PREVALENCE OF URINARY TRACT INFECTION, MICROBIAL AETIOLOGY, AND ANTIBIOTIC SENSITIVITY PATTERN AMONG ANTENATAL WOMEN PRESENTING WITH LOWER ABDOMINAL PAINS IN KENYATTA NATIONAL HOSPITAL

DISSERTATION IN PARTIAL FULFILMENT FOR THE DEGREE OF MASTER OF MEDICINE IN OBSTETRICS AND GYNECOLOGY, UNIVERSITY OF NAIROBI

SUBMITTED BY

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DEDICATION

This book is dedicated to my parents whose love, care and guidance has made my studies possible and enjoyable.

Acknowledgement

I wish to thank the almighty God for the good health as I complete my masters training in Obstetrics and Gynaecology

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DECLARATION

I declare that this dissertation is my original work and it has not been presented by any other student for a degree award in any other university.

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LIST OF ABBREVIATION

ANC ___ Antenatal Clinic

ERC____ Ethics and Research Committee

HIV ____Human Immunodeficiency Virus

KNH ___Kenyatta National Hospital

LNMP__ Last Normal Menstrual Period

LAPs__ Lower Abdominal Pains

M. MED _Master of Medicine

SPSS__ Statistical Package for Social Sciences

UON __University of Nairobi

UTI ___Urinary Tract Infection

WHO_ World Health Organization

MDGs- Millennium development goals

CFU—colony forming units

ABSTRACT

Back ground.

Lower abdominal pain is one of the commonest complaints among antenatal women. In the absence of accessible laboratory services bacterial infection is a presumptive diagnosis. This is justified by the feto-maternal complications of untreated urinary tract infection in pregnancy. Therefore antibiotics are frequently prescribed empirically. In absence of bed side dipsticks and microbiology services, this results in excessive prescription of antibiotics with precedent complications including but not limited to resistant microbial agents in the population.

Lower abdominal pain has multiple a etiology, not limited to urinary tract infections, and routine prescription of antibiotics increases the population risk of antibiotic resistance.

In presence of infection there is need for institution guidelines on sensitivity patterns to advise on prescription and increase cure rates.

Research Objectives: To determine the prevalence of bacterial urinary tract infection as a cause of lower abdominal pains, microbial etiology and antibiotic sensitivity, among women attending antenatal clinics and labor ward in Kenyatta National Hospital.

Study design: A cross sectional study among antenatal women at Kenyatta National Hospital.

Methods: One hundred and fifty women who were not in labour but complaining of lower abdominal pain were enrolled. They were recruited from antenatal clinics and wards at the hospital and enrolled by consecutive sampling until the desired sample size was attained. Social and obstetric history was obtained and a clean catch mid stream urine sample was collected from each of the women for dipstick testing, microscopy culture and sensitivity. The urine was cultured on cysteine lactose electrolyte deficient (CLED) and blood agar media. Any organism isolated with colony counts of greater than 100000/ml of urine was considered significant and indicative of a UTI. Bacterial identification was done using the methods of Cowen and Steele. Antibiotic sensitivity patterns were studied using the disc diffusion method.

RESULTS:

Among antenatal women presenting with lower abdominal pains in Kenyatta National Hospital, 26.7% were confirmed with bacterial urinary tract infection.   E.coli was isolated in 40%, Staphylococcal species in 25%, klebshiella species in 10% and proteus

species in 10% of urine samples. Other isolates were enterococus, enterobacter and citrobacter specie. There was 100% sensitive to meropenem, imepenem, augmentin, ceftazidime and levofloxacin and about 81% to cefuroxime among isolated gram negative bacteria. Resistance to gentamycin and ampicilin was 80%. Gram positive bacteria were 100% sensitive to augmentin, cefuroxime, ceftriaxone, ceftazidime, meropenem and imepenem, with 20-80% resistance to levofloxacin, gentamycin, nitrofurantoin and ampicilin.

The dipstick screening test is 77.5% sensitive and 83.6% specific in diagnosis of bacterial urinary tract infection with positive predictive value of 63.3% and negative predictive value of 91.1%. Urine microscopy test showed a sensitivity of 67.5% and specificity of 88.2%, with positive predictive value of 67.5% and negative predictive value of 88.2%.

Conclusions

Less than one third of pregnant women presenting with lower abdominal pains actually had bacterial urinary tract infection. The microbial profile included E.coli at 40%, staph spp at 25% and other gram negative species

There clear sensitivity patterns and some resistance was noted

Recommendations

Empirical treatment of women with lower abdominal pain in pregnancy with antibiotics results in overtreatment and is not justified. We recommend routine screening of all antenatal mothers with lower abdominal pain with urine dipstick tests to determine presence of UTI before initiation of antibiotics. Augmentin is universally highly effective against all the microbes and is recommended for empirical use where laboratory facilities are not available. Routine feedback of antibiotic sensitivity patterns to advise clinicians on prescription is recommended.

1.0: BACKGROUND

1.0 Introduction

Lower abdominal pain is a common complaint in pregnancy and one of the common causes is urinary tract infection which is the commonest bacterial infection of mankind (1, 2). Urinary tract infection is the growth and multiplication of micro-organisms within the urinary tract that includes organs which collect, store, and void urine from the body i.e. the kidney, ureter, bladder, and the urethra.

Urinary tract infection affects millions of people world wide children and adults, male and female (3). However it is more prevalent in females because of the shorter and wider female urethra and its proximity to the anus. Bacteria from the rectum can easily cross over to the urethra and cause infection (4).

Urinary tract infection in women is more prevalent during pregnancy, with a rate of 12-35% (5, 6). This is due to the various anatomical, physiological, and biochemical changes of pregnancy along side the structural alterations caused by the gravid uterus in the pelvis. The increased progesterone levels lead to reduced ureteral, bladder, and urethral tone with dilatation and urine stasis. The increased glomerular filtration rate leads to increased urine volume, glycosuria and proteinuria that form good culture media for bacteria; the gravid uterus compresses the ureter causing stasis and dilatation leading to infection in the kidneys (7).

Urinary tract infection can occur as asymptomatic bacteriuria with a prevalence of 2-13%. This is when up to 100 000 colon forming units of pathogenic bacteria are cultured from the urine without any urinary symptoms. When left untreated, 20-30% develops into pyelonephritis (8).

Urinary tract infection also occurs in the symptomatic form as pyelonephritis involving the kidneys, as cystitis involving the bladder with clinical symptoms of dysuria, frequency supra-pubic and loin pains along side fevers and nausea and vomiting.

Predisposing factors to urinary tract infection include the female sex, pregnancy, poor general and perineal hygiene, young age, multiparty, diabetes mellitus, sickle cell disease, and previous treatment for UTI, low socio-economic status, asymptomatic bacteriuria and sexual intercourse (9).

Urinary tract infection is mainly caused by gram negative organisms that include E.Coli 60-70%, Klebshiella 10%, Proteus 5-10%, Pseudomonas 2-5%, gram-positive

bacteria, group B streptococcus and staphylococcus species (10). These organisms are mainly from the external genitalia, vagina, the genital tract, rectum and gastro-intestinal tract.

Both the asymptomatic bacteriuria and the symptomatic UTI are associated with adverse pregnancy out comes, several researchers have demonstrated that UTI results into low birth weight infants, intra-uterine growth retardation, preterm labour and premature babies, intra-uterine fetal death and increased perinatal mortality and morbidity. Maternal complications include anemia, pre-eclampsia, renal failure, septicemia and adult respiratory syndrome. (11)

With the mother and the fetus at so much risk due to urinary tract infection in pregnancy it is important that both asymptomatic bacteriuria and symptomatic UTI be treated.

1.2: LITERATURE REVIEW

Urinary tract infection is the commonest bacterial infection in pregnancy. It occurs more frequently in developing countries among the low socio-economic populations including Kenya. In the USA surveys estimated that there about 8 million cases of UTI annually with huge economic implications (12). No similar surveys have been done in Africa and developing countries, Fox man. B (6) found prevalence rate of UTI in pregnant women in America to be 2.5-8.7% where as valiquez et al 2000 estimated the prevalence of UTI in pregnancy to be 12-40% in developing countries in Africa .This was due to the differences in the socio-economic levels and standards of living (13). UTI was said to be about 4-10 times more common in pregnancy than in the non-pregnant women (14). This was because during pregnancy, there is a change in urine chemical composition with increase in glucose and amino acids which facilitate bacterial growth in urine (9). Its high frequency is also due to physiological, anatomical and functional changes that occur in the urinary tract during pregnancy. It also tends to be recurrent in association with urinary tract anomalies. It's management is mostly empirical and local microbial pattern and sensitivities ought to be adhered to in prescription as urine culture's and blood cultures are not always done or important (15).

If asymptomatic urinary tract bacteriuria is not treated 25% of the patients develop acute symptomatic infections in that pregnancy. It is thus of significance to screen all pregnant mothers for bacteriuria on the first antenatal visit. Screening is by cost effective methods like leucocytes – nitrite dip stick test especially when its prevalence is low but screening by culture is justified if prevalence is high.

Asymptomatic bacteriuria has been associated with preterm labour and low birth weight infants. (6). In a multivariate analysis Strieve et al (16) found increased risk of preterm delivery, low birth weight infants, Hypertension, pre-eclampsia and maternal anemia. Bacteriuria may persist after delivery, may result into overt symptomatic infections and chronic infections.

Sepsis syndrome and septicemia occurs in 15-20% of pregnant women which manifests with thermoregulatory instability manifesting with hyperthermia interspersed with hypothermia (17) causing fetal bradycardia and increased cardiac output. Twenty percent of mothers develop renal dysfunction. Respiratory insufficiency occurs in 1-2% of women due to endotoxin induced alveolar injury and pulmonary edema (14). Also

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intrauterine growth retardation and fetal death are increased. The pulmonary injury can be severe to cause acute respiratory distress syndrome.The endotoxin induced heamolysis leads to anaemia in 23% of patient when untreated.

According to Hill et al (17) the disease is more prevalent in young prime gravidae and occurs more in the second trimester. Patient with asymptomatic bacteriuria are more likely to develop symptomatic urinary tract infection than those without (3, 18). Diabetic pregnant women are four fold more likely to develop UTI as compared to non-diabetic pregnant women (18). Sickle cell disease women are more susceptible to urinary tract infections in pregnancy and are associated with a higher complication rate. General body immune suppression as in HIV women, chronic drug abusers and low socio-economic status with poor genital and perennial hygiene predispose to U.T.I.

Urinary tract infection can involve the kidneys and is called pyelonephritis or it may involve the bladder and is called cystitis, urinary tract infection can also be without symptoms termed asymptomatic bacteruiria. The signs and symptoms vary with the type of UTI. Asymptomatic bacteriuria (ASB) is significant bacterial colonization of the lower urinary tract without any symptoms. Diagnostic criteria are culture of 100,000 colony forming units /ml of a single uropathogen on two consecutive clean catch specimens.

Predisposing factors to ASB are; low socio-economic status, increasing age, multiparity, sexual behavior, urinary tract anomalies, previous treatment for UTI, other medical conditions like diabetes, sickle cell disease, and immune compromised states like AIDS and spinal cord injuries (20, 21). ASB will be complicated by progression to pyelonephritis in up to 20-40% if left untreated and only 3% will progress to symptomatic infection if treated (19).

Acute bacterial cystitis which is infection of the urinary bladder, presents with clinical signs and symptoms of dysuria, frequency, pyuria, and heamaturia without evidence of systemic illness. It complicates 1-4% of all pregnancies. (13). Diagnosis is mainly clinical, but also by positive urine culture of 100.000cfus/ml of a single uropathogen.

Acute pyelonephritis occurs in 1-2% of pregnancies and is the most severe form of UTI, and most common indication for ante partum hospitalization (20, 21, and 22). Risk factors for acute pyelonephritis are same as for ASB, but also include prior history of pyelonephritis, urinary tract anomalies, and renal calculi (24). About 67% is unilateral

and occurs on the right due to the uterus dextrotation and mainly in the late second trimester and third trimester (25).

Pyelonephritis presents with predominantly systemic signs and symptoms. These include, fever, flank pains, costal vertebral angle tenderness, chills and rigors, nausea and vomiting, dehydration, dysuria and frequency. Most common symptoms are fever and flank pains (26).

Diagnosis of pyelonephritis is clinical and confirmed on urine cultures of at least 100000 CFUs/ml of a single uropathogen in clean catch midstream urine. (11). Other diagnostic tools should include urine microscopy that shows bacteriuria, pyuria and leucocyte casts, together with complete blood cell count and serum biochemistry. Radiological tests and blood cultures are not necessary for diagnosis of uncomplicated pyelonephritis (27).

The causative organisms of UTI in pregnancy are the same as in non-pregnant women and are mainly gram negative enterobacteriae, which are the same for ASB, cystitis and pyelonephritis. The organisms are E.Coli accounting for 80-90% in primary infections and 70-80% in recurrent infections. Other gram negative pathogens are klebshiella pneumonia, proteus mirabilis, and pseudomonas auroginosa. The gram positive pathogens are; streptococcus species, and staphylococcus species (33, 28).

The spectrum of uropathogens is the same in ASB, pyelonephritis and cystitis with predominance of E.Coli (34, 29). Klebshiella pneumonia and proteus spp are rare in pyelonephritis except in recurrent cases. Gram positive bacteria do not ascend to the upper urinary tract except with instrumentation or obstruction (30).

Treatment of UTI varies with the type, but is usually empirical because of the common spectrum of uropathogens. The standard practice is to treat ASB with oral antibiotics for at least 7 days (32, 34). The common antibiotic used includes cephalexin, amoxicillin, ampicilin and nitrofurantoin. There are however the 3-day course and single dose treatment which are equally effective in the treatment of ASB, but they are associated with early recurrences (32) pregnancy. Cystitis is treated in the same way as ASB with oral antibiotics in 7or 3 or single day courses

1.3: JUSTIFICATION.

Lower abdominal pain is a common problem among antenatal women and has a number of causes among them UTI. In KNH pregnant with lower abdominal pain and not in labor are commonly treated as urinary tract infection in pregnancy. This leads to over use of antibiotics unnecessarily and causing antibiotic resistance. Therefore there was need to establish the prevalence of UTI among antenatal women who present with lower

abdominal pain in order to justify this practice. Therefore it is important to establish a very sensitive and specific were of diagnosing UTI and determine the involved bacterium and there sensitivity pattern in our institution.

UTI that presents with lower abdominal pains is associated with serious and poor obstetric outcomes like preterm labor, low birth weights and intrauterine growth restriction, hypertension and maternal anemia hence the need to treat it fast and rightly.

In order to achieve MDG 4 and 5, which is to reduce the less than 5 mortality rate and improve maternal health respectively, we should be able to prevent and reduce preterm births, which is the commonest cause of perinatal deaths and maternal morbidity by promptly and adequately treating UTI. And we should also avoid overuse and abuse of antibiotics to minimize development of resistance.

1.4: CONCEPTUAL FRAME WORK
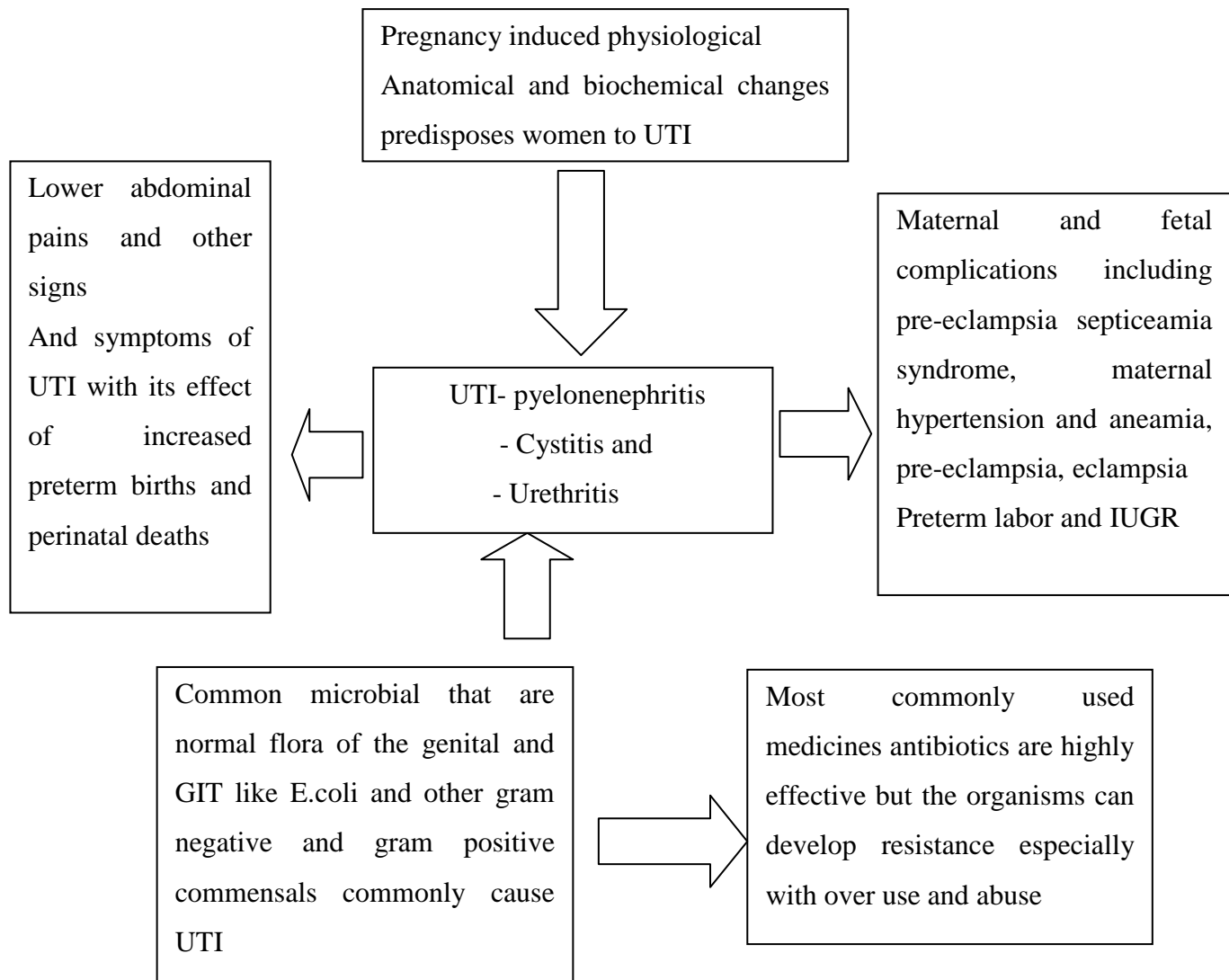
1.4.1 Narrative

UTI is defined as growth and multiplication of micro-organisms in the urinary tract that involves the bladder, ureters and the kidneys. UTI is the commonest bacterial infection of mankind. It is more common in pregnant mothers due to the physiological, anatomical and biochemical adaptations of pregnancy. It is a very serious infection and if untreated is associated with adverse outcomes to the mother and the baby. A number of risk factors are associated with development of UTI. These are both demographic and obstetric, including parity, age, sexual behavior, socio-economic status, gestational age other inter-current medical illnesses and previous history of UTI.

UTI can involve the lower or the upper parts of the urinary tract, each giving different symptoms but abdominal pains is common to both of them. Despite the high maternal and perinatal morbidity and mortality associated with untreated UTI in pregnancy, the process of diagnosis and treatment is not standardized. Often patients who present with LAPs in pregnancy are empirically treated for UTI as presumptive diagnosis.

The causative agents of UTI are known but their relative prevalence may vary from location to location and time to time and with the advent of HIV the epidemiology of most other diseases has been significantly altered. It is thus important to research and keep abreast with the rapidly changing patterns. The high prevalence and the diagnostic dilemma of UTI lead to overuse of antibiotics and development of resistant microbial species

It is thus of paramount importance to determine the microbial profiles and their drug sensitivity patterns in cases of empirical treatment.

1.4.2 Diagrammatic

Pregnancy induced physiological Anatomical and biochemical changes predisposes women to UTI

Lower abdominal pains and other signs
And symptoms of UTI with its effect of increased preterm births and perinatal deaths

UTI- pyelonenephritis
- Cystitis and
- Urethritis

Maternal and fetal complications including pre-eclampsia septiceamia syndrome, maternal hypertension and aneamia, pre-eclampsia, eclampsia Preterm labor and IUGR

Common microbial that are normal flora of the genital and GIT like E.coli and other gram negative and gram positive commensals commonly cause UTI

Most commonly used medicines antibiotics are highly effective but the organisms can develop resistance especially with over use and abuse

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1.5 STUDY QUESTION

1. What is the prevalence, the microbial causes and their sensitivity pattern, of bacterial urinary tract infections among pregnant women not in labour who present with abdominal pains in KNH?

1.6: STUDY OBJECTIVES

1.6.1: Broad Objective.

To determine the prevalence of UTI as a cause of lower abdominal pain, the common bacteria and their sensitivity pattern of UTI, among pregnant women attending KNH antenatal units.

1.6.2: Specific Study Objectives

1. To determine the prevalence of bacterial urinary tract infection among pregnant women who present with abdominal pains in KNH.
2. To determine the common microbes causing UTI among pregnant women with lower abdominal pain in KNH
3. To determine the anti-microbial sensitivity patterns of the microbes causing UTI and lower abdominal pain in antenatal women in KNH

2.0: METHODS AND MATERIAL

2.1: Study design

This was a cross sectional study among 150 pregnant women attending clinics/wards in KNH. It involved collection of data from the subjects in form of interviews and questionnaires. Data regarding demographic and reproductive characteristics was collected. The participants / subjects were randomly selected among women attending antenatal clinics in KNH with lower abdominal pain. The inclusion and exclusion criterion was applied. Clean catch urine specimens were collected from each of the 150 study participants. This was tested with urine dipsticks, microscopy and cultured for bacterial growth and subjected to drug sensitivity tests

2.2: Study area.

This study was carried out in the antenatal clinics, antenatal wards and maternity wards of Kenyatta National Hospital. KNH was chosen because it is a national referral hospital with many patients of varied socio-demographic and reproductive characteristic.

It was purposely chosen because of its large patient turn over, making it easy to achieve the desired sample size and its proximity and convenience to the investigator as a resident in the department attending to patients in the said antenatal units.

Kenyatta National Hospital microbiology laboratory was used to run the dipstick tests, urine microscopy tests and the culture and sensitivity test.

2.3: Study Population

The study was conducted among 150 consenting pregnant women attending KNH clinics in the ANC, antenatal wards and labor ward. Selection into the study was by set criteria.

2.3.1: Sample size determination

Minimum sample size was calculated using the formulae by Fitcher et al 1998 as shown below.

$$N = \frac{Z^2 \ PQD}{d^2}$$

N = Desired sample size

Z = Normal deviation = 1.96 that corresponds to 95% confidence
   Interval

P = Proportion of the target population estimated to have desired
   Characteristics 0.08 = 8 %(16)

Q = 1 – P.

d = degrees of freedom = 0.05.

D = design effect = 1.

$$N = \frac{1.96^2 \ x \ 0.08 \ x \ 0.92 \ x \ 1}{(0.05)^2}$$

= **113**

Thus a sample size of 150 pregnant women was taken to increase the representativeness of the sample, minimize sampling errors, increase generalisability of the result and cater for any attrition. Also there was no problem getting the desired sample size because of abundance of subjects who meet the desired criteria.

2.3.2: Sampling method

The study utilized purposive sampling technique. Purposive sampling was used to select women who presented with lower abdominal pains in the antenatal clinics and then simple random sampling was used to choose women to include in study with strict application of the inclusion criteria. Eligible participants were approached and requested to give a voluntary consent to participate in the study. Upon consenting, a study number with a code was assigned for identification. Inclusion into the study was done consecutively until the required sample size of 150women was achieved.

2.3.3: Inclusion criteria.

1. Pregnant women no in labour presenting in the antenatal clinic in KNH with lower abdominal pains and willing to participate in the study by giving informed consent.

2. No prior treatment in the preceding one week with antibiotics or any other medications that may affect the culture results.

3. Greater than 20 weeks of gestation.

2.3.4 Exclusion criteria.

1. Pregnant women with lower abdominal pains due to specific causes

2. Those women already on antibiotics treatment for any other reason were excluded from the study

3. Pregnant women in labor and those who delivered within 24hrs of LAPs

2.3.5: Recruitment and consenting

The study involved recruitment of pregnant women who reported to the antenatal

Units with lower abdominal pains and those who walk into labor Ward with non-labor related abdominal pains. Also women admitted to wards with abdominal pain in pregnancy were recruited into the study after applying the inclusion criteria. The purpose of the study and any ethical concerns were explained. A written consent form (appendix no: 1) was availed and signed for accepting to participate. There after they were interviewed and a questionnaire was completed.

2.4. Data collection instrument.

Data was collected with structured questionnaire with both open and closed ended questions. It was availed to the study participants by principle investigator or the research assistants. It was composed of two sections. It is attached herein as appendix 2 and 3.

2.4.1: Social demographic and obstetrics profile

A prior prepared set of specific questions was administered to mothers in regard to their demographic information, obstetric information and any other information of relevance to the study. This was done in ANC clinics the labor ward and antenatal wards. This was designed by the researcher to capture personal information and obstetric data.

2.4.2: Urinary Dipstick Test/culture and sensitivity

All subjects recruited into the study were asked to provide a specimen of clean catch midstream urine that was subjected to a dipstick test, urine microscopy, culture and sensitivity tests and results were entered into the data base.

The clean catch midstream urine specimens from all the subjects was cultured to determine the micro organisms involved and subjected to a sensitivity test to determine the antibiotic sensitivity pattern. This too was documented entered into data base.

The urine was cultured on cysteine lactose electrolyte deficient (CLED) and blood agar media. In this study any organism isolated with colony counts of greater than100000/ml of urine was considered significant and indicative of a UTI. Bacterial identification was done using the time honored methods of Cowen and Steele. Antibiotic sensitivity patterns were studied using the disc diffusion method.

2.4.3: Quality assurance procedures

Samples were collected with clear instructions to the participants to collect mid stream urine after vulval swabbing with clean water.

The specimen were put in a cool box, and delivered to the laboratory within one hour of collection. Processing of the specimen was done under set standards for best results.

3.0: DATA COLLECTION PROCEDURE

On every day during the study period the study team was available in the labor ward, antenatal wards and the antenatal clinics for recruitment of study participants.

After identifying the pregnant women who meet the inclusion criteria .the following was done.

1. The women were explained to about the study and voluntary consent to participate in the study sought those who agreed were asked to sign the consent form

2. Social demographic and obstetric data form was completed

3. Each of the study participants was asked to provide a clean catch urine specimen that was delivered to the laboratory within 1 hour

This study continued at the said sites till the desired sample size was attained for data analysis.

3.1: Training procedure

The research assistants-mid-wives were explained the study details, what the roles were, different terminologies were explained and training on how the questionnaire was to be filled in a standardized and uniform manner was done.

Three laboratory technicians were also explained about the study and the test to be done for all the samples.

3.2: Data management

At the end of each interview the filled questionnaire was cross checked for completeness and any missing entries were corrected.

The laboratory request forms were cross checked for the desired tests and results.

3.2.1: Data retrieval and storage

All data collected in the study was sorted, coded and entered in a computer using SPSS program. Data was crossed checked against the data files for any inconsistencies and obvious data entry errors. The data entry and editing was done throughout the study process.

3.2.2 Data Analysis

The demographic details and characteristics and the obstetric and gynecological particulars of the subjects in terms of predictability and determination of risk factors of U.T.I were analyzed using SPSS.

Central tendencies measures like the mean, median and mode were computed; cross tabulations was done to establish relationships between variables and CHI-square tests used to test association.

Data from deep sticks and urine culture sensitivity was analyzed using quantitative methods. The study findings were presented using pie-charts bar-graphs and diagrams.

4.0 ETHICAL CONSIDERATIONS

Clearance to conduct the study was obtained from the Department of Obstetrics and Gynaecology after presentation of the study proposal. Subsequently, permission to carry out the study was sought and obtained from the Kenyatta National Hospital / University of Nairobi ethics and research committee (ERC). Written informed consent was obtained from all the women after the purpose of the study had been explained to them. Participation in the study was voluntary and no form of inducements was made as the interview and investigations was conducted at normal hospital visits or admission. No extra cost was met by the patient as the principal investigator covered all the cost including the laboratory charges. Confidentiality was maintained by use of identification numbers instead of individual names.

There was no risk to the participants as there were no invasive procedures done; participants with suspected UTI were empirically treated before the test results. Participants whose test results showed any growth of microbes benefitted by being treated as per the culture and sensitivity results. No adverse reactions to the drugs were expected as these were the drugs routinely used in the Department. Failure to participate in the study did not affect services rendered to the patient from the hospital in any way.

5.0 STUDY LIMITATIONS

Due to resources limitation, the study did not assess other causes of lower abdominal pains by doing other investigations like stool microscopy and ultra sound scanning. If the participant required these tests they were requested but the cost was paid by them.

The culture growth media used was only able to culture bacteria as the causative agents of urinary tract infection thus did not assess other organisms like viruses, fungi, mycoplasma, and Chlamydia, trichomonas, this was because of the cost and the time required.

After screening for UTI, some of the participants were not available for the results although the benefits of the study was explained and they were encouraged to give their contacts for feedback, and prescription as per the sensitivity if need be.

Despite taking all due precautions, and instructing women how to take a clean catch urine specimen, the possibility of contamination cannot be completely eliminated.

6.0: RESULTS

6.1: Socio-demographic distribution of the participants

A total 150 antenatal women with lower abdominal pains were screened for UTI.

The majority of women we aged between 25-34 yrs (66%), married 88% with above primary level (72%). At enrollment more than 80% were above 35weeks of gestation and 40% were para1.

TABLE: 1 socio-demographic characteristic of the participants

characteristics	population	Frequency %
All women	N=150	
Age in years		
15-24	23	15.3%
25-34	99	66.0%
35-44	28	18.7%
Marital status		
Married/cohabiting	132	88.0%
Single	18	12.0%
Socio-economic status		
employed	94	62.7%
unemployed	56	37.3%
Previous UTI		
yes	44	29.3%
no	106	70.7%
Education level		
Standard 8&<	42	28.0%
Above standard 8	108	72.0%

Table 2: obstetric characteristics

Characteristics	Population	Frequency %
All women	N=150	
Parity		
0	59	39.3%
1	44	29.3%
2	26	17.3%
3	9	6.0%
4& above	12	8.1%
Gestational age in weeks		
20-24	2	1.3%
25-29	2	1.3%
30-34	9	6.0%
35-39	81	54.0%
40-44	56	37.4%
Previous obst/gyne surgery		
Positive	29	19.3%
Negative	121	80.7%
Other urinary symptoms		
(Apart from LAPs)	24	16%
Present	126	84%
Absent		

Of the 150 women enrolled in the study 59 (39.3%) were prime gravid

44(29.3%) had a parity of one,

About 25 women 16.7% had had at least one abortion in their obstetric career.

Twenty four women (16%) had other UTI symptoms in addition to the lower abdominal
pains

Table 3: Factors associated with Bacterial culture positive UTI.

Characteristic	Women with bacteria Culture positive UTI N=40	Women with bacteria Culture negative UTI N=110	P-value
Age groups			
15-24	11(27.5%)	12(10.9%)	
25-34	25(62.5%)	74(67.3%)	
35-44	4 (10.0%)	24(21.8%)	0.75
Marital status			
Single	7 (17.5%)	11(10.0%)	
Married	33(82.5%)	99(90.0%)	0.26
Parity			
Primegravidae	14 (35.0%)	45(40.9%)	
Multigravidae	26(65.0%)	56(59.1%)	0.41
Previous UTI			
yes	5(12.5%)	39(35.5%)	
no	35(87.5%)	71(64.5%)	0.25
Previous obst surgery			
Present	7 (17.5%)	12 (10.9%)	
absent	33(82.5%)	99 (89.1%)	0.14
Presence of other signs			
Present	4 (10.0%)	20(18.2%)	0.19
Absent	36(90.0%)	90(81.8%)	

Maternal age, marital status, parity, prior UTI episodes or obstetric surgeries were not risk factors for UTI

Table: 4a Relationship between dipstick positive urine, microscopy positive and culture positive

	Among culture positives (N= 40)	Among culture negatives (N=110)
Dipstick positive	31 (77.5%)	18 (16.3%)
Urine microscopy positive	27(67.5%)	13(11.8%)

Of the 40 women whose urine was positive for growth of bacteria, 31(77.5%) also were positive on dipstick testing of the urine, and 27(67.5%) were positive on urine microscopy. thus the dipstick and urine microscopy tests are simple and highly sensitive highly specific tests that can be used to screen for UTI.

Table 4b Sensitivity, specificity and predictive values of urine dipstick tests

Dipstick test	UTI positive culture	Negative culture	Totals
Positive	31	18	49
Negative	9	92	101
Total	40	110	150

Sensitivity =   31/40 x100 = 77.5%   false positives= 18

Specificity =   92/110x100 = 83.6%   false negative=9

Positive predictive value = 31/49x100 = 63.3%

Negative predictive value= 92/101x100= 91.1%

Table 4cSensitivity specificity and predictive values of urine microscopy test

Urine microscopy	UTI positive Urine culture	no UTI negative urine culture	totals
Positive	27	13	40
Negative	13	97	110
Totals	40	110	150

Sensitivity = 27/40 x 100= 67.5%   false positives =13

Specificity = 97/110x 100= 88.2%   false negatives=13

Positive predictive value=27/40x100=67.5%

Negative predictive value=97/110 x100=88.2%

6.3: Microbiological profile

Table: 6 Bacteria species isolated.

Bacterial species	No. of isolates N=40 (total no of bacterial culture positives)	% of the total
E.coli	16	40.0%
Klebshiella Spp	5	12.5%
Enterobacter Spp	4	10.0%
Proteus Spp	4	10.0%
Citrobacter spp	1	2.5%
Staph. spp	10	25.0%

Of all the bacteria cultured (n=40) (26.7%), the gram negative bacteria E.coli, klebshiella spp, proteus spp enterobacter and citrobacter spp,were the most prevalent at 30 (75%) than the gram positive staph spp,at 10 (25%). Most commonly isolated bacteria were E.coli 12 (40%) followed by staphylococcus spp at 25%, followed by klebshiella spp 5 (12.5%) enterococcus spp and proteus spp both at 4 (10%) each. Citrobacter spp was also isolated in 2.5% of the cultures.

6.4: DRUG SENSITIVITY PATTERNS

Table 7: Drug sensitivity

	E.coli	Staph spp	Klebshiela spp	Proteus spp	Enterobacter spp	Citrobacter spp
Augmentin	100%	100%	100%	100%	100%	100%
Cefuroxime	80%	100%	100%	50%	100%	100%
Gentamycin	72%	60%	50%	100%	0%	20%
Nitrofurantoin	100%	50%	100%	100%	100%	100%
Ampicilin	50%	20%	50%	70%	70%	80%
Ceftazidime	100%	100%	100%	100%	100%	0%
Levofloxacin	100%	75%	100%	100%	100%	100%
Ceftriaxone	100%	100%	100%	100%	100%	100%
Meropenem	100%	100%	100%	100%	100%	100%
Imepenem	100%	100%	100%	100%	100%	100%

All the gram negative isolates showed high sensitivity to augmentin, ceftriaxone, ceftazidime levofloxacin, nitrofuratoin, meropenem and imepenem with variable sensitivity to gentamycin and ampicilin. The gram positive isolates showed high sensitivity to similar antibiotics except levofloxacin ampilin nitrofurantoin and gentamycin which demonstrated significant resistance. E. coli was sensitive to all the antibiotics except ampicilin and gentamycin and Cefuroxime, citrobacter spp was also 100% resistant to ceftazidime

6.5: DISCUSSION

The overall prevalence of urinary tract infection among pregnant women with lower abdominal pains in KNH in this study was 26.7%. This is comparable to studies done elsewhere in the world. The prevalence of UTI reported in Addis Ababa, Ethiopia was 11.6 % (17), and in a study in Northern Tanzania was 16.4 % (18), Mwanza, North-western Tanzania (14.6 %)(19), and Khartoum North Hospital, Sudan (14.0 %) (20).

This variation may be explained by the differences in the environment, social habits of the community, the standard of personal hygiene and education. Also the fact that this study was conducted among women who had lower abdominal pains, which is a symptom of UTI, as opposed to the general ANC women studied in the other studies, explains the slightly higher prevalence of 26.7% in our study. There was no association between maternal age, Parity, gravidity, occupation, marital status and education with UTI in this study. This was in agreement with studies in Tanzania (19) and Sudan (20).

Other studies had earlier showed that age, parity and previous history of UTI were risk factors. But closer analysis of the published literature revealed that the age and parity had no correlation with UTI in pregnancy. For example, some studies showed that the prevalence of UTI increased with age (22), while others found it more with a younger age group (23). There was no difference in prevalence of urinary tract infection in pregnant women with previous history of urinary tract infection and those without. This was in contrast to studies in Pakistan which had shown that previous episode of UTI was a risk factor urinary tract infection in pregnancy. This might have been due to effective treatment for the earlier UTI episodes without any resistance strains.

Results show that the dipstick test and the urine microscopy tests have high sensitivity and specificity with equally high negative and positive values in screening for urinary tract infection. These are simple and inexpensive tests that can be used to predict UTI in centers where urine cultures are not available. The dipstick and urine microscopy are easy simple and fast tests that can be used for fast prediction of UTI and avoidance of delays in treatment

Gram-negative bacteria isolate were more prevalent (75%) than Gram-positive bacteria isolates (25 %). Similar rate of isolation of Gram-negative and Gram-positive

Bacteria, 60 % and 40 % respectively, were reported in Tikur Anbessa Specialized Hospital Addis Ababa, Ethiopia [17] and 61.9 % and 38.1 % in Tanzania [26]. This could be due to the presence of unique structure in Gram negative bacteria which facilitate their attachment to the uro-epithelial cells, multiplication and tissue invasion, resulting in invasive infection and pyelonephritis in pregnancy (9.)

E. coli was the most predominant pathogen with overall isolation rates of 40.0%. Comparable findings have been reported in Yemen, 41.5 %, Nigeria, 42.1 %

 Khartoum North Hospital, Sudan 42.4 % [20], and Tikur Anbessa Specialized Hospital Addis Ababa, Ethiopia44 %. E. coli is the most common microorganism in the vaginal and rectal area [29]. Anatomical and functional changes and difficulty of maintaining personal hygiene during pregnancy may increase the risk of acquiring UTI from E.coli. Gram-positive staphylococci were the second dominant pathogen with overall isolation rate of 25 %, comparable findings were also reported from Tikur Anbessa Specialized Hospital Addis Ababa, Ethiopia 16 % (17), and Tanzania 16.7 % (23).

There was high correlation between positive testing on dipstick and urine microscopy and culture positive specimens. Of the 40 women with culture positive urine, 31 (77.5 %) were also positive on dipstick, and 27women (67.5%) were positive on urine microscopy.

. In this study, susceptibility pattern of Gram-negative bacteria showed that most of the isolates were sensitive to amoxicillin-clavulanic acid (100 %), ceftriaxone (100 %), meropenem (100%), gentamicin (72%), imepenem (100 %), levofloxacin (100%), ampicilin (50 %), and nitrofurantoin (100 %), ceftazidime (100 %) cefuroxime (81%) . The gram positive isolates showed a slightly different sensitivity pattern with 100% sensitivity to amoxicillin-clavulanic acid, cefuroxime, imepenem, meropenem, ceftazidime and ceftriaxone. There was significant resistance to gentamycin, levofloxacin, nitrofurantoin and ampicilin,. The easy availability and indiscriminate use of commonly used drugs such as ampicilin and gentamycin may lead to an increase to resistance.This is not in line with the report in Tikur Anbessa Specialized Hospital Addis In this study the effectiveness of amoxicillin-clavulanic acid to both Gram-positive bacteria   and gram negative bacteria is 100%. Therefore amoxicillin-clavulanic acid

may be used for empiric therapy. Some of the uropathogens isolated demonstrated resistance to more than 2 of the commonly used antibiotics. Staph species was resistant to ampicilin, nitrofurantoin, and gentamycin. Citrobacter was resistant to ceftazidime and

gentamycin. This was also reported in Tikur Anbessa Specialized Hospital Addis Ababa, Ethiopia [17].This can be explained by antibiotic overuse and abuse [31]. Other reasons for this phenomenon might be inappropriate and incorrect administration of antimicrobial agents in empiric therapies

6.6: Conclusions

In the current study, less than one third ofpregnant women presenting with LAPs were confirmed with bacterial UTI. Use of simple dipstick or urine microscopy predicted more than three quarters of culture positive UTI. there was high sensitivity of the bacterial isolates to ceftaziddime, ceftriaxone, meropenem, imepenem, and amoxicillin- clavulanic acid. A small number of the isolates were resistant to ampicillin, gentamycin, nitrofuratoin. Drug resistance was minimal but present.

.6.7: Recommendations

Given a low prevalence of UTI of 26.7%, there is no justification for empirical treatment of pregnant women with lower abdominal pains for urinary tract infection. This would mean that over 70% of women with lower abdominal receiving unnecessary antibiotic treatment. It is recommended that   a simple dipstick test be done prior to administration of antibiotics, and routine antibiotic profiling be done to advise clinicians on prescription patterns. In view of our study findings we recommend amoxicillin-clavullunic acid as a first line drug in treatment of urinary tract infections on the basis of its demonstrated high sensitivity, safety, wide availability and inexpensiveness.

That nitrofurantoin hitherto regarded as a highly effective drug for treatment of UTI especially in outpatient setting, is still 100% effective against gram negative bacteria but showed significant 50% resistance to gram positive bacteria as per this study finding. Gentamycin and ampicillin have very low sensitivity and should not be used in the unit.

We also recommend that regular microbial screening and sensitivity profiles should be done with a broader microbial profile to include non bacterial aetilogy like candida, mycoplasma and others. Dipstick testing of urine and simple microscopy of centrifuged urine sediment is recommended as a screening test for antenatal women with lower abdominal pains suspected of urinary tract infection.

We also recommend a similar but comparative study with the HIV positive pregnant women to observe for any variation in the prevalence of UTI, the microbiological profiles and their sensitivity patterns.

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8.0 APPENDICES

8.1: Appendix 1

Consent form

Study tittle: PREVALENCE, MICROBIAL ETIOLOGY, AND SENSITIVITY PATTERNS OF URINARY TRACT INFECTION
IN WOMEN, PRESENTING WITH LOWER ABDOMINAL PAINS, IN KNH STUDY

Investigator	Institution	Contact
Dr Nabbugodi W. Fred	Kenyatta National Hospital/University of Nairobi	0723- 459595 0735-256525

Investigator's statemement

My name is Dr Nabbugodi W. Fred, am doing this study as part of the requirements to complete a specialist degree in obstetrics and gynecology in university of Nairobi. The purpose of this form is to give you information about the study. Kindly read it carefully, and ask me questions about anything that is not clear to you, regarding what I will ask you to do, the risks and benefits involved and your rights as a volunteer. You can also ask a bout anything you wish to know about the study. When all is well under stood to you can make an informed consent whether to participate in the study or not. If you wish to be contacted with the results of the tests, you will be requested to provide your mobile telephone numbers. You will also be asked to sign or thumb print on the form as a sign that you have accepted by your choice to participate in the study.

Back ground information

You are being asked to take part in this study because you have lower abdominal pains in pregnancy. Lower abdominal pain is a common complaint in pregnancy. It can be caused by infections in the urinary bladder and kidneys or other conditions in pregnancy like early labour or intestinal problems. Infections in the bladder and kidney are called urinary tract infections are caused by germs called bacteria that can be treated with medications called antibiotics medications. If a pregnant woman does not have urine test, we can not be sure that the urine infection is causing the abdominal pains. This infection if untreated

can cause serious complications to the mother and her baby. We there fore some times ask you to take antibiotics as we wait for laboratory urine test. This study is to help to reduce over use of antibiotics and in making correct diagnosis for the abdominal pain.

Purpose

This study will find out how often lower abdominal pains in pregnancy is due to urinary tract infection. We shall know the common bacteria causing these infections in women coming to KNH and the best medications (antibiotics) to use to avoid complications from the infection.

Number of women to take part in the study

This study will enroll 150 pregnant women coming to KNH for treatment of lower abdominal pain

Procedures

If you agree to take part in this study, we shall ask you some questions related to you and your pregnancy we shall also ask you to provide urine for laboratory testing, the results of the urine test will be in your file and will be used to treat you

There will be only one visit for this study, that will over with your antenatal hospital visit or admission

Risks or discomfort

There is no anticipated mediate, short term, or long term risks or distresses that may arise out participation in this study. But should you be uncomfortable with any of the questions asked or with giving urine sample, you are free to decline and withdraw you consent. It will not in anyway affect your access to services in this department

Benefits and compensations

The information gained from this study will be used to treat you if you are found with an infection. The study findings will also be used to guide rational use of antibiotics in mothers presenting with lower abdominal pains in the department

There is no additional cost to you due to your participation in the study, and no physical injuries are anticipated. There will be no compensations

<u>Confidentiality</u>

Participation in this study is voluntary and you can decline and your consent without loss of any benefits or any penalties. Your name will not be used on the study data forms only study numbers will be used. All your personal information will be treated confidentially. The investigator may use the data for analysis and quality control purposes or publication but your identity will never be reported. The urine sample you provide shall only be used for purposes described in this consent form.

<u>Who to call in case of a query or problem after the study</u>

You can call the investigator on the phone lines listed below, and additional contacts for the supervisors and ethics and research committee

1. **Principal investigator-** DR. Nabbugodi W. Fred

                Telephone: 0735-256525/ 0723-459595

2. **Supervisors:**

            1. DR. Nelly Mugo

               Department of obstetrics and gynaecology

               University of Nairobi

               Telephone: 020-2726360.

            2. DR. Gichuhi Wanyoike

               Consultant obstetrician/gynaecologist

               University of Nairobi

               Telephone: 020-2726360

3. **KNH/UON Ethics and Research Board**

               Kenyatta National Hospital

               Telephone: 020-2726300 Ext44102.

Participants' statement and signature

The study described above has been explained to me. I have had a chance to ask questions and feel satisfied to make an informed consent to take part in this study. If in future I wish to ask any questions about the study I can contact the investigator through the provided contacts.

_____   _____

Participant signature/thumb print   Date

_____   _____

Witness's signature/informer   Date

Mobile number (optional)   _____

8.2: Appendix 2   `

Questionnaire

Date   _____

Patient's study number   _____

SECTION A: SOCIAL DEMOGRAPHIC CHARACTERISTICS.

1. What is your age in completed years? _____

2. What is your highest level of education?

   ☐ None (no formal education)

   ☐ Primary

   ☐ Secondary

   ☐ College/university

3. What is your current marital status?

   ☐ Single

   ☐ Married

   ☐ Divorced/separated

   ☐ Widowed

   ☐ cohabiting

4. What is your current occupation?

   ☐ House wife

   ☐ Student

   ☐ Self employed

   ☐ Formal employment

☐ Casual laborer

☐ Unemployed

5. Have you ever been treated for chronic kidney or bladder disease/problem?

☐ Yes

☐ No

☐ I do not know.

6a. how many times have been pregnant? _____

6b.of these pregnancies how many terminated before 7 months (28 weeks)? _____

7. How many living children do you have? _____

8. When was your last normal menstrual period ?_____GBD =_____

9. Have ever had any of the following operations before?

Operation	yes	no
C/section		
Myomectomy		
Laparatomy		
Pelvic surgery		

10. Have you been told that you have a urine infection in this pregnancy?

☐ Yes

☐ No

☐ Do not know

11. Do you suffer from diabetes?

☐ Yes

☐ No

☐ Do not know

11. Genital urinary symptoms.

      a.   Do you have pain on passing urine? _____

      b.   Do you have any discharge that stains your inner wears? _____

      c.   Do have any itching in you genital area? _____

      d.   Do have any bleeding from the birth canal? _____

12. Physical signs

Parameter	Present	Absent
pyrexia		
Pallor		
Abdominal tenderness		
Vaginal discharge		

8.3:APPENDIX 3:

 LABORATORY RESULT

Patients study no:

Urine microscopy

Crystals

Leucocytes

Bacteria

Epithelial cells

Casts

Yeast cells

Urine dipstick results

Glucose

Bilirubin

Ketones

Protein

Blood

Urobilinogen

Leucocytes

Nitrites

PH

Urine culture result

E. Coli

Klebshiella spp

Proteus spp

Citrobacter spp

Enterococcus spp

Staphylococcus spp

Drug sensitivity results

Augmentin

Cefuroxime

Ceftriaxone

Ampicilin

Gentamycin

Meropenem

imepenem

Nitrofurantoin

ceftazidime

APPENDIX 4:

ERC APPROVAL CERTIFICATE

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
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Ref: KNH-ERC/A/348

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
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
13 December 2012

Dr. Nabbugodi Willy Fred
Dept. of Obs/Gynae
School of Medicine
University of Nairobi

Dear Dr. Nabbugodi

RESEARCH PROPOSAL: PREVLAENCE OF URINARY TRACT INFECTION, MICROBIAL ETIOLOGY AND SENSITIVITY PATTERN AMONG ANTENATAL MOTHERS PRESENTING WITH LOWER ABDOMINAL PAINS IN K.N.H. (P481/08/2012)

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 13th December 2012 to 12th December 2013.

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**

Yours sincerely

PROF. A.N. GUANTAI
SECRETARY, KNH/UON-ERC

c.c.   The Deputy Director CS, KNH
        The Principal, College of Health Sciences, UoN
        The Dean, School of Medicine, UoN
        The Chairman, Dept. of Obs/Gynae, UoN
        The HOD, Records, KNH
        Supervisors: Dr. Gichuhi Wanyoike, Dept. of Obs/Gynae, UoN
                       Dr. Nelly Mugo, Dept.of Obs/Gynae, KNH