

Unapokubali kushiriki katika utafiti huu, hakuna faida ya kuelekeza ambayo utaipata, isipokuwa kupata uchunguzi wa bure wa kujua hali yako ya afya. Habari ambazo tutazipata

kutoka kwa utafiti huu utasaidia nchi kujua hali ya afya ya wanawake kwa jumla na inaweza kusaidia kupanga jinsi ya kuwapima wanawake wanapoenda kliniki ya upangaji wa uzazi.

Mbali na uchungu kidogo utakaosikia wakati wa kuchukua 'swab', hakuna madhara mengine ambayo yanatarajiwa kupatikana kutokana na kushiriki utafiti huu.

Gharama na Fidia

Unapokubali kushiriki katika utafiti huu, hakuna gharama yoyote ambayo itakupata.Lakini inaweza kukugharimu kati ya dakika thelathini ama saa moja zaidi ya masaa ya kawaida ya kliniki.Hakuna fidia utakayopata kwa kukubali kushiriki kwa utafiti huu.

HiariyaUshiriki

Ushiriki wako ni kwa hiari kabisa na pia unayo haki ya kujitoa katika utafiti huu wakati wowote ule utakapojisikia kufanya hivyo.Uamuzi wako wa kushiriki ama la katika utafiti huu,

Hauta adhiri hata kidogo haki yako kama mgojwa ya kupata huduma natiba.

Nitafurahi ukikubali kushiriki katika utafiti huu.

Maswali/Mawasiliano

Kama una swali lolote juu ya utafiti huu unatakiwa uwasiliane na mtafit imkuu, Dr.Anne Njeri Maina Namba-**0727490540**.Chuo kikuu cha Nairobi.

Ikiwa una swali lolote juu ya haki zako kama mshiriki katika utafiti huu, unaweza wasiliana na KNH/UON ethics committee namba- 020 2726300 amauonknh_erc@uonbi.ac.ke.

APPENDIX 4: CERTIFICATE OF CONSENT (**SWAHILI VERSION**)

* *

Mimi _____

Nimeelewa maelezo yaliyoandikwa hapo juu na kuridhika na maelezo niliyopewa kwa maswali yangu yote. Mimi kwa hiari yangu mwenyewe, bila kushurutishwa na mtu, ninakubali kushiriki kwenye utafiti huu.

Sahihi ya mgonjwa:_____Tarehe:_____

Jina la shahidi _____Tarehe:_____

Sahihi ya shahidi _____

APPENDIX 5: **STUDY QUESTIONNAIRE**

STUDY TITLE: Prevalence and risk factors for sexually transmitted infections among women attending the family planning clinic at Kenyatta National Hospital.

DATE OF INTERVIEW _____/_____/2013

CODE OF THE PARTICIPANT: _____

VISIT TYPE: FIRST VISIT REVISIT

SECTION A: SOCIODEMOGRAPHIC CHARACTERISTICS

1. Date of birth ____/____/_____(**Tarehe ya kuzaliwa**)
2. Age of patient (**Miaka**)
3. Where do you live? (**Unaishi wapi**?)

   County (**Jimbo**)_____Village/Estate(**Kijiji**) _____
4. Marital Status: (**Hadhi ya ndoa**)

   Put a tick ( )or a cross(×) in the appropriate box(Weka alama kwenye sanduku lifaalo)

[1]Single **Sijaolewa**

[2]Married **Nimeolewa.**

[3Widowed **Mjane**

[4]Separated/Divorced **Utengano/Talaka**

5. Level of education.(**Kiwango cha elimu**.)

Put a tick ( ) or a cross (×) in the appropriate box (Weka alama kwenye sanduku lifaalo)

[1]None **Hakuna**

[2]Primary school **Shule ya msingi**

[3]Secondary school **Shule ya upili**

[4]College/university **Chuo/Chuo kikuu**

6. Occupation (**Kazi uifanyayo**)?

[1] Student **Mwanafunzi**

[2] Housewife **Mke nyumbani**

[3]Casual labourer **Kibarua**

[4]Self employed **Kujiajiri kibinafsi**

[5]Salaried employment **Kazi ya kuajiriwa**

[6]Unemployed **Sijaajiriwa**

7. Personal income per month(**Kiwango cha mshahara kwa mwezi**)

   [1] <10,000(**Chini ya 10,000**)

   [2]10,000-20,000(**Kati ya 10,000 na 20,000**)

   [3]20,000-30,000(**Kati ya 20,000 na 30,000**)

   [4]30,000-40,000(**Kati ya 30,000 na 40,000**)

   [5]>40,000(**Zaidi ya 40,000**)

SECTION B: HISTORY OF SYMPTOMS

8. Have you had any of the following symptoms in the last three (3) weeks? (**Je, umepata dalili zozote kati ya zifuatazo katika wiki tatu (3) zilizopita**?)

   1) Vaginal discharge (**kutoka uchafu katika sehemu za siri**)

      Yes (**Ndio**) No (**Apana**)

   2) Pain on passing urine (**uchungu wakati wa kukojoa**)

      Yes (**Ndio**) No (**Apana**)

   3) Vaginal itch(**kujikuna sehemu za siri**)

      Yes (**Ndio**) No (**Apana**)

   4) Intermenstrual vaginal bleeding((**kutoka damu ya mwezi kabla ya wakati wa mwezi**)

Yes (**Ndio**) No (**Apana**)

5) Bleeding after sexual intercourse(**kutoka damu baada ya kushiriki ngono**)

Yes (**Ndio**) No (**Apana**)

6) Genital ulcer(**Kidonda katika sehemu za siri**)

Yes (**Ndio**) No (**Apana**)

7) Lower abdominal pain(**uchungu katika pande ya chini ya tumbo**)

Yes (**Ndio**) No (**Apana**)

SECTION C: SEXUAL HISTORY

9. At what age did you have your first sexual intercourse? (**Ulikuwa na umri wa miaka mingapi wakati uliposhiriki ngono kwa mara ya kwanza**?)

10. Have you had a new sexual partner in the last three (3) months? **(Je, umekuwa na mpenzi mpya ambaye umeshiriki naye ngono katika miezi mitatu (3) iliopita**?)

YES NDIO

NO APANA

11. How many sexual partners have you had in the past one year (**Je,umeshiriki ngono na watu wangapi katika mwaka mmoja uliopita**?)

0	3
1	4
2	>4

12. Did you use a condom during your last sexual intercourse? (**Je, ulitumia mpira wakati wako wa mwisho kushiriki ngono**?)

YES	NDIO
NO	APANA

13. Have you or your sexual partner(s) been treated for a sexually transmitted infection (STI) in the last three (3) months (**Je,kuna mmoja wenu kati yako na mpenzi/wapenzi wako ambaye ametibiwa ugonjwa wa zinaa katika miezi mitatu iliyopita**?)

YES	NDIO
NO	APANA

APPENDIX 6: STUDY QUESTIONNAIRE CODEBOOK

STUDY TITLE: Prevalence and risk factors for sexually transmitted infections among women attending the family planning clinic at Kenyatta National Hospital.

DATE OF INTERVIEW _____/_____/2013

CODE OF THE PARTICIPANT: _____

VISIT TYPE: FIRST VISIT =1 REVISIT =2

SECTION A: SOCIODEMOGRAPHIC CHARACTERISTICS

1. Date of birth ____/____/_____(**Tarehe ya kuzaliwa**)
2. Age of patient (**Miaka**)
3. Where do you live? (**Unaishi wapi**?)

   County (**Jimbo**)_____Village/Estate(**Kijiji**) _____
4. Marital Status: (**Hadhi ya ndoa**)

   Put a tick ( )or a cross(×) in the appropriate box(Weka alama kwenye sanduku lifaalo)

   [1]Single =1 **Sijaolewa**

   [2]Married =2 **Nimeolewa.**

   [3Widowed =3 **Mjane**

[4]Separated/Divorced =4 **Utengano/Talaka**

5. Level of education.(**Kiwango cha elimu**.)

Put a tick ( ) or a cross (×) in the appropriate box (Weka alama kwenye sanduku lifaalo)

[1]None =1 **Hakuna**

[2]Primary school =2 **Shule ya msingi**

[3]Secondary school =3 **Shule ya upili**

[4]College/university =4 **Chuo/Chuo kikuu**

6. Occupation (**Kazi uifanyayo**)?

[1] Student =1 **Mwanafunzi**

[2] Housewife =2 **Mke nyumbani**

[3]Casual labourer =3 **Kibarua**

[4]Self employed =4 **Kujiajiri kibinafsi**

[5]Salaried employment =5 **Kazi ya kuajiriwa**

[6]Unemployed =6 **Sijaajiriwa**

7. Personal income per month(**Kiwango cha mshahara kwa mwezi**)11

[1] <10,000(**Chini ya 10,000**) =1

[2]10,000-20,000(**Kati ya 10,000 na 20,000**) =2

[3]20,000-30,000(**Kati ya 20,000 na 30,000**) =3

[4]30,000-40,000(**Kati ya 30,000 na 40,000**) =4

[5]>40,000(**Zaidi ya 40,000**) =5

SECTION B: HISTORY OF SYMPTOMS

8. Have you had any of the following symptoms in the last three (3) weeks? (**Je, umepata dalili zozote kati ya zifuatazo katika wiki tatu (3) zilizopita**?)

8) Vaginal discharge (**kutoka uchafu katika sehemu za siri**)

Yes (**Ndio**) =1 No (**Apana**) =0

9) Pain on passing urine (**uchungu wakati wa kukojoa**)

Yes (**Ndio**) =1 No (**Apana**) =0

10) Vaginal itch(**kujikuna sehemu za siri**)

Yes (**Ndio**) =1 No (**Apana**) =0

11) Intermenstrual vaginal bleeding((**kutoka damu ya mwezi kabla ya wakati wa mwezi**)

Yes (**Ndio**) =1 No (**Apana**) =0

12) Bleeding after sexual intercourse(**kutoka damu baada ya kushiriki ngono**)

Yes (**Ndio**) =1 No (**Apana**) =0

13) Genital ulcer(**Kidonda katika sehemu za siri**)

Yes (**Ndio**) =1 No (**Apana**) =0

14) Lower abdominal pain(**uchungu katika pande ya chini ya tumbo**)

Yes (**Ndio**) =1 No (**Apana**) =0

SECTION C: SEXUAL HISTORY

9. At what age did you have your first sexual intercourse? (**Ulikuwa na umri wa miaka mingapi wakati uliposhiriki ngono kwa mara ya kwanza**?)

10. Have you had a new sexual partner in the last three (3) months? **(Je, umekuwa na mpenzi mpya ambaye umeshiriki naye ngono katika miezi mitatu (3) iliopita**?)

YES =1 NDIO

NO =0 APANA

11. How many sexual partners have you had in the past one year (**Je,umeshiriki ngono na watu wangapi katika mwaka mmoja uliopita**?)

0 =1

1 =2

2 =3

3 =4

4 =5

>4 =6

12. Did you use a condom during your last sexual intercourse? (**Je, ulitumia mpira wakati wako wa mwisho kushiriki ngono**?)

YES =1 NDIO

NO =0 APANA

13. Have you or your sexual partner(s) been treated for a sexually transmitted infection (STI) in the last three (3) months (**Je,kuna mmoja wenu kati yako na mpenzi/wapenzi wako ambaye ametibiwa ugonjwa wa zinaa katika miezi mitatu iliyopita**?)

YES =1 NDIO

NO =0 APANA

APPENDIX 7: LABORATORY REPORT FORM

Study Title: Prevalence and risk factors for sexually transmitted infections among women attending the family planning clinic at Kenyatta National Hospital.

TEST: Wet mount for *Trichomonas vaginalis*, culture for *Neisseria gonorrhoeae* and PCR for *Chlamydia trachomatis*

Code of Participant

RESULTS:

1. *Trichomonas vaginalis* present

   Yes =1 No =0

2. Growth of *Neisseria gonorrhoeae* obtained

   Yes =1 No =0

3. *Chlamydia trachomatis* present

   Yes =1 No =0

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
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Ref: KNH-ERC/A/96

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Website: www.uonbi.ac.ke
Link:www.uonbi.ac.ke/activities/KNHUoN

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

21st April 2013

Dr. Anne Njeri Maina
Dept.of Medical Microbiology
School of Medicine
University of Nairobi

Dear Dr. Maina

Research proposal: Prevalence and risk factors for Sexually Transmitted Infections among Women attending Family Planning Clinic at Kenyatta National Hospital (P23/01/2013)

This is to inform you that the KNH/UoN Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above revised proposal. The approval periods are 21st April 2013 to 20th April 2014.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

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

Protect to Discover

Yours sincerely

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

c.c. Prof. A.N. Guantai, Chairperson, KNH/UoN-ERC
The Deputy Director CS, KNH
The Principal, College of Health Sciences, UoN
The Dean, School of Medicine,UoN
The Chairman, Dept. of Medical Microbiology, UoN
The HOD, Records KNH
Supervisors: Prof. Omu Anzala,Dept of Med Microbiology, UoN
Dr. Joshua Kimani, Clinical Director at KACP

KENYATTA NATIONAL HOSPITAL,
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KNH/RH/16/VOL.1 DATE: 21st May, 2013

To

In-charge of
Clinic 66
KNH

RE: RESEARCH PROPOSAL : PREVALENCE AND RISK FACTORS FOR STI AMONG WOMEN ATTENDING FP CLINIC AT KNH

This is to inform you that the above study which will be conducted by Dr. Anne Njeri Maina has been approved and kindly facilitate the implementation of the study. The study was also approved by KNH-UON ERC.

Dr. J. Ong'ech
ASSISTANT DIRECTOR
REPRODUCTIVE HEALH