PREVALENCE OF NEISSERIA GONORRHOEAE AND CHLAMYDIA TRACHOMATIS AND ANTIBIOTIC SUSCEPTIBILITY PATTERNS AMONG FAMILY PLANNING CLIENTS AT KENYATTA NATIONAL HOSPITAL, REPRODUCTIVE HEALTH CLINIC.

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2016

DECLARATION

This dissertation is my original work and has not been presented for academic award in any other university. References to work done by others have been clearly indicated.

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ACKNOWLEDGEMENT

I would like to express my sincere and heartfelt appreciation to my supervisors; Prof. J. G. Karanja for his steadfast supervision and to Dr. Lubano Kizito for his guidance, critique, persistent encouragement and patience; without which this work would not have reached fruition.

I would like to thank all the nurses in the reproductive health clinic (clinic 66) for their co-operation and help during the infancy of this study.

I would like to thank Mr. Juma of the University of Nairobi and Magdalene for their steadfast support and help with the microbiological aspects of this study.

I would also like to thank Dr. Phillip Ayieko for the statistical input in this study and Mr. Patrick Irungu for his IT support during the write up of this study.

DEDICATION

To my parents who have stood by me during my medical career thus far. To my wife Sandra, my daughter Jasmine and my son Russel for their support, understanding and constant encouragement.

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LIST OF ABBREVIATIONS

AIDS	-	Acquired Immunodeficiency Syndrome
CDC	-	Centre for Disease Control
CT	-	Chlamydia trachomatis
DGI	-	Disseminated gonococcal infection
DALYS	-	Disability adjusted life years
ED	-	Emergency Department
HIV	-	Human Immunodeficiency Virus
HPV	-	Human Papilloma Virus
KDHS	-	Kenya Demographic Health Survey
KNH	-	Kenyatta National Hospital
LGV	-	Lymphogranuloma venereum
MoH	-	Ministry of Health
NG	-	Neisseria gonorrhoeae
PID	-	Pelvic Inflammatory Disease
STD	-	Sexually Transmitted Diseases
STI's	-	Sexually Transmitted Infections
WHO	-	World Health Organization

ABSTRACT

Background.

Sexually transmitted infections are common among women of the reproductive age in Kenya (Chlamydia, gonorrhoeae, syphilis, and trichomoniasis). We do not routinely screen for these infections. Despite their public health importance, the focus on HIV/AIDS in the last 10-15 years has overshadowed the importance of STIs. The burden of disease in Kenya has not been ascertained yet the numerous sequelae of these infections (P.I.D, infertility, abortions, prematurity, opthalmia neonatorum) are evident. To compound the problem, drug resistance patterns are rapidly changing. This study will ascertain both the disease burden/magnitude and the current drug resistance patterns in our setting and in so doing determine effective treatment modalities.

Objective.

To determine the prevalence of gonococcal and Chlamydia infection among women attending the reproductive health clinic (clinic 66) at Kenyatta National Hospital and also elucidate on the current drug sensitivity patterns in the sample population.

Methodology.

This was a cross-sectional study. The study was carried out between January 2015 and March 2015 in the reproductive health clinic (clinic 66) situated at the Kenyatta National Hospital. An interviewer administered questionnaire was used to gather socio-demographic data and to determine risk factors from all eligible women. Two endo-cervical swabs were collected from each participant and used to screen for N. gonorrhoeae using gram stain and culture technique and to conduct NAAT for C. Trachomatis.

Results.

197 women attending the reproductive health clinic in KNH consented to participate in the study. The prevalence of N. gonorrhoeae was 8% while that of C. trachomatis was 2%. A majority of participants found to have C. trachomatis (50%) and N. gonorrhoeae (37%) were aged between 30-39 years. Majority of the participants found to have C. trachomatis were single (3/4, 75%) while those with N. gonorrhoeae were married (14/16, 87%). All participants who tested positive for C. trachomatis and N. gonorrhoeae were asymptomatic (100% for abdominal pain and 100% for per vaginal discharge). Resistance to routinely used antibiotics was noted and this is a cause of great concern.

Conclusion.

A significant proportion of women with Chlamydia trachomatis was identified among women attending the reproductive health clinic at Kenyatta National Hospital majority of whom were single. The prevalence of Neisseria gonorrhoeae was also found to be high. Majority of the patients were asymptomatic. The study reinforces the need to move away from syndromic approach for management of STIs and implement routine point of screening for STIs among FP clinic attendants and to increase preventive measures among. Regular antibiotic updates are required and a National programme on the rationale use of antibiotics is required.

Recommendations.

1. There is need for point of care STI screening services to be introduced in FP clinics.
2. Antibiotic sensitivity monitoring for STIs should be instituted.
3. A National policy on the rational use of antibiotics for the management of STIs should be formulated.

INTRODUCTION.

STIs remain one of the leading disease burdens in Kenya. Globally, there are about 340 million new cases of curable sexually transmitted infections (Chlamydia, gonorrhoeae, syphilis, and trichomoniasis) each year. The largest proportion occur in South and South East Asia followed by sub-Saharan Africa, Latin America and the Caribbean.

Global estimated incidence of gonorrhoeae is 62 million infected people annually. The World Health Organization estimates that 1% of the world's population has Neisseria gonorrhoeae, one of the most common sexually transmitted diseases. A vaccine against the gonococcus seems quite a distance away and not in the short-term future. Chlamydia trachomatis infections are the most common bacterial STIs worldwide. In 1999 WHO estimated that there were 92 million new cases worldwide and the incidence of infection has continued to increase each year in both developed and developing countries.

STIs have been shown to increase vulnerability to HIV infection. There are about 30 million people living with HIV infection, two thirds of who live in sub-Saharan Africa. The presence of untreated STIs (both those which cause ulcers and those which do not) increase the risk of both acquisition and transmission of HIV by a factor of up to 10. Prompt treatment for STIs is thus important to reduce the risk of HIV infection. Controlling STIs is important for preventing HIV infection, particularly in people with high-risk sexual behavior. Grosskurth and colleagues conducted the first cluster randomized population-based trial in Mwanza, United Republic of Tanzania, from 1991 to 1994, providing improved routine health-care services for syndromic management of people with symptoms of STIs. They found that the incidence of HIV infection two years later was 42% lower in villages receiving the intervention compared with those that did not.

The highest rates of sexual infections occur in the 20-24 year olds followed by the 15-19 year olds. Many STIs are entirely attributable to unsafe sex. Disease burden linked to unsafe sex amounted, in 2004, to 70 million disability-adjusted life years (DALYs) worldwide, of which 52 million were accounted for by developing countries. Strategies to control STIs, such as abstinence, screening programs and condoms have had limited success. Vaccines are an attractive addition to the STI prevention tools as they could provide durable protection and offer the additional advantage of potential protection of the non-immunized through the induction of herd immunity. With the exception of the Human Papilloma virus (HPV) vaccine, much work remains to be done on vaccines on the prevalent STIs.

Untreated gonococcal and Chlamydia infections in females will result in PID in 40% of cases, and one in four of such cases will result in infertility. Because of the common route of transmission through sexual networks, interventions against STIs need to be targeted to whole populations. Untreated STIs are associated with congenital and perinatal infections in neonates, particularly in regions where rates of infection remain high. Up to 35% of pregnancies among women with untreated gonococcal infection result in spontaneous abortions and premature deliveries, and up to 10% in perinatal deaths. In the absence of prophylaxis, 30 - 50% of infants born to mothers with untreated gonorrhoeae and up to 30% of infants born to mothers with untreated Chlamydia infection will develop a serious eye infection (opthalmia neonatorum), which can lead to blindness if not treated early. Worldwide, 1000 - 4000 newborn babies become blind every year because of this condition.

In view of the numerous sequelae of N. gonorrhoeae and C. trachomatis, the objective of this study was to determine the prevalence of gonococcal and Chlamydia infection among women attending the reproductive health clinic (clinic 66) at Kenyatta National Hospital which caters for the urban poor populace in Nairobi.

LITERATURE REVIEW

Gonorrhoeae was one of the first infections to be treated with penicillin in the 1940's and was the most common STD worldwide for at least most of the 20th century. It has been 5 years since fluoroquinolones such as ciprofloxacin have been no longer recommended for the treatment of gonococcal infections because of rapidly rising rates of resistance.

Numerous reports have shown reduced trends in susceptibility testing to not only ceftriaxone but also the oral alternatives, such as cefixime, in a number of countries. Two recent reports are especially disturbing. A report from Japan last year commented on high levels of ceftriaxone and cefixime resistance, rendering both drugs unusable. More recently, Unemo and colleagues reported that a second and different strain was detected in Europe, with high levels of resistance that seem to be due to novel altered penicillin-binding proteins. Starting from the late 1970s and early 1980s, the incidence of gonorrhea had decreased sharply, and by an order of magnitude, in the USA and Canada. Between 20% and 60% of patients infected with Neisseria gonorrhoeae are also infected with Chlamydia trachomatis. Since the cost of therapy for C. trachomatis is less than the cost of testing for the presence of this infection, the US Centers for Disease Control and Prevention (CDC) recommend treating gonococcal infections with dual therapy, including presumptive therapy for uncomplicated Chlamydia infection. In areas where co-infection rates are low, clinicians may prefer to test for Chlamydia infection, although presumptive treatment is still recommended for patients who may not return for follow-up treatment.

Penicillin continues to be used for treatment of gonorrhoeae in most countries which have a low incidence of penicillinase producing Neisseria gonorrhoeae (PPNG). However for women who are sensitive to penicillin or who are infected with PPNG, there is uncertainty as to what is the most effective antibiotic therapy.

The risk of transmission of N. gonorrhoeae from an infected woman to the urethra of her male partner is approximately 20% per episode of vaginal intercourse and rises to 60-80% after 4 or more exposures. In contrast, the risk of male-to-female transmission approximates 50-70% per contact, with little evidence of increased risk with more sexual exposures.

An estimated 200 million new cases of gonorrhoeae occur annually. In 1999, the number of new cases of gonococcal infection diagnosed in North America was 1.56 million, 1.11 million in Western Europe, 27.2 million in South and Southeast Asia and 7.27 million in Latin America and the Caribbean. Gonococcal infection is still the second most common notifiable disease in the United States. Western European rates approximate those in the United States and although the frequency data are unknown in most developing nations, these countries are considered to have the highest rates of gonorrhoeae and its complications. Gonococcal infection rates in pregnant women in the Central African Republic and South Africa were found to be 3.1% and 7.8%, respectively.

In Kenya, a study done between 1989 -1991 showed a prevalence rate of N. gonorrhoeae of 3.2% among women attending family planning clinics in Nairobi, Kenya (C. C. Daly et al). In another study carried out in 1985 among infants with opthalmia neonatorum in Nairobi, Neisseria gonorrhoeae was recovered from 43%, Chlamydia trachomatis from 13%, and both microorganisms from 4% (Lieve Fransen et al).

All sexually active populations are at risk for gonococcal infection, and the level of risk rises with the number of sexual partners and the presence of other STDs. Although race has no intrinsic effect on susceptibility to gonorrhoeae, the frequency of gonorrhoeae in the United States is increased among urban dwellers, individuals of lower socio-economic status and minorities of any population.

This may be due to decreased access to diagnosis and treatment, lack of adequate care (i.e. education, diagnosis, and treatment) leading to increased transmission rates, and/or reflection bias due to data collection site preference (e.g. urban emergency departments [EDs] and STD clinics), as well as true differences in prevalence.

Overall, the African American-to-white Caucasian ratio of gonococcal infections declined from 23:1 in 2002 to 18:1 in 2006. Infection rates have been trending downward since 1998. However, between 2005 and 2006, the CDC noted a 6.3% increase in the rate of gonococcal infections in African Americans. Subsequently, rates have begun to downtrend once again. The male-to-female ratio for gonorrhoeae is approximately 1:1.2. However, females may be asymptomatic, whereas males are rarely asymptomatic. Women younger than 25 years are at the highest risk for gonococcal infection.

Homosexuals (men who have sex with men) are much more likely to acquire and carry gonorrhoeae and have far higher rates of antibiotic-resistant bacteria. Serious sequelae are much more common in women, in whom pelvic inflammatory disease (PID) may lead to ectopic pregnancy or infertility and in whom disseminated gonococcal infection (DGI) is more likely, owing to menstruation, pregnancy, and a higher incidence in occult infection. Scientists have reported finding a strain of gonorrhoeae in Japan in 2008 that was resistant to all recommended antibiotics and have warned that it could transform a once easily treatable infection into a global health threat/pandemic. The emergence of drug-resistant strains of gonorrhoeae is caused by unregulated access to and overuse of antibiotics. An added problem with gonorrhoeae is that its strains tend to retain their genetic resistance to previous antibiotics even after their use has been discontinued.

In the outpatient setting, patients with clinical presentation suggestive of gonorrhoeae, should have specimens from likely sites of infection sent to the laboratory to be cultured for N. gonorrhoeae and Chlamydia species. Nucleic acid amplification tests (NAATs) may be used in addition to or in place of culture depending on availability and laboratory preferences. The possibility of other sexually transmitted diseases (STDs) should be evaluated. For example, 10 - 40% of women with untreated Chlamydia infection develop symptomatic pelvic inflammatory disease. Post-infection tubal damage is responsible for 30 - 40% of cases of female infertility. Furthermore, women who have had pelvic inflammatory disease are 6 - 10 times more likely to develop an ectopic (tubal) pregnancy than those who have not, and 40 - 50% of ectopic pregnancies can be attributed to previous pelvic inflammatory disease.

Untreated STIs are associated with congenital and perinatal infections in neonates, particularly in regions where rates of infection remain high. In pregnant women with untreated early syphilis, 25% of pregnancies result in stillbirth and 14% in neonatal death i.e. an overall perinatal mortality of about 40%.

Up to 35% of pregnancies among women with untreated gonococcal infection result in spontaneous abortions and premature deliveries, and up to 10% in perinatal deaths. In the absence of prophylaxis, 30 - 50% of infants born to mothers with untreated gonorrhoeae and up to 30% of infants born to mothers with untreated Chlamydia infection will develop a serious eye infection (opthalmia neonatorum), which can lead to blindness if not treated early. Worldwide, 1000 - 4000 newborn babies become blind every year because of this condition.

The presence of untreated STIs (both those which cause ulcers and those which do not) increase the risk of both acquisition and transmission of HIV by a factor of up to 10. Prompt treatment for STIs is thus important to reduce the risk of HIV infection. Controlling STIs is important for preventing HIV infection, particularly in people with high-risk sexual behaviors.

Chlamydia bacterium is usually spread through sexual activity and an infected male has a 25% chance per sexual encounter of transmitting the infection to an uninfected female. Chlamydia can be vertically spread as well. The transmission rate from infected mother to newborn is 50-60%, causing conjunctivitis (in most cases) or pneumonia (in 10-20% of cases). Infection of the genital tract is the most common clinical presentation. The incubation period is 1-3 weeks and approximately 50% of infected males and 80% of infected females are asymptomatic, but infection may cause a mucopurulent cervicitis in females and urethritis in males. Ascending infection can result in PID in women and is the most common cause of epididymitis in men younger than 35 years. In women with PID, 5-10% develop peri-hepatitis (i.e. Fitz-Hugh-Curtis syndrome).

Although patients with any STD are at increased risk of co-infection with another STD, co-infection of Chlamydia and gonorrhoeae is most common. Forty percent of women and 20% of men with Chlamydia infection are co-infected with gonorrhoeae. Patients with Chlamydia also have a higher frequency of Reiter syndrome (i.e. urethritis, conjunctivitis, reactive arthritis) than the general population.

LGV is rare in the United States but is responsible for 10% of cases of genital ulcer disease in tropical countries. Localized inguinal adenopathy and ulceration develop 2-12 weeks after exposure. Proctitis, rectal strictures, and lymphatic obstruction with secondary elephantiasis can occur in untreated disease.

Chlamydia infection is the most commonly reported STD in the United States. Approximately 3-4 million cases of Chlamydia infection are reported each year, with more than half of them occurring in females aged 15-24 years. In sexually active female populations the average Chlamydia carriage rate is about 20%. Many patients are asymptomatic. The incidence is 2-3 times that of Neisseria gonorrhoeae. The prevalence of Chlamydia has been reported to be as high as 14% among African American females aged 18-26 years and 17% among females with a history of gonorrhoeae or Chlamydia in the previous 12 months. In addition, approximately 100,000 neonates are exposed to Chlamydia annually.

Sero-surveys have documented similar incidence figures in Australia, New Zealand, France, Germany and the Netherlands. A report from the World Health Organization (WHO) Initiative for Vaccine Research (IVR) estimated that there were more than 140 million cases of C. trachomatis infection worldwide. Men with asymptomatic infection serve as carriers of the disease, spreading the infection while only rarely suffering long-term health problems. Women, in contrast, are at high risk of severe complications of infection.

STUDY JUSTIFICATION

STIs remain one of the leading disease burdens in Kenya. Gonococcal and Chlamydia infections are often asymptomatic, especially in women, 50% and 80% respectively. The prevalence of these diseases in Kenya has not been established, yet they are curable. Recent data by W.H.O indicate increased resistance of gonorrhoeae to cephalosporin's (the last treatment option). Untreated gonococcal and Chlamydia infections have serious health implications on women, men and children including infertility in both men and women, increased risk of HIV infection and transmission, ectopic pregnancy, spontaneous abortion, still births, premature deliveries, severe eye infections with resultant blindness of newborn children and infection of the urethra, cervix and rectum.

It is therefore imperative that we determine the prevalence of Neisseria gonorrhoeae and C. trachomatis in our local setting and in so doing design specific public health interventions. It is expected that the results and recommendations of this study will enable the establishment of proper screening and treatment policies and also elucidate on the current antibiotic resistance patterns in the urban poor populace of Nairobi.

CONCEPTUAL FRAMEWORK

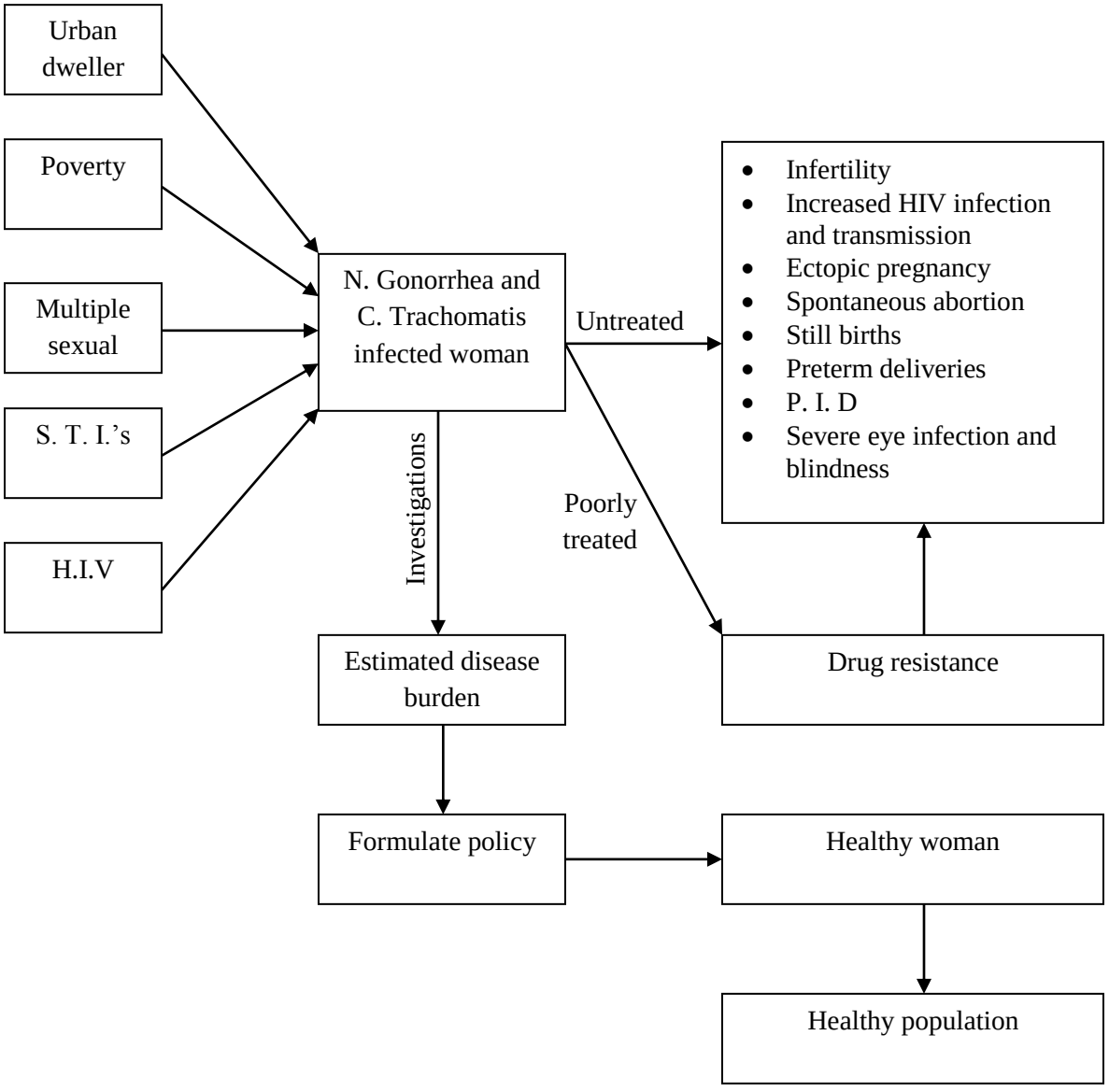
NARRATIVE

All sexually active populations are at risk for STIS. STIs remain as one of the leading disease burdens in Kenya yet they are curable. A large proportion of STIs occur in Sub-Saharan Africa. Contributing factors to this include urban dwellers, individuals of lower socioeconomic status, multiple sexual partners and minorities of any population. In addition, STIs increase susceptibility to HIV infection.

The sequelae of untreated or poorly treated gonococcal and Chlamydia infections include infertility in both men and women, increased risk of HIV infection and transmission, ectopic pregnancy, spontaneous abortion, still births, premature deliveries, severe eye infections with resultant blindness of newborn children and infection of the urethra, cervix and rectum. Recent studies in Japan and Europe have shown a worrying trend with increased drug resistance of C. trachomatis and N. gonorrhoeae to antibiotics. This now threatens to transform easily curable STIs to a global pandemic.

This dire situation can be addressed by carrying out studies to determine the actual prevalence, socio-demographic factors, drug resistance patterns of gonococcal and Chlamydia infections and in so doing determine the burden of disease in Kenya. From the study, policies and interventions on screening, treatment modalities and drug resistance patterns can then be implemented. This will then eliminate the serious complications of STIs and bring Kenya closer to achieving the MDG's.

The schematic representation of the conceptual framework is as below:



RESEARCH QUESTION.

1. What is the prevalence and antibiotic sensitivity pattern of Neisseria gonorrhoeae and Chlamydia trachomatis diseases among family planning clients in Kenyatta National hospital reproductive Health Clinic?

OBJECTIVES.

Broad:

To determine the prevalence of N. gonorrhoeae and C. trachomatis and the antibiotic sensitivity pattern of the isolates among family planning clients attending the reproductive health clinic (Clinic 66) at Kenyatta National Hospital.

Specific:

1. To determine the reproductive and socio-demographic characteristics of women attending the reproductive health clinic at Kenyatta National Hospital.
2. To determine the prevalence of N. gonorrhoeae and C. trachomatis among women attending the reproductive health clinic at Kenyatta National Hospital.
3. To determine the antibiotic susceptibility patterns of N. gonorrhoeae and C. trachomatis (as per the test antibiotics) among women attending the reproductive health clinic at Kenyatta National Hospital.

METHODOLOGY.

STUDY DESIGN.

This was a Cross-Sectional Study whose aim was to determine the prevalence of N. gonorrhoeae and C. trachomatis among women attending the reproductive health clinic at Kenyatta National Hospital. This design enabled the description of women suffering from N. gonorrhoeae and C. trachomatis as well as estimation of the disease burden and antibiotic resistance patterns.

STUDY SITE.

The study was carried out at Kenyatta National Hospital. KNH was founded in 1901 and is the oldest hospital in Kenya. It is a Government owned hospital and is the National Referral and Teaching Hospital and also plays a role in research in Kenya and is situated In Nairobi County, Upper Hill area. K.N.H has 50 wards, 22 out-patient clinics, 24 theatres (16 of which are specialized) and Accident & Emergency Department. It has a total bed capacity of 1800. At any given day the Hospital hosts in its wards between 2500 and 3000 in-patients. On average the Hospital caters for over 80,000 in-patients and over 500,000 out-patients annually. Majority of the patients are the urban poor.

The hospital offers comprehensive medical services including medical, surgical, paediatric, obstetric and gynaecological, diagnostic, pharmaceutical and emergency services. The study was carried out in the reproductive health clinic (Clinic 66). This is an out-patient clinic situated next to the Accident and Emergency Centre. This clinic offers various services including family planning, colposcopy, fistula treatment, day case gynaecological surgery and well-baby immunization. The staff who run the clinic include consultants, registrars, nurses and clerks.

Monthly attendance averages 400 patients per month with 250 new patients every month. As such the clinic is well suited for this hospital based prevalence study.

STUDY POPULATION.

The study comprised of women in the reproductive age group, aged between 15-49 years attending the reproductive health clinic at Kenyatta National Hospital during the study period. The choice of this population was suitable as it constituted the reproductive age which is the population at risk of N. gonorrhoeae and C. trachomatis.

INCLUSION AND EXCLUSION CRITERIA.

Inclusion criteria:

1. All women attending the reproductive health clinic at Kenyatta National Hospital during the study period who gave written and informed consent to participate in the study.

Exclusion criteria:

1. Clients who were either too sick to participate in the study.
2. Clients who had been on antibiotics in the last/ preceding 2 weeks.

DATA COLLECTION TOOL

The study instrument constituted a structured questionnaire which was both categorical and open ended. It was administered to the eligible women. The questionnaire is as attached in Annex 1.

SAMPLE SIZE DETERMINATION.

1.1 SAMPLING FRAME

This included all women/clients of reproductive age, seeking family planning services at the reproductive health clinic (Clinic 66). All clients were initially approached and requested to participate in the study after the purpose of the study had been clearly explained to them. The benefits of the study were also explained to the clients after which informed consent was sought.

1.2 SAMPLE SIZE

Literature review done in Africa as a whole show that prevalence of chlamydia of 5.1 million and of Neisseria 4.4 million. In Kenya the prevalence of both infections is not known. For purposes of this study, prevalence of Chlamydia trachomatis and Neisseria gonorrhoeae was taken as an average of 50%. The formula shown below was used to determine the sample size.

$$n' = \frac{N Z^2 P(1-P)}{d^2(N-1) + Z^2 P(1-P)}$$

n'= sample size with finite population correction,

N= population size at 400,

Z= Z statistic for a level of confidence at 1.6,

p= prevalence of chlamydia and gonorrhoeae at 50%

d=precision/reliability to determine p=5%

Thus n= 197

A minimum sample of 197 women was appropriate and was targeted.

1.3 SAMPLING TECHNIQUE

Systematic sampling was done and every 2nd consenting client was selected to participate in the study.

DATA COLLECTION.

Data was collected by qualified research assistants. After training of the research assistants, the questionnaire (Annex 1) was tested in order to determine its applicability. The questionnaire was examined for clarity, ambiguity, time taken to fill it out and analyzability. Internal and external quality controls of the laboratory procedures were done according to the manufacturers specifications where necessary. The Principal investigator in collaboration with trained and highly experienced laboratory technologists handled the entire specimen testing throughout the entire study to ensure consistency. The research assistants introduced themselves to the patients and purpose of study was explained. Ultimate benefits to the patients were stressed upon after which an informed consent was signed (Annex III). The questionnaire was administered in a private room to ensure confidentiality. During the interview, bilateral conversations were encouraged. All the information collected was entered in the questionnaire. All specimen collected were stored in a safe place awaiting transfer to the laboratory.

SAMPLE COLLECTION AND HANDLING.

Specimens were collected with Dacron or rayon swabs because calcium alginate may be toxic to gonococci. To minimize the inhibitory effects of unknown substances in the specimen, the swabs were inoculated directly onto growth medium and placed in a CO2 candle jar immediately after sampling. In cases of suspected co-infections of N. gonorrhoeae and Chlamydia trachomatis, the cervical specimen for N. gonorrhoeae detection was collected before the specimen for C.

trachomatis, because N. gonorrhoeae is present in the mucus from the endocervix and C. trachomatis is present in the cervical epithelial cells.

SPECIMEN STORAGE AND TRANSPORTATION.

Specimens were inoculated onto culture medium immediately after collection to preserve the viability of gonococci for isolation. Because the inoculated media were to be transported to a local laboratory, the plates were held at room temperature for no more than 5 hours in a CO_2-enriched atmosphere using a candle jar and transported to Bacteriology Laboratory, Department of Medical Microbiology College of Health Sciences University of Nairobi. Swabs were processed using molecular techniques to detect both gonorrhoeae and chlamydia in the Molecular Laboratory at the same place.

LABORATORY SPECIMEN HANDLING.

A direct smear for Gram staining was performed as soon as the endo-cervical swab specimen was collected. The swab was rolled gently onto the slide to preserve cellular morphology and over an area less than 1 cm^2 and was examined under oil immersion (1000x magnification), to check for intracellular Gram-negative kidney-shaped diplococci in polymorph nuclear leukocytes, the presence of which is required for the presumptive diagnosis of gonorrhoeae. The presence of extracellular Gram-negative diplococci was an equivocal finding and was to be confirmed by culture and nucleic acid test.

Because the preferred laboratory method for the diagnosis of N gonorrhoeae infections is the isolation and identification of the agent, culturing of the specimens was carried out for antimicrobial susceptibility testing, surveillance purposes, detecting treatment failure and characterizing outbreaks.

Media and cultural conditions for isolation:

The primary specimens were inoculated onto selective agar containing antimicrobial agents and incubated at 35°C to 37°C in a moist atmosphere enriched with CO_2 (3% to 7%) for 18 to 24 hours. Plates showing no growth were re-incubated overnight. Plates with an 18 hr. to 24 hr. culture were used as the inoculum for additional tests growth the Isolates were sub cultured at least once on nonselective medium after initial isolation before being used in a diagnostic test that required pure culture or heavy inoculum.

Presumptive identification of N gonorrhoeae:

The presumptive identification of N. gonorrhoeae was gram staining of colonies showing the following colonial morphological changes:

Colonies of Gonorrhoeae with varying diameter from 1 to 4.0 mm after 48 hours, owing to the formation of different colony types (designated T1, T2, T3, and T4). The colonies were smooth and non-pigmented. Some strains may produce atypical small colonies. The oxidase test uses the tetra methyl derivative of the oxidase reagent (1% aqueous solution of N, N, N, N-tetramethyl-1, 4-phenylenediamine) that is commercially available (BACTIDROP Oxidase, Remel Inc, USA) or prepared in-house. To perform the test, a drop of reagent was applied to filter paper or the tip of a cotton swab. Culture was then applied to the filter paper or cotton swab tip using a platinum or plastic loop, wooden applicator stick or toothpick. A dark-purple colour change within 10 seconds indicated a positive sample. The catalase test (3% hydrogen peroxide) or superoxol (30% hydrogen peroxide) were other rapid tests used in the presumptive identification of N gonorrhoeae. A drop of the reagent was placed in the center of a clean glass slide and the suspect colony is picked with a loop and emulsified in the reagent. N gonorrhoeae will produce a positive reaction with bubbling within 1-2 seconds.

Weak bubbling or bubbling after 3 seconds indicated a negative reaction. The reagents were tested daily against reference oxidase-positive and - negative cultures to ensure quality.

DNA Chlamydia and Gonorrhoeae extraction

DNA extraction was carried out on the endo-cervical specimens according to manufacturer's instructions. The DNA extracts were then frozen at -80C until PCR was carried out. The samples were analyzed by PCR using the Qiagen© CT PCR kit 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 and Neisseria gonorrhoeae included in the kit.

Antimicrobial Susceptibility Testing

The E-test was performed using a procedure similar to that of disk diffusion. The E-test which was a strip containing a known gradient of an antimicrobial agent and calibrated to give results as minimal inhibitory concentrations (MICs) of the agents. E-test strips were placed on the surface of a 150-mm plate (containing a nonselective medium inoculated as in the disk diffusion method) in a radial pattern with the lowest concentration of the agent toward the center of the plate and the highest concentration of the agent toward the edge of the plate). If MICs for ATCC 49226 correspond with CLSI-designated QC values, MICs of clinical isolates were interpreted according to CLSI interpretive criteria and CDC criteria.

The isolates were stocked in to vials using tryptone broth with 10% glycerin into liquid Nitrogen and in the -80o C at the department of Medical Microbiology College of health sciences university of Nairobi for future studies and reference.

RESULTS HANDLING

All results were confidential. Results were entered into the laboratory questionnaire (Annex 2) form as well as into the clients' file. Both positive and negative results including culture and sensitivity reports were placed in the clients file for treatment during the next visit i.e. within two weeks of testing. Those who tested positive were also advised to inform their sexual partner(s) and to use condoms during the interim period. Clients with obvious discharge were offered syndromic treatment. Benefits of this study included immediate treatment of the clients as well as treatment based on culture and sensitivity patterns for those with positive results.

DATA MANAGEMENT PLAN.

1.1 DATA ENTRY AND STORAGE

At the end of each day of data collection, the principal investigator inspected each questionnaire for completeness. Any missing information was completed by referring back to the source documents. Custom made data bases designed in MS Access were used for data entry. The data bases contained in-built range and consistency checks to minimize data entry errors.

1.2 DATA CLEANING

Upon completion of data entry, data was transferred to SPSS version 18 for cleaning. Data cleaning involved inspection of each variable using SPSS frequency procedure to check on the validity of each entry. Where invalid entries are noted data was cleaned prior to analysis. Initial cleaning was based on referring back to questionnaires.

1.3 DATA ANALYSIS

Data analysis was conducted in SPSS version 18. The initial stage involved conducting descriptive analysis using univariate approach. For continuous variables, means and standard deviations were calculated. In the case of categorical variables, frequencies and percentages were calculated. Descriptive statistics were presented using tables, graphs and narratives. The prevalence of bacterial infections was calculated and presented as percentage. The proportion of cultures which were sensitive to test antibiotics were determined.

1.4 DATA ARCHIVING

Data will was stored in a password protected data bases on a PC with additional backup. No personal identifiers were contained in the archive data. Access was restricted to the investigator and analyst.

ETHICAL APPROVAL.

Approval to carry out the study was sought from and granted by the Kenyatta National Hospital (K.N.H)/ University of Nairobi (UoN) Ethics and Research Committee (KNH/UoN ERC).

ETHICAL CONSIDERATIONS.

There were no serious ethical issues for this study. This study was minimally invasive as it did not interfere with the laid down reproductive health clinic protocols. The study capitalized on events taking place during routine family planning care. Names were not entered in this study, instead, serial numbers were used to ensure confidentiality and therefore no results were traceable to individual patients at the time of analysis. The research results were used for the intended purpose only i.e. partial fulfillment of the Masters of Medicine degree in Obstetrics and Gynecology at the University of Nairobi. However it may be quoted or cited by any other interested parties, anywhere in the world. Informed consent was included in the study. This consent was obtained freely and without coercion.

RESULTS

A total of 197 clients attending KNH family planning clinic were screened for N. gonorrhoeae and C. trachomatis infection during the study period, between January 2015 and March 2015.

Demographic characteristics:

Age.

The mean age of the participants was 35.7 years (SD 8.2) with a range between 15 and 60 years. The modal age group was composed of participants aged between 30 and 39 years who accounted for 45.7% (90) of the participants. Approximately one-quarter of participants were aged between 19 and 29 years (24.9%) and 23.7% were aged between 40-49 years.

Figure 1 presents the age distribution in ten-year age groups.

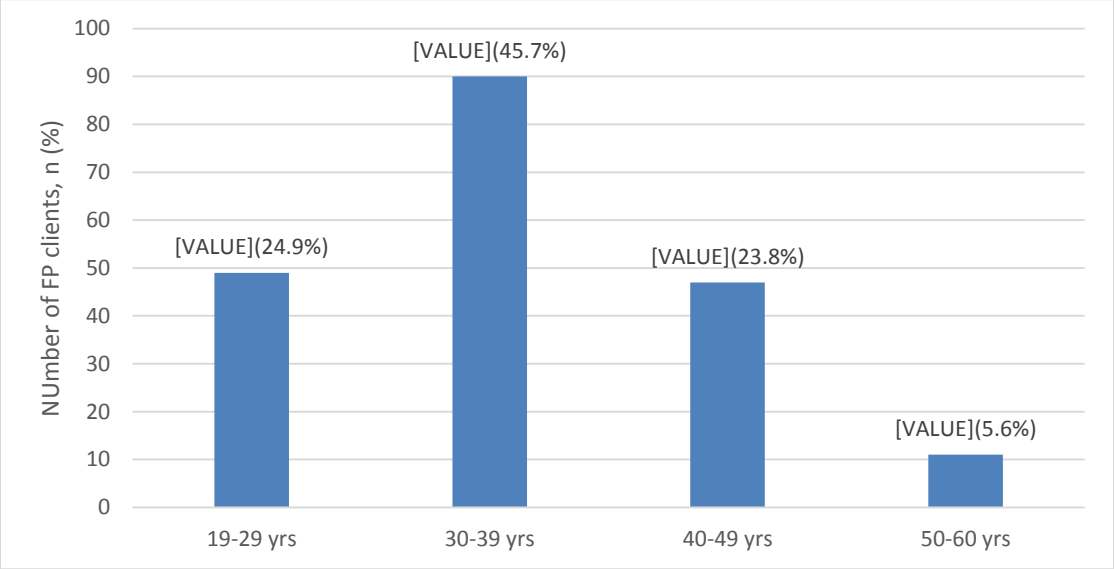


Figure 1: Age distribution of FP clients at KNH

Education level

Most of the participants seen at the KNH reproductive health clinic had either college 69 (35%) or secondary 60 (30.5%) level education (Table 1).

Table 1: Level of education of FP clients at KNH

	Frequency	Percent (%)	Cumulative %
Level of formal education			
Primary school	43	21.8	21.8
Secondary school	60	30.5	52.3
College	69	35.0	87.3
University	25	12.7	100.0
Total	**197**	**100**	

Marital status

146 (74.5%) of the participants reported that they were married and 39 (19.9%) were single.

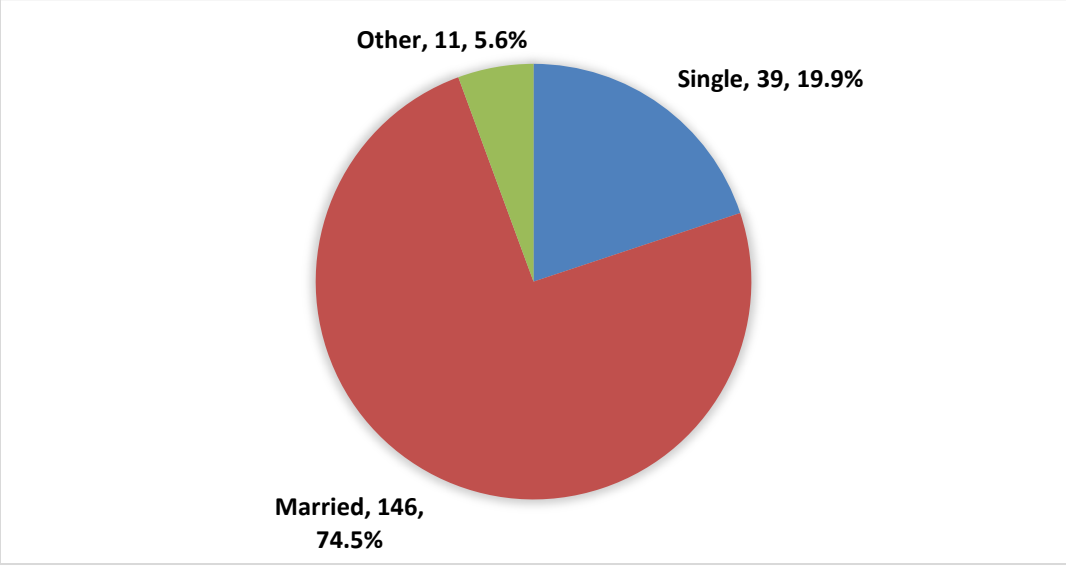


Figure 2: Marital status of FP clients in KNH

Occupation

95 (48.5%) of the participants indicated that they were in self-employment, 67 (34.2%) were formally employed and 34 (17.4%) were unemployed.

Table 2: Occupation of FP clients in KNH

	Frequency	Percent (%)	Cumulative %
Occupation			
Formal employment	67	34.2	34.2
Self-employment	95	48.5	82.7
Unemployed	34	17.4	100.0

Reproductive health characteristics

Most participants had delivered previously with most participants reporting that they had between 1 and 3 viable pregnancies (Table 4). Of the FP clinic attendees there were 41 (20.8%) para 1, 61 (31%) para 2 and 45 (22.8%) para 3. Twenty-one (10.7%) of clients were nulliparous.

Table 4: Parity of FP clients in KNH

	Frequency	Percent (%)	Cumulative %
Parity			
Nulliparous	21	10.7	10.7
Para 1	41	20.8	31.5
Para 2	61	31.0	62.4
Para 3	45	22.8	85.3
> Para 3	29	14.7	100.0
Total	197	100	

The majority participants, 161 (81.7%), reported that they had a single sexual partner, whilst 10 (5.1%) had multiple sex partners and 12 (6.1%) said that they did not have a sexual partner at the time of the study (Table 5).

Table 5: Number of sexual partners of FP clients in KNH

	Frequency	Percent (%)	Cumulative %
Number of partners			
0	12	6.1	6.1
1	161	81.7	87.8
2	10	5.1	92.9
No response	14	7.1	100.0
Total	197	100.0	

Contraceptive use

Majority of participants 67 (34%) reported using IUCD as the mode of contraception while 17 (8.6%) used implants. 13 (6.6%) used the daily pill and another 13 (6.6%) were on injectable contraceptives. 8 (4.1%) were using condoms as the mode of contraception.

Table 6: Mode of contraceptive use among FP clients in KNH

	Frequency	Percent (%)
IUCD	67	34.0
Injectable	13	6.6
Oral pills	13	6.6
Implants	17	8.6
Surgical	8	4.1
Condoms	8	4.1
None	71	36.0

Prevalence of N. gonorrhoeae and C. trachomatis infection

Of the 197 participants, 69 (35%) were found to have positive gram staining for N. gonorrhoeae. These 69 samples were further subjected to DNA analysis using PCR and 16 samples were confirmed to be positive for N. gonorrhoeae corresponding to a prevalence of 8.1% (95% CI 4.3 – 12.0%) for N. gonorrhoeae infection (Table 6). The mean age of the clients with confirmed N. gonorrhoeae infection was 35.3 years (±9.6) compared to 35.7 years (±8.0) for the negatives (p = 0.839).

Out of the 197 clients 4 had positive PCR DNA for C. Trachomatis corresponding to a prevalence of 2% (95% CI 0.04-4.0%).

One participant was found to have co-infection with both N. gonorrhoeae and C. trachomatis 1/197(0.5%)

Table 6: Prevalence of N .gonorrhoeae and C. trachomatis infection

	Frequency	Percent (%)	95% CI	
Chlamydia trachomatis	4	2.0%	0.04%	4.0%
Neisseria gonorrhea	16	8.1%	4.3%	12.0%

Characteristics of participants with C. trachomatis infection.

Table 7: Characteristics of participants with C. trachomatis

	Chlamydia infection		OR (95% CI)	P value
	Yes	No		
Age				
19-29 years	1(2.0)	48(98.0)	1.0	
30-39 years	2(2.2)	88(97.8)	1.09(0.1-12.34)	0.944
40-49 years	1(2.1)	46(97.9)	1.04(0.06-17.18)	0.976
50-60 years	0(0.0)	11(100.0)		Na
IUCD				
No	3(2.3)	127(97.7)	1.0	
Yes	1(1.5)	66(98.5)	0.64(0.07-6.29)	0.703
Marital status				
Married	1(2.6)	38(97.4)	1.0	
Single	3(2.1)	143(97.9)	0.8(0.08-7.88)	0.846
Other status	0(0.0)	11(100.0)	1(1-1)	
Number of sexual partners				
0	0(0.0)	12(100.0)	Na	Na
1	3(1.9)	158(98.1)	Na	Na
2	0(0.0)	10(100.0)	Na	Na
Discharge				
No	4(2.1)	187(97.9)	Na	Na
Yes	0(0.0)	6(100.0)	Na	Na
Pain				
No	4(2.1)	188(97.9)	Na	Na
Yes	0(0.0)	5(100.0)	Na	Na

A majority of C. trachomatis positive patients 2/4 (50%) patients were aged between 30-39 years and evenly distributed 1/4 (25%) between those aged 19-29 years and 40-49 years; 3/4 (75%) were single; 1/4 (25%) used IUCD as the mode of contraception; 3/4 (75%) had 1 sexual partner; none (100%) had abdominal nor per vaginal discharge. None of these characteristics was statistically significant.

Characteristics of participants with N. gonorrhoeae infection.

Table 8: Characteristics of participants with N. gonorrhoeae

	Gonococcal infection		OR(95%CI)	P value
	Yes	**No**		
Age				
19-29 years	5(10.2)	44(89.8)		
30-39 years	6(6.7)	84(93.3)	0.63(0.18-2.18)	0.464
40-49 years	4(8.5)	43(91.5)	0.82(0.21-3.25)	0.776
50-60 years	1(9.1)	10(90.9)	0.88(0.09-8.38)	0.911
IUCD				
No	8(6.2)	122(93.8)		
Yes	8(11.9)	59(88.1)	2.07(0.74-5.78)	0.166
Marital status				
Single	1(2.6)	38(97.4)		
Married	14(9.6)	132(90.4)	4.03(0.51-31.64)	0.185
Other status	1(9.1)	10(90.9)	3.8(0.22-66.22)	0.36
Number of sexual partners				
0	0(0.0)	12(100.0)	Na	Na
1	14(8.7)	147(91.3)	Na	Na
2	0(0.0)	10(100.0)	Na	Na
Discharge				
No	16(8.4)	175(91.6)	Na	Na
Yes	0(0.0)	6(100.0)	Na	Na
Pain				
No	16(8.3)	176(91.7)	Na	Na
Yes	0(0.0)	5(100.0)	Na	Na

A majority of N. gonorrhoeae positive participants 6/16 (37%) were aged between 30-39 years followed by 5/16 (31%) 19-29 years and 4/16 (25%) 40-49 years; 14/16 (87%) were married; 8/16 (50%) used as the mode of contraception; 14/16 (87%) had one sexual partner over the last 6 months; none (100%) reported pain nor per vaginal discharge. None of these characteristics was statistically significant.

Antibiotic susceptibility patterns

Table 8 shows the susceptibility patterns of N. gonorrhoeae isolates to nine commonly used antibiotics. Resistance (both intermediate and resistant) was common for five antibiotics but no N. gonorrhoeae isolates were resistant to four of the antibiotics: ceftriaxone, cefixime, spectinomycin and gentamicin. Conversely, all the six isolates were resistant to tetracycline. One-half of isolates were resistant to azithromycin (intermediate n = 2, resistant n = 1), and more than one-half showed resistance to ciprofloxacin (intermediate n = 2, resistant n = 2), penicillin (intermediate n = 3, resistant n = 1), and erythromycin (intermediate n = 4).

We were unable to carry out culture and E-test for C. trachomatis as no laboratory in Kenya performs these tests and the financial implications of carrying out these tests were beyond the budget of this study.

Table 9: Resistance patterns of six N. gonorrhoeae isolates to nine antibiotics determined by E-test

Antibiotic	**Total number of samples**	**Susceptible**		**Intermediate**		**Resistant**		**Minimum MIC**	**Maximum MIC**
	N	MIC	n	MIC		MIC	n		
Ciprofloxacin	16	≤0.06	2	0.12 – 0.5	2	≥1	2	0.032	1
Azithromycin	16	≤0.25	3	0.5	2	≥1.0	1	0.064	0.32
Penicillin	16	≤0.06	2	0.12 – 1.0	3	≥2	1	0.032	>0.32
Erythromycin	16	≤0.25	2	0.38 – 1.0	4	1.5 – 4.0	0	0.047	0.75
Ceftriaxone	16	≤0.25	6	Na	Na	≥0.25	0	<0.016	0.016
Cefixime	16	≤0.25	6	Na	Na	≥0.25	0	0.016	0.016
Spectinomycin	16	≤ 32	6	64	0		0	0.75	3
Tetracycline	16	≤0.25	0	0.5 – 1.0	0	≥2	6	1.5	24
Gentamicin	16	≤ 4	6	8 – 16	0	≥32	0	0.038	2

DISCUSSION

The prevalence of Chlamydia trachomatis (2%) found in this study is lower than what has been previously published in studies in which similar laboratory methods/procedures were used. A C. trachomatis prevalence of 13.3% was found among women attending KNH FP clinic in 2013 (Maina A. et al., 2013); Kohli et al (2013) found a prevalence of 6% among women attending outpatient clinics in Nairobi; 9% was found among women complaining of vaginal discharge (Fonck K. et al. ,2000). It was not clear why the prevalence of C. trachomatis was low in this study as most studies have shown a higher prevalence in women above 30 years of age, which was the age of a majority of women in this study.

The prevalence of N. gonorrhoeae (8%) found in this study is comparable with that which has been reported in similar published studies. Fonck et al (2000) found a prevalence of 7% among women with complaints of discharge; Daly et al (1994) found a N. gonorrhoeae prevalence of 3.2% among women attending FP clinic in Nairobi. Maina et al found a prevalence of 0% among women attending KNH FP clinic in 2013.

Majority of the women diagnosed with C. trachomatis (75%) and N. gonorrhoeae (87%) had 1 sexual partner in the preceding 6 months and this finding suggests 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. The high proportion of asymptomatic patients who tested positive for N. gonorrhoeae and C. trachomatis corroborates findings in other studies and further stresses the importance of aetiological approach as opposed to the syndromic approach of managing STI's.

The findings of this study therefore lead to the conclusion that the syndromic approach to management of STI's leads to an underestimation of the proportion of infected individuals as majority tend to be asymptomatic. The CDC recommendations for the treatment of N. gonorrhoeae and C. trachomatis were used in treating the infected participants. All infected participants were informed of their results and advised to come to the KNH reproductive health clinic where prescriptions were given to them. They were also advised to disclose their results to their partners and to assist them to get screened and treated at a medical facility of their choice.

CONCLUSION

The burden of disease is high with the prevalence of N. gonorrhoeae at (8%) among women attending the reproductive health clinic in KNH while that of C. trachomatis is (2%). A majority of participants found to have C. trachomatis (50%) and N. gonorrhoeae (37%) were aged between 30-39 years. Majority of the participants found to have C. trachomatis were single (3/4, 75%) while those with N. gonorrhoeae were married (14/16, 87%). All participants who tested positive for C. trachomatis and N. gonorrhoeae were asymptomatic (100% for abdominal pain and 100% for per vaginal discharge). There is need to maintain vigilance on the antibiotic sensitivity patterns as drug resistance was noted for routinely used groups of antibiotics that we have been using for syndromic treatment.

RECOMMENDATIONS

1. There is need for point of care STI screening services to be introduced in FP clinics.
2. Antibiotic sensitivity monitoring should be instituted.
3. A National policy on the rational use of antibiotics should be formulated.

STUDY LIMITATIONS

The assessment of potential risk factors for acquisition of Chlamydia Trachomatis and Neisseria gonorrhoeae involved asking very confidential information like the number of sexual partners and history of STIs/per vaginal discharge. This may have elicited in-sincere 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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ANNEX 1: QUESTIONNAIRE (ENGLISH VERSION)

I.P NO…….

STUDY NO……

CONTACT (MOBILE NUMBER)……..

1. General Information

1. Age (Date of Birth)……..
2. Parity
   a) Nulliparous
   b) Para 1
   c) Para 2
   d) Para 3
   e) >Para3
3. Method of contraception ……..
4. Education level
   a) Primary school
   b) Secondary school
   c) College
   d) University
   e) Other
5. Marital status
   a) Single
   b) Married
   c) Separated/divorced
   d) Widowed
   e) Other
6. Number of partners (In last 6 months)……
7. Occupation
   a) Formal employment
   b) Self-employment
   c) Not employed
8. Physical residence/address……
9. Have you douched in last 24 hours…….
10. Have you used any antibiotics in last week……..
11. If yes to question number 10. Which antibiotics have you used…….

2. Last normal menstrual period (LNMP)……

3. General examination

a) Normal
b) Abnormal
c) If any abnormality detected, please specify…….

4. Abdominal examination

a) Normal
b) Abnormal
c) If any abnormality detected please specify……

5. Physical Examination

(Yes/No)

a) Vaginal discharge……..
b) Color of discharge…….
c) Cervical abnormalities……
d) Vaginal abnormalities……....

ANNEX 2: QUESTIONNAIRE (KISWAHILI VERSION)

I.P NO…….

STUDY NO……

WASILIANA (MOBILE NUMBER)……..

2. Maelezo

1. Umri (Tarehe ya kuzaliwa)…….
2. Usawa
   a) Nulliparous
   b) Para 1
   c) Para 2
   d) Para 3
   e) >Para3
3. Namna ya kupanga uzazi……..
4. Ngazi ya Elimu
   a) Shule ya msingi
   b) Shule ya sekondari
   c) College
   d) Chuo Kikuu
   e) Nyingine
5. Hali ya ndoa
   a) Pekee
   b) Ndoa
   c) Kinachotenganishwa/talaka
   d) Mjane
   e) Nyingine
6. Idadi ya washirika (Katika miezi 6 iliyopita)……
7. Kazi
   a) Ajira rasmi
   b) Kujiajiri
   c) Si walioajiriwa
8. Kimwili makazi / anwani…….
9. Je, umedouched katika masaa ya mwisho 24……

10. Je, umetumia antibiotics katika wiki iliyopita…….
11. Kama ndiyo kwa swali nambari 10. Ni antibiotics gani uliyotumia……..

2. Tarehe ya kuanza kwa hedhi ……

3. Uchunguzi wa ujumla

a) Kawaida
b) Siyo ya kawaida
c) Kama abnormality yoyote yaonekana tafadhali taja…….

4. Uchunguzi wa tumbo

a) Kawaida
b) Siyo ya kawaida
c) Kama abnormality yoyote yaonekana tafadhali taja ……

5. Mitihani wa Kimwili

(Ndio / Hapana)

a) Majimaji Kutokwa …….
b) Rangi ya majimaji inayotoka……
c) Abnormalities ya kizazi…….
d) Abnormalities ya ukeni…….

ANNEX 3: LABORATORY FORM

I.P NO…….

STUDY NO…….

Study no	Positive for C.trachomatis	Negative for C.trachomatis	Culture and sensitivity results

Study no	Positive for N. gonorrhoeae	Negative for N. gonorrhoeae	Culture and sensitivity results

ANNEX 4: CONSENT FORM FOR PARTICIPATION IN STUDY ON PREVALENCE OF N.GONORRHOEAE AND C.TRACHOMATIS AS SEEN IN THE REPRODUCTIVE HEALTH CLINIC, KENYATTA NATIONAL HOSPITAL F.P CLINIC ATTENDANTS.

Principal investigator: Dr. Martin Mutua Nzioka

Introduction

I am Dr. Martin Mutua Nzioka, a masters student in obstetrics and gynaecology at the University of Nairobi. I am conducting a study on the prevalence and drug sensitivity profiles of N. Gonorrhoeae and C. Trachomatis among family planning clinic attendants at Kenyatta National Hospital, Reproductive health clinic.

Investigators' statement

I am asking to recruite you into this study. The purpose of this consent form is to give you the information you will need to help you decide whether or not to participate in the study. Please read this form carefully. You may ask questions about what we will ask you to do, the risks, the benefits and your rights as a volunteer, or anything about the research or in this form that is not clear. When all your questions have been answered, you can decide if you want to participate in this study or not. This process is called "seeking informed consent".

Purpose, benefits and risks.

This study aims at determining the prevalence and drug sensitivity profiles of N. Gonorrhoeae and C. Trachomatis among family planning clinic attendants at Kenyatta National Hospital, Reproductive health clinic. There are no additional risks that you will be exposed to by participating in this study. You will not receive any monetary compensation for participating in the study. Participating in this study will not be of direct benefit to you.

Confidentiality

We will keep your identity as a research subject confidential. Only the investigator, institutional review board of Kenyatta National Hospital and University of Nairobi Ethics and Research Committee will have access to information about you.The information about you will be identified by the study code number and will not be linked to your name in any records.Your name will not be used in any published reports about this study.

Voluntary participation

Patient participation is voluntary.Refusal to answer any of the questions asked above at any time will not result in loss of benefit or penalty. Should you choose to withdraw from the study,you will receive the standard treatment entitled to you.

Whom to contact

If you have any questions regarding the study,feel free to contact the investigator at any time;

Dr.Martin Mutua Nzioka on telephone number +254 722 674 907.

This study has been approved by the Kenyatta National Hospital / University of Nairobi Ethics and Research Committee,and any questions and issues regarding the study could be addressed to;

The Chairperson,KNH/UON –ERC

Hospital Road, Along Ngong Road

P.O Box 20793,Nairobi

Tel.2726300 Ext 44102

Please confirm that you have agreed to participate in this study by signing the consent form provided to you.

CONSENT FORM.

Subject's statement (Individual patient consent form)

I…….of……

do consent to take part in this research, after having read the explanation form and having the study purpose explained to me by the researcher. My participation is voluntarily given.

I also understand that no harm shall come to me and no treatment will be denied to me should I choose to withdraw from the study,

Signature of Participant……Or Thumbprint……..

Date……

Witness/Translator

Signature……

Date……

Researcher

Signature…….

Date…….

ANNEX 5: SWAHILI TRANSLATION OF THE INFORMED CONSENT FORM

Fomu ya kufafanua utafiti

Mtafiti: Dkt. Martin Mutua Nzioka

Majina yangu kamili ni Daktari Martin Mutua Nzioka, mwanafunzi katika chuo kikuu cha Nairobi kitengo cha Afya ya Wanawake. Nafanya utafiti kuhusu kiwango cha magonjwa ya gonorrhoeae na chlamydia utakao wahusu wanawake ambao wamekuja kutafuta matibabu katika kliniki ya kupanga uzazi katika hospitali kuu ya Kenyatta.

Utafiti huu una lengo la kuchunguza kiwango cha magonjwa haya kati ya wanawake wanaotibiwa katika kliniki hii na pia kuchunguza ni madawa yapi ambayo yanaweza kutumiwa kutibu magonjwa haya.

Washiriki watafanyiwa utafiti baada ya wao kutia sahihi ya kuonyesha wamekubali bila ya kulazimishwa kuwa washirika kwa utafiti huu. Yeyote yule atakayebadilisha nia ya kujiondoa kwa huu utafiti hatanyimwa haki yake ya matibabu.

Habari itakayo kusanywa kwako itatumika kwa utafiti pekee. Tafadhali tia sahihi yako kwa fomu ya idhini kudhibitisha kuwa umekubali kuwa mshirika.

Idhini ya kushiriki katika utafiti

Mimi……wa……..Nakuba li kushiriki katika utafiti unaoendelea katika kliniki ya wanawake ya kupanga uzazi katika hospitali kuu ya Kenyatta. Nimejisomea fomu ya kufafanua utafiti huu na nikaelezwa umuhimu wa utafiti huu.

Nimeelewa ya kwamba sitadhulumiwa wala kunyimwa matibabu kamili nikiamua kujiondoa kwa utafiti.

Sahihi ya muhusika……AU kidole……

Tarehe……

Sahihi ya mtafsiri…….

Tarehe……

Sahihi ya mtafiti…….....

Tarehe……

APPENDIX 6: KNH ETHICAL APPROVAL LETTER