POST CAESAREAN SECTION SURGICAL SITE INFECTION, MICROBIAL PATTERNS AND SENSITIVITY TO ANTIBIOTICS AMONG WOMEN WHO DELIVERED AT KENYATTA NATIONAL HOSPITAL BETWEEN 2014 AND 2020.

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DECLARATION

This research has been undertaken in part fulfilment of the Master of Medicine in Obstetrics and Gynecology from the University of Nairobi and is my original work and has not been undertaken and presented for a degree in any other University.

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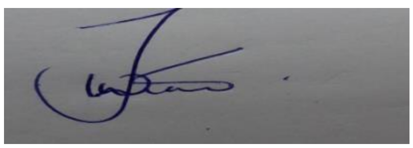
Signature  Date 23/03/2022

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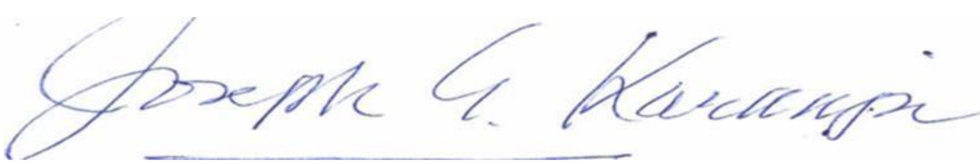

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DEDICATION

To God, my Higher Power, my source of wisdom, knowledge and strength.

To my mother,Charity Mutahi for her unconditional love and support, for giving me the best education and making me who I am today.

To my lovely son, Nathan Kirumwa, who has brought great joy and blessings into our lives. My source of inspiration and constant motivation during my training.

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OPERATIONAL DEFINITIONS

Surgical site infection: is defined as an infection that occurs within 30 days after the operation and involves the skin and subcutaneous tissue of the incision (superficial incisional) and/or the deep soft tissue (for example, fascia, muscle) of the incision (deep incisional) and/or any part of the anatomy (for example, organs and spaces) other than the incision that was opened or manipulated during an operation (1).

The CDC definition (Horan, et al., 1992) describes three levels of SSI(2):

1. Superficial incisional SSI- Infection affecting the skin and subcutaneous tissue. These infections may be indicated by localized signs such as redness, pain, heat or swelling at the site of the incision or by the drainage of pus.

2. Deep incisional SSI – Infection affecting the fascia and muscle layers. These infections may be indicated by the presence of pus or an abscess, fever with tenderness of the wound, or a separation of the edges of the incision exposing the deeper tissues.

3.Organ or space SSI – Infection which involves any part of the anatomy other than the incision that is opened or manipulated during the surgical procedure, for example joint or peritoneum. These infections may be indicated by the drainage of pus or the formation of an abscess detected by histopathological or radiological examination or during re- operation.

LIST OF ABBREVIATIONS

ACOG	American College of Obstetrician and Gynecologists
ANC	Antenatal Care
BMI	Body Mass Index
CDC	Centre for Disease Control
CS	Caesarean Section
KNH	Kenyatta National Hospital
MRSA	Methicillin-Resistant Staphylococcus Aureus
NICU	Newborn Intensive Care Unit
NNIS	National Nosocomial Infection Surveillance
SSI	Surgical Site Infection
WHO	World Health Organization

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ABSTRACT

Introduction: Surgical site infection (SSI) is a common complication following a Caesarean section which places an emotional and physical burden to a mother and has a significant financial burden to the health care system. SSI infections have been associated with maternal morbidity and mortality, and it is expected that the incidence of these infections are likely to go up with increasing number of Caesarean sections. At the Kenyatta National Hospital, being the largest referral hospital in Kenya has a Caesarean rate of about 30% of the total deliveries. There have been limited studies documenting the microbiology of the infections resulting from Caesarean deliveries at this setting.

Objectives: The objective of this study was to describe the characteristics of patients with SSIs and to determine the microbial pattern and sensitivity to antibiotics among women with surgical site infection post Caesarean delivery at the Kenyatta National Hospital.

Methodology: This was a cross sectional study of women who underwent a CS at the Kenyatta National Hospital and later developed surgical site infections. Clinical records of a total of 149 women who developed Surgical Site Infection (SSI) were examined. Demographic and clinical data were collected via an electronic data collection form. Data was analyzed using STATA version 15. Descriptive statistics were summarized as mean (standard deviation), median (Interquartile range) or frequencies (percentage). Results have been presented in tables and graphs.

Results: A total of 149 participant data were used. The mean age of participants was 27 (6.9) years, ranging between 15-45 years. Majority of the participants, 63/149(42.3%) had attained primary school education while 59/149 (39.6% and 27/149 (18.1%) had secondary and tertiary education respectively. Most of the participants were Christian 143/149 (96.0%), Unemployed 104/149 (69.8%) and most were married 121/149 (81.2%).

A total of 83 out of the 149 (55.7%) participants had a positive culture, while 66/149 (44.3%) had negative culture. The organisms grown by culture was E.coli 23/83 (27.2%), Staphylococcus aureus 16/83 (19.3%), Klebsiella pneumoniae 9/83 (10.8%) and Acinetobacter baumanii

9/83(10.8%). Other organisms grown were coagulase negative staphylococcus 8(9.6.%), enterococcus faecalis (4.8%) and others (4.8%).*E.coli isolates* were mostly sensitive to meropenem(82.5%) and mostly resistant to cephalosporins(62.5).*Staphylococcus aureus* isolates were most susceptible to gentamicin (75.0%)and were most resistant to benzyl penicillinampicillin (68.8%) .*Klebsiella pneumonia* isolates were most sensitive to meropenem(80%) and most resistant to cephalosporins(50%).

Conclusion: The most isolated organism was E.coli, which was mostly sensitive to meropenem and mostly resistant to cephalosporin.

1.0 INTRODUCTION

Caesarean section if performed when indicated to beneficial at saving the lives of mothers and fetuses(3)but when it is performed without appropriate indication, then there is added risk to both the mother and baby. Of concern is the dramatic rise of Caesarean deliveries over the past few decades, with an estimated 22.9 million Caesarean deliveries done in 2012 alone(4), which has led to a global consensus on the importance of combating these increasing rates. The World Health organization (WHO) recommends that Caesarean section deliveries should not account for more than 15% of all recorded deliveries in a hospital (5). Some hospitals have increased Caesarean deliveries rates as a strategy of preventing maternal deaths, and in some cases, the indications stated for Caesarean section, such as patient's preference, fear of vaginal delivery, social norms, and financial gain for hospitals, do not qualify as medical indication(6).

CS being a surgical procedure is prone to a host of complications such as surgical site infection (SSI). By definition, a SSI is described as an infection occurring within the first 30 days, post incision(7). Worldwide, the estimated rate of SSI ranges from 3% to 15% (8), and the variation of this incidence is reflective of the differences in characteristics of the population and associated risk factors, as well as the perioperative practices and the duration taken to perform the surgery.

The most common isolated organism is the *Staphylococcus aureus* which accounts for 15%–20% of cases, and is followed by the Gram-negative bacilli, coagulase negative staphylococci, *Enterococcus* species, and the *Escherichia coli* (9). Despite witnessing a notable decrease in the risk for developing SSI in the last three decades attributable to proper timing and use of antibiotic prophylaxis, coupled with significant improvements in the hygienic conditions and use of sterile procedures(8), it is expected that the occurrence of SSI will likely increase as the rate of Caesarean deliveries goes up thereby increasing the maternal morbidity and mortality(8). Recovering from a surgical procedure complicated by an SSI and taking care of a newborn may increase the burden to the mother in addition to the prolonged maternal hospitalization, additional heath care costs which may likely lead to other socioeconomic implications(8). Given the huge burden caused by SSI to the under-developed healthcare systems in the developing countries, there is no doubt that prevention of SSI should be a top priority in these countries.

Caesarean delivery is the most common major operation conducted across the globe. Worldwide, the rate of Caesarean deliveries accounted for roughly 15% of all deliveries as reported in a study published in 2007(8), however this prevalence was revised upwards in a study published by World Health Organization (WHO) in 2010 (10).

In a study conducted in India that analyzed 22,111 live births, the prevalence of Caesarean deliveries was higher in private hospitals compared to public hospitals a follow up analysis of where 13.7% Caesarean cases were from public hospital while 37.9% were from private hospitals(6). By 2015, the rate of CS in Kenya was estimated at 14.4%, which is higher than the African continent average. Data from Nairobi County revealed a CS rate of 24.9%, way above the national rate (11). The high CS rates in Nairobi are thought to be due to complicated cases being referred there from peripheral counties and, high number of private hospitals in the county and high number of patients accessing these facilities compared to the national figures. At Kenyatta National Hospital where this study was undertaken, the prevalence rate of CS is 30%(11).

Despite improved infection control practices around the world, surgical site infection (SSI) is still among the complications that ensue post Caesarean section (12). The infection can involve the tissues at incision or adjacent resulting to either superficial or deep tissue infection in addition to organs with close proximity to the incision site. In a study by Weigelt et al.(13), post-Caesarean section infections were linked to increasing the risk and prevalence of patient outcomes such as morbidity, mortality, high cost of care, length of hospitalization, hospital stay, and secondary infertility (13)(14). Furthermore, being diagnosed SSI was also associated with post-surgery bacterial load, especially at incision region and notable decline in host's immunity level (15).

A study done in Malaysia that included 400 Caesarean deliveries revealed that the incidence of SSI within the first 14 days was 18.8%(16). In another study conducted in Ethiopia that enrolled 592 mothers, 11.0% developed post CS SSI, with 70% and 26.1% of these infections being superficial and deep respectively (17). A different study conducted in Ethiopia involving 384 Caesarean deliveries in a teaching and referral hospital reported a SSI incidence of 6.8%(18). A study conducted in Kenya at Kiambu Level Five hospital revealed an SSI incidence of 19% rate(19)

2.0 LITERATURE REVIEW

2.1.1 Maternal Socio-and Bio-Demographic Factors

One of the most reported bio-demographic factors to have significant impact on development of surgical site infection is body mass index (BMI)(20). In general, the body mass index of more than 25 is often considered a critical factor affecting the adverse outcome of any form of surgery(21).The risk of SSI from a high BMI is postulated to be due to increase in adipose tissue which contributes to a large incision, reduced subcutaneous tissue circulation, and further trauma to area tissue following aggressive retraction (21). In a study by Schneid-Kofman et al, the findings reported an increase in imbalance and disruption of body immune homeostatic factors during wound healing for the overweight and obese patients(22). In concurrence to the link between high BMI and increased risk for SSI, Ketcheson et al found that pre-pregnancy weight of over 87kg or gaining over 30kg during pregnancy increased the risk of SSI recording to an adjusted risk ratio of more than 1.5(23). A study such as that done by Mpogoro et al, demonstrated that factors such as parity, gravidity, age, and gestational age did not show statistical significance influence on the risk for SSI for post CS mothers(24), elsewhere, Farret et al in their study also found that factors such pre-eclampsia, ethnicity, and education level did not show statistical significance in predicting the occurrence of SSI on the Caesarean section site (25).

2.1.2 Maternal Medical Factors

Anemia has emerged as a common medical condition predisposing Caesarean site infection, as it diminishes the body’s resistance to infections, which makes the incision site vulnerable for bacterial access to the body(21). A study involving 100 mothers with infections post-delivery indicated that 48% of them had anemia(26).

Poorly controlled blood sugar also has a significant influence on development of post-Caesarean incision site infection(21).Increased blood sugars spilling on the incision site acts as a catalyst to microbial propagation and multiplication leading to increased risk of SSI(26).Another health condition identified from a number of studies to have significant impact on predisposing SSI is immunosuppressive disorders(16). These disorders compromise the immunity level of the mother increasing the risk of opportunistic conditions and nosocomial infections while the patient is recovering from the CS surgery(21).

2.1.3 Labour Characteristics

Premature rupture of membranes predisposes surgical site infection among mothers post Caesarean section delivery. Prolonged rupture of membranes (which is premature rupture of membranes lasting over 24 hours) causes large bacterial inoculum causing the liquor to be infected consequently leading to infections. After rupture of membranes, the amniotic fluid losses the sterility shifting to being a medium for pathogen gaining access to the uterine and skin incisions(26).Delayed prophylaxis with appropriate antibiotics can result in the increase of the risk of SSI and septicemia.

A Tanzanian study by Mpogoro et al, found that those mothers who labored for over 18 hours before undergoing Caesarean section had an incident rate of 33% compared to an incident rate of 15% among those who labor for 12 hours of less(24).In the study they found that prolonged duration of labor was also reported as a significant factor influencing the risk for SSI among post CS mothers ($p = 0.002$)(26). Having progressed to second stage of labor before progressing to Caesarean delivery was also a predictive factor for SSI. There is a strong link between prolonged duration of labor, premature rupture of membranes and number of vaginal infections.

Vagina examination when done without adhering to aseptic techniques acts a means of introducing microbial into the vaginal and uterine cavity and has been associated with SSI(26).

2.1.4 Surgery Related Factors

Emergency Caesarean predisposes more to Caesarean site infection compared to elective Caesarean. Elective Caesarean is associated with fewer SSI due to the possibility of adequate preparation that is done before CS to ensure that the patient has been well educated, while all predisposing factors for SSI are addressed well in advance as opposed to those emergency cases where such preparation is not done due to the emergency nature of it (21).

Patient undergoing second or more CS deliveries have the risk of infection increased due to prolonged time of healing secondary to previous scaring. In another study, the higher wound class were associated with increased risks for SSI(24).The type of incision, vertical or transverse is also a critical predictor for incision site infection as reported in the literature. The evidence presented from previous studies indicates there is a progressive departure from the traditional vertical incisions to bikini incisions. A transverse incision is associated with a low possibility of wound dehiscence(21). In a study conducted in Tanzania, vertical skin incision was associated with high risks compared to bikini incisions with a ($p = 0.034$)(24). These findings are further supported by literature from different studies conducted across the globe (26-28).

The duration taken to complete the surgery procedure has an impact on the risk of SSI. Prolonged duration of operation lasting over one hour leads to higher risks as opposed to short durations operation ($p = 0.020$) (24). In a study by Devjani et al, 53.3% of mothers whose operation lasted over 45 minutes developed infections, a factor that was statistically significant ($p > 0.05$)(21). In another study, surgeries that lasted more than 2 hours recorded a rate of 38.46% for SSI(27). In support to the evidence linking prolonged duration of surgery to SSI.

Procedures performed by junior doctors were significantly more prone to SSI compared to those done by experienced obstetricians(24). The amount of blood loss during surgery, also can predispose a mother who has delivered through CS to SSI. According to Tran et al, the risk of SSI increases by roughly 30% for every 100 milliliters of blood loss. Increased blood loss results in prolonged retraction, more suturing, prolonged duration of operation and increased tissue damage due to site manipulation to arrest the bleeding(16).

The vitality of controlling the risks and rate of SSI for post-CS mothers is a major goal that has seen profound efforts made to prevent maternal mortality cases secondary to Caesarean section. One of the reported interventions towards reducing or controlling the levels of SSI obstetric is provision of prophylactic antibiotics for mothers prior to CS(21).The medications are either administered before delivery or post-delivery depending with the level of risk as per patient assessment. However, the debate is no yet over on the use of prophylactic antibiotics in CS patients.

In some cases, administrations of prophylactic antibiotics are withheld only to be administered after the clamping of the umbilical cord. Mainly, the patient is given the selected antibiotic(s) during/after the membranes have ruptured or half an hour before the operation. Timing is crucial in prophylactic antibiotics administration with evidence linking less SSI for patient who had the drugs administered within two hours as opposed before operation as oppose to untimely administration. De et al in this study noted the common prophylactic drugs used before CS included ampicillins, metronidazole, and gentamicin. However, they noted the drugs varied depending with the level of exposure, culture and sensitivity of the lab result(21).

Given the association between the operating rooms and their influence on predisposing nosocomial infections and SSIs, efforts such as strict adherence to aseptic technique should be followed(28). The operating rooms should be sterilized, with the operation equipment sterilized, and adequate ventilation ascertained. The operating teams should be advised to use barriers methods to prevent transmitting microbial agents to the patient (29).

Patient at risk of SSI should be identified in advance and appropriate measures taken to reduce the risks, for instance, evidence from a study assessing the impact of glycemic control on postoperative infections indicated that controlled blood sugars among diabetic patient reduced the risks of postsurgery infections(30).

Patient preparation involves adequate education on hygienic practices and early ambulation. Cleaning the incision site with topical antimicrobial agents such as chlorhexidine solution also reduces the risks of SSI (31).

The most isolated pathogens in post Caesarean section SSI are the Gram-negative bacteria, anaerobes, and Staphylococcus aureus. In a study by Gur et al, enteric gram negative bacilli were reported to be the most common causes of surgical site infection post CS followed by enterococci and gram B streptococci among the aerobic organisms.(32) For the anaerobic microbes, Clostridia and *Bacteroicides spp* were the most common, mainly introduced due to multiple vaginal examinations. In another study, *Acinetobacter* species (32.03%) had a high prevalence in SSIs (21) while National Nosocomial Infection Surveillance (NNIS) service survey covering 1997 through 2011 in England identified *Staphylococcus aureus* (47%) with MRSA and *Staphylococcus epidermidis* as top most pathogens noted in cases of SSI (33).

From the literature reviewed, a number of studies have identified predominance of *Staphylococcus aureus* in wound infections. The *S. aureus* and *S. epidermidis* were more common to with an average rate of 22.1% of the isolated organism(21). Polymicrobial etiology was found in 7 out of 121 SSIs identified. In support to this observation, a study by Lilani et al. reported polymicrobial etiology present in two out of seven SSIs cases where one of the most prevalent bacteria isolated was *Staphylococcus aureus*(27). *Staphyococcus aureus* elicits significant interest and special attention given its notable role in common nosocomial infections and emergence of virulent antibiotic resistant strains. In a study done in India by De et al, 66.67% of S. aureus strains were found to be resistant to penicillin (21).

In a study involving 600 participants who delivered via CS at the University of Calabar Teaching Hospital, Nigeria, it was found that gram-negative organisms were more prevalent (62.7%) than gram-positive bacteria (37.3%) in those with infected CaesareanCaesarean incision site. The isolated bacteria were *S. aureus* (37.3%), *Klebsiella pneumoniae* (27.1%), *E. coli* (22.0%), *Pseudomonas aeruginosa* (5.1%), *Klebsiella oxytoca*(5.1%), and Bacteroides (3.4%) (34).

Prophylactic antibiotics mostly suggested was STAT dose of cephalosporin (1st generation) or penicillin than other antibiotics(35). Those with significant history of allergic reactions to cephalosporin should be considered for a single dose of combined clindamycin and aminoglycosides. The dosage should be dependent on the patient's body mass index (BMI) with those having a BMI less than 30 taking 1 gram (cefazolin) while those with BMI over 30 taking 2 grams of cephalosporin (cefazolin)(36).

In a study done at the People's Hospital of Linyi in Shandong, China, found that the frequency on antibiotic use in postnatal ward for post Caesarean incision site infection showed Beta-lactam antibiotics as the most used at 25% followed by macrolides at 23%, beta-lactamase inhibitors at 22%, cephalosporin at 20% and Fluoroquinolone at 10%(37).

At the Kenyatta National Hospital, antibacterial therapy is guided by the nature of the operation and patient's baseline characteristic. For emergency caesarean section, the preferred antibiotics include Cefazolin (15 minutes to 60 minutes) before skin incision, or Clindamycin or erythromycin for those with penicillin allergy. For those CS deliveries involving patients with chorioamnionitis, amoxicillin/clavulanic acid, or cetriaxone combined with metronidazole are preferred. Patient with PROM, prolonged labour, over 5 vaginal examinations, PPH, or prolonged surgery, they should receive broad spectrum antibiotics, especially cefazolin plus azithromycin (38).

In a study by Kaplan et al, 86.9% of 107 infected wounds post Caesarean section had culture positive lab results(39). Out of these, *Staphylococcus aureus* was the most common found organism at 42%. Organisms seen by Gram stain yielded a sensitivity of 96.6%, specificity of 88.9%. The positive predictive value was at 97.7% and negative predictive value of 84.2% when used to predict positive culture results for bacterial wound infection (39). *S. aureus* resistance to methicillin has been reported in some studies at 23.8%. MRSA infections are of great concern due to high morbidity and mortality rates.In a study conducted in Nepal, Staphylococcus strains showed resistance to penicillin at 84.6% and 58% for vancomycin (40).These findings were consistent with literature evidence on ineffectiveness to penicillin by these strains of bacteria

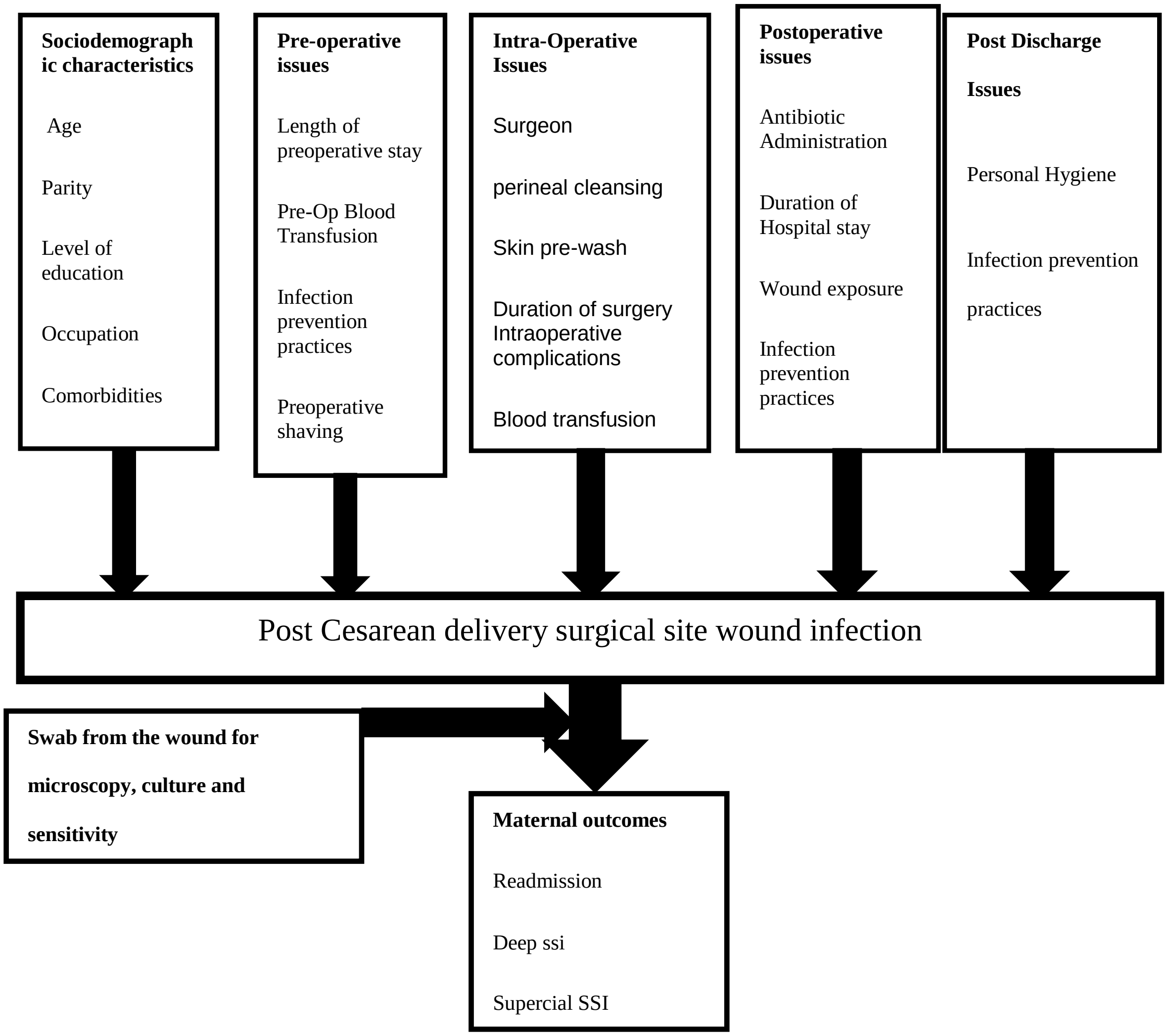
(39). Amikacin has been demonstrated to have sensitivity of over 96% for Staphylococcus group. Other effective drugs to Staphylococcus group include imipenem, meropenem, and linezolid(40).

Ciprofloxacin, which is often used as a prophylaxis drug for Caesarean mothers recorded high insensitivity for methicillin-resistant *Staphylococcus aureas*. Similarly, the resistance for cephalosporin and clavulanate was also high between 88-100%(40).However, there were contradictory data on cephalosporin resistance from two studies conducted in Nepal showing a resistance of 12%(41) and 17% (42).

In summary, a number of studies have focused on understanding predictive factors, preventive and management of post Caesarean section incision site infections. The evidence presented indicates that there are common predictive factors ranging from those that fall in maternal profile, medical conditions, labor related factors, and surgery related factors. The frequency of common pathogens associated with incidences of surgical site infections post Caesarean section varies from one setting to another. This variation makes it more important to undertake a study at Kenyatta National Hospital in order to understand the situation and possibly come up with prevention measures and appropriate antibiotics to initiate on patients who develop SSI.

3.0 CONCEPTUAL FRAMEWORK

Figure1: Conceptual Framework



The conceptual framework shows how the interrelation of socio-demographic factors, the pre-operative, intra-operative, postoperative, and post-discharge issues are linked to the post Caesarean delivery surgical site wound infection as discussed in the literature. The maternal and fetal outcomes are dependent on the antibiotic cover offered as well as findings of the swab taken from the surgical site wound which is done for microscopy, culture and sensitivity. The literature has extensively examined the relations as shown from ***Figure 1*** above.

4.0 STUDY JUSTIFICATION

To put the study into perspective, there is every need to ensure that patient undergoing Caesarean delivery does not develop SSIs. Patients who develop SSI post CS delivery have a 2–11 times higher risk of death than those without surgical site infections(18). Furthermore, majority (77%) of deaths associated with surgical site infections are directly linked to SSI (18). As far as the researcher is aware, there is a research gap on the common microbial causing infection after Caesarean section and their sensitivity patterns in Kenyatta National Hospital Obstetrics and Gynecological department. Limited studies have been done on microbial and drug sensitivity SSI post CS at Kenyatta National Hospital; this study will help clinicians develop treatment protocols of SSI.

Clinicians find it most challenging delivering empirical therapy due to the existing evidence gap. Understanding the patterns can help fill the gap on current paucity of studies on the extent to which anaerobes are involved in the etiology of SSI post Caesarean delivery. A clearer understanding of the spectrum of pathogens mostly associated or identified in SSI cases and their susceptibility pattern is imperative. Such an understanding would offer improved patient care and delivery of evidenced-based antibacterial therapy prescribed timely soon after SSI is diagnosed. The timely intervention would then enable suppression of the pathogen reducing the risk of complications while awaiting wound swab microscopy, culture and sensitivity in 48-72 hours. Ultimately, the availability of such data would come in handy towards informing an effective management protocol for hospital prevention, aggressive surveillance, and management of SSIs.

5.0 RESEARCH QUESTION

What is the microbial and drug sensitivity patterns among women with postsurgical site infection following Caesarean section delivery at the Kenyatta National Hospital?

6.0 STUDY OBJECTIVES

To determine the microbial and drug sensitivity patterns among women with surgical site infection post Caesarean delivery at the Kenyatta National Hospital.

1. To describe the clinical characteristics of patients who develop surgical site infection following Caesarean delivery at the KNH between 2014 and 2020.
2. To determine the microbial patterns among women with postsurgical site infection following Caesarean section delivery at KNH between 2014 and 2020.
3. To determine the drug sensitivity patterns of the microbial causing surgical site infections following Caesarean section delivery at KNH between 2014 and 2020.

7.0 METHODOLOGY

7.1 Study Design

The study was a descriptive cross –sectional study. This was because the study sort to describe the characteristics and patterns of microbial and their drug sensitivity causing SSI in Kenyatta National Hospital.

7.2 Study Site

The study was conducted by examining records at the records department of the women who underwent Caesarean section at Kenyatta National Hospital and had developed post Caesarean section surgical site infection and readmitted to the post-natal wards(GFA,GFB,1A and ward 1D (Acute gynecology ward) at the Kenyatta National Hospital. The hospital serves as a training site for University of Nairobi's College of Health Science as well a national referral facility. The Reproductive Health Department consists of the maternity theatre, NICU, ANC, antenatal and postnatal wards, as well as the gynecology ward.

There is a standard guideline to empherical antimicrobial therapy, which was developed by the KNH Antimicrobial Stewardship committee since 2014 and reviewed in 2018.

7.3 Study Population

The study consisted of medical records of 149 women who had undergone Caesarean section (elective or emergency) at KNH and developed surgical site infections.

7.4.1 Inclusion Criteria

All patients whose records had complete results on, microscopy, culture and sensitivity of pus swabs taken from the infected post Caesarean section surgical site having had the Caesarean section at KNH.

7.4.2 Exclusion Criteria

- All patients admitted with SSI after having had CS in other hospitals.
- All patients who ***did not*** have a pus swab taken from the infected surgical site hence had no results on microscopy, culture and sensitivity of the same.

7.5 Sample Size Determination

This was a descriptive cross sectional study

Sample size was calculated based on desired accuracy. The target population was estimated at 200 women who get SSI post CS.

We estimated the proportion of deep tissue infections at 50% since there were no preceeding studies. Using a p= 50% and N (finite population) = 200, the formula below was used to calculate the sample size .The final sample was then inflated by 10% to account for any inaccuracies or incomplete data from the chart review.

Z= 1.96, p = 0.5 (50%), e = 0.05 N= 200

The approximate final sample size required is 146.

$$\text{Sample size} = \frac{\dfrac{z^2 \times p\,(1-p)}{e^2}}{1 + \left(\dfrac{z^2 \times p\,(1-p)}{e^2 N}\right)}$$

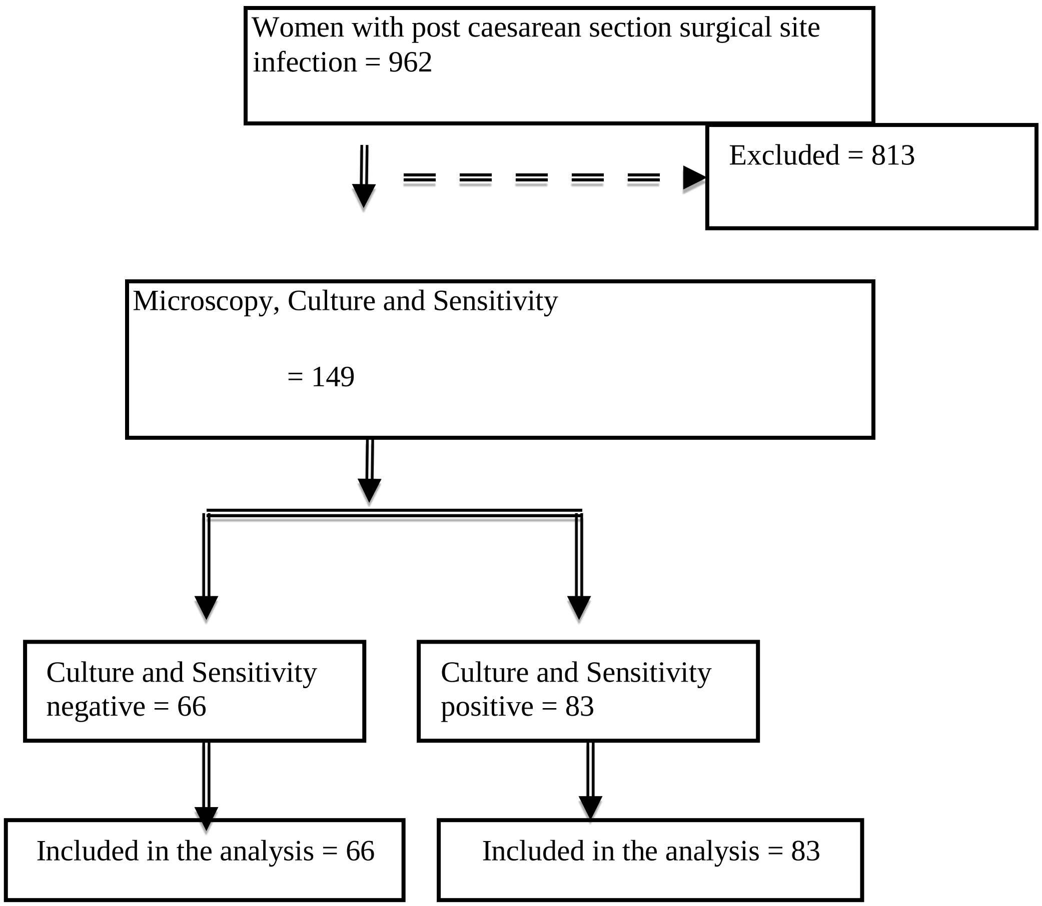
7.6 Sampling Procedure

A random sample of records of all patients with a diagnosis of post Caesarean section surgical site wound infection was selected for the study. The data was collected from February 2020 to

February 2014. 962 Medical records of patient who had developed SSI , were examined and 813 files were excluding for various reasons most of which lacked results of the pus swab microscopy , culture and sensitivity .

7.7 Study Flow

Figure 2: Study Flow



7.8 Data Variables

Table1: Data Variables for each objective described in the study

Objectives	Exposure Variables	Outcome Variables	Source (s) of Data

To describe the socio demographic and reproductive characteristics of patients who develop surgical site infection following caesarian delivery at the KNH	1. Age 2. Occupation 3. Parity 4. Religion **medical comobidities** 1. HIV Status 2. Diabetes mellitus 3. Anemia **Labour characteristics** 1. PROM 2. PPH 3. Prolonged labour	SSI	1. Patient Files
To assess the microbial and drug sensitivity patterns among women with post-surgical site infection following caesarian section delivery	1. Microscopy, culture and sensitivity	1. Microscopy, Culture and Sensitivity patterns	Study data collection tool Laboratory results
To describe the antibiotics used in the management of patients with SSI following caesarian	1. SSI	1. Type of antibiotics used	Study data collection tool

section at the KNH	
	Patient's records/files

Data was collected by the principal investigator and the research assistants from the patients' records using a specially designed data collection form and entered to an Excel spreadsheet prior to exporting to STATA 15 software for coding and analysis.

7.10 Data Management and Analysis Data

was analyzed using STATA 15.

Before analysis, the variables were checked for outliers, inconsistencies, missing data and distribution. Visual inspection of all continuous variables using scatter plots, box plots or histograms was done to identify outliers and distribution of the data. There was grouping of the categorical values especially where the numbers were small.

Descriptive analysis was carried out to provide a description of the population characteristics through means (standard deviations) or medians (interquartile range) and frequencies (percentages) and presented in the tables shown in the results section.

Frequencies were used to describe the pattern of antibiotic sensitivity or resistance.

Sensitivity and specificity were carried out to compare the utility of gram staining compared to the culture as gold standard. Predictive values and their 95% Confidence intervals were also computed.

Bivariate analysis was carried out to determine association between clinical characteristics and maternal outcome of whether the participants had deep surgical site infection or superficial surgical infection. Odds ratios and their 95% Confidence intervals were calculated to determine this.

The study is data was analyzed using STATA 15 as per the study objectives as follows:

1. **Objective 1**: **To describe the clinical characteristics of the study participants:** This was presented as using means and standard deviations for continuous data, as well as frequencies and proportions for categorical data.
2. **Objective 2: To assess the microbial and drug sensitivity patterns among women with post-surgical site infection following Caesarian section delivery:** This was analyzed and presented as frequencies and proportions.
3. **Objective 3: To describe the antibiotics used in the management of patients with postsurgical site infection following Caesarian section at the KNH:** This was analyzed and presented as frequencies and proportions.

8.0 ETHICAL CONSIDERATIONS

Permission was sought from the KNH and UON Ethics Research Committee (ERC) to carry out this study as part of the UON thesis dissertation.

Before commencing the study, administrative approval was obtained from KNH research department, and Obstetrics and gynaecology department.

The participant's personal details were not be used, instead they were assigned a unique identifier, only applicable to the study. This coded information was uploaded to an Excel spreadsheet with password protection. Back up data was kept in a password encrypted external hard drive, only known to the PI.

All information was handled with utmost confidentiality throughout the study period, held in trust by the investigator, research assistants and the study institution. A password protected computer with access permitted to primary investigator and research assistants only was used.

9.0 RESULTS

Table 2: Baseline characteristics of women who developed post Caesarean SSI in KNH between 2014 and 2020

Maternal characteristic		**Frequency**
Age	< 25 years	76(51.0%)
	≥25years	73(49.0%)
Education	none/Primary	63 (42.3%)
	Secondary	59 (39.6%)
	Tertiary	27 (18.1%)
Religion	Christian	143 (96.0%)
	Muslim	6 (4.0%)
Employment	Unemployed	104 (69.8%)
	self employed	31 (20.8%)
	formal employment	14 (9.4%)
Marital status	Single	21 (14.1%)
	Married	121 (81.2%)
	widowed/divorced	7 (4.7%)

The mean age of participants was 27 years. Majority of the participants had none or primary education 42.3%. (96 %) were Christians while (4 %) were Muslim. Majority were unemployed with (69.8%). Most were married (81.2%).

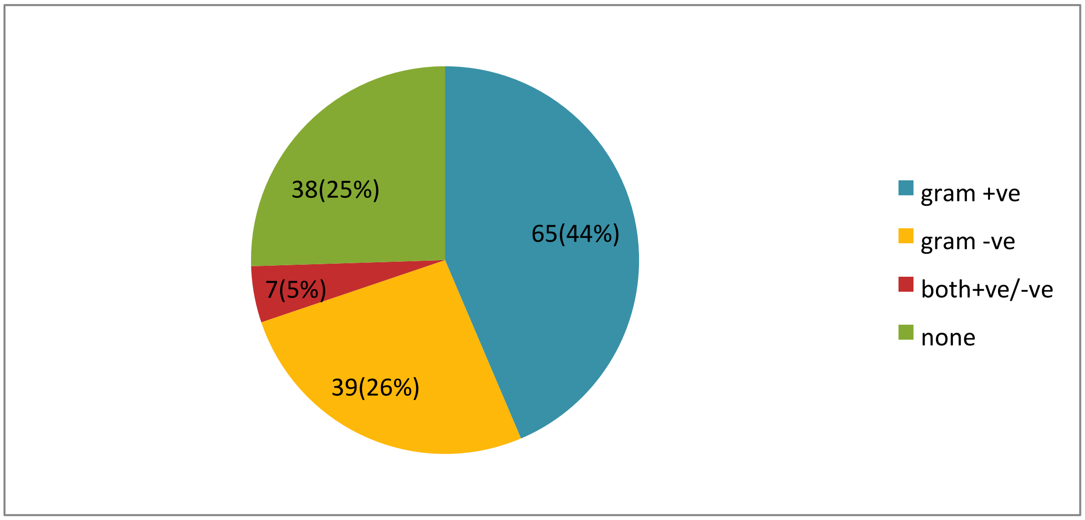
Table 3: Clinical characteristics of women who developed post Caesarean section SSI in KNH between 2014 and 2020

Clinical characteristic		**frequency N=149**
Parity	1	58 (38.9%)
	2	42 (28.2%)
	>3	49 (32.9%)
Hemoglobin level mg/dl	<10g/dl	19(12.8%)
	≥10g/dl	130(87.2%)
Diabetes	Yes	4 (2.7%)
	No	145 (97.3%)
HIV status	Reactive	8 (5.4%)
	Non-reactive	141 (94.6%)
Type of C/S	Elective	8 (5.4%)
	Emergency	141 (94.6%)
History of PPH	Yes	5 (3.4%)
	No	140 (94.0%)
	Not reported	4 (2.6%)
Post-partum hemorrhage during the c/s	Yes	18 (12.1%)
	No	131 (87.9%)
Premature rupture of membranes	Yes	7 (4.7%)
	No	142 (95.3%)
Surgeon	Consultant	16 (10.7%)
	MO/Registrars	133 (89.3%)
Length of Labour	Prolonged labour	117(78.5%)

	Not prolonged labour	32(21.5%)
Duration of surgery	< 60mins	82(55.0%)
	60mins -90 mins	42(28.4%)
	>90mins	25(16.8%)
Post- op day that SSI developed	7^{th} day	36 (24.2%)
	8 – 14^{th} day	85 (57.0%)
	$\geq 15^{th}$ day	28 (18.8%)
Type of SSI	Superficial SSI	79(53%)
	Deep SSI	70(47%)

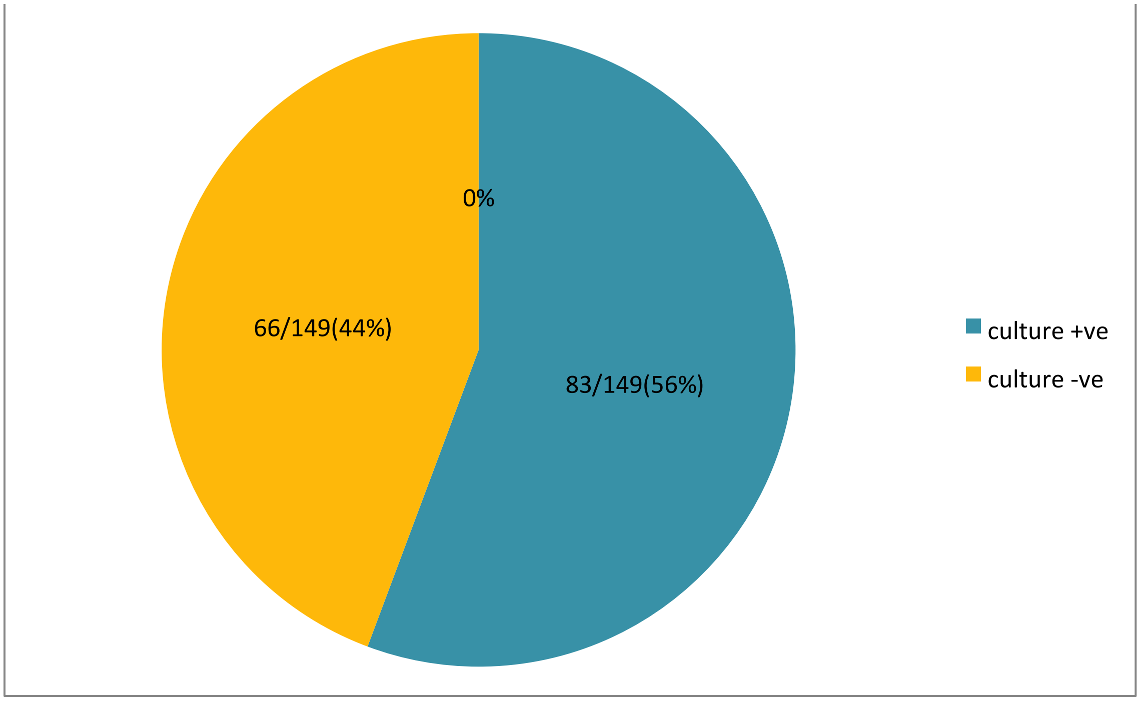
Most Women who developed post C/S SSI had emergency Caesarean section 141(94.6%). Most had prolonged labour 117(78.5%). Most of the Caesarean sections that preceded the SSI were done by medical officers and resident doctors 133(89.3%). Most women had SSI develop between the 8^{th} and 14^{th} day post-operatively 85(57.0%), while most women developed superficial SSI 79(53%).

Figure 3: Distribution of Gram Stain Microscopy results seen in women who developed SSI in KNH between 2014 and 2020



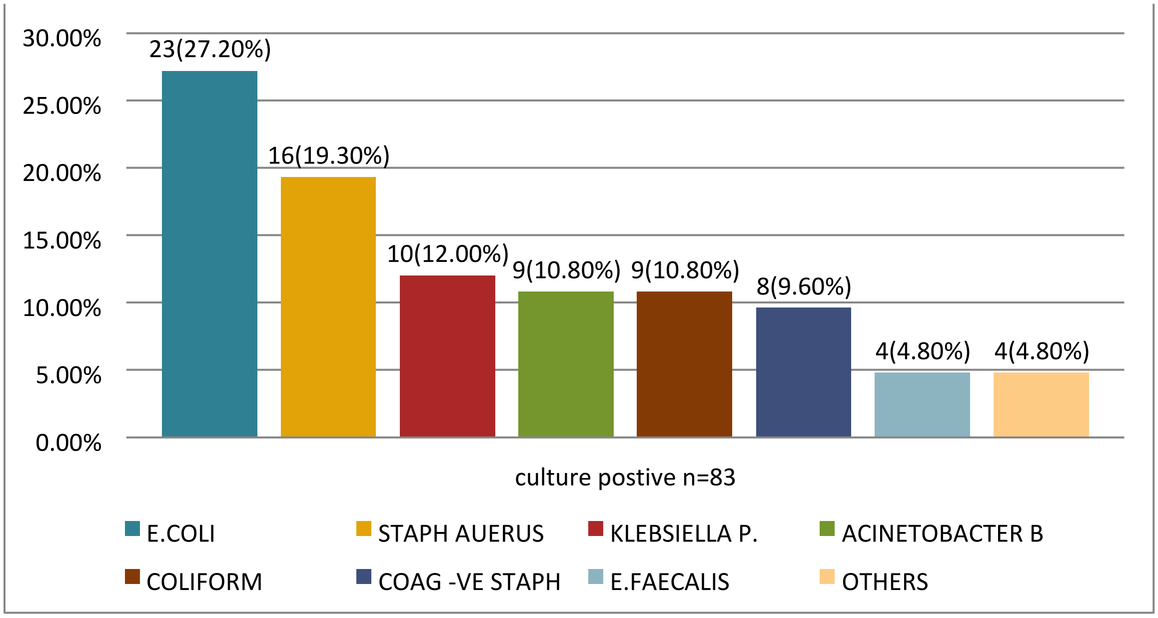
The most commonly observed organisms microscopically stained gram positive 65(44%). While only 7(5%) had both gram-positive and gram-negative organisms.

Figure 4: Distribution of outcomes of culture results of pus swabs taken from women who developed SSI in KNH between 2014 and 2020



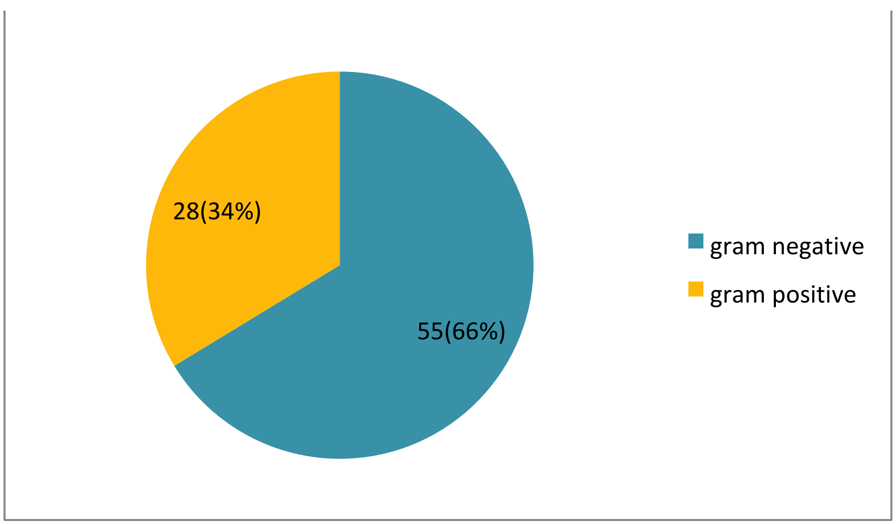
Most pus swab cultures taken from the women who developed SSI in KNH between 2014 and 2020 were positive for growth of an organism 83(56%)

Figure 5: Microbial Patterns of Isolated Organisms from wound pus swabs of women who developed SSI at KNH between 2014 and 2020.



The most commonly isolated organism from wound pus swabs of women who developed SSI at KNH between 2014 and 2020 was E. Coli 23(27.2%), followed by Staphylococcus Auerus 16(19.3%). Acinetobacter and Klebsiella both contributed to a large number of SSI at 9(10.0%) each.

Figure 6: Bacterial Categories isolated on wound pus swabs of women who developed SSI at KNH between 2014 and 2020.



Most isolates cultured on the wound pus swabs of the women who developed SSI at KNH between 2014 and 2020 were gram negative organism 55(66%).

Table 4: The Culture Sensitivity, Specificity and predictive values of the microscopy and culture results of wound pus swabs from women with SSI at KNH between 2014 and 2020

Parameter	Value	95% CI
Sensitivity	86.8%	77.52% to 93.19%
Specificity	40.9%	28.95% to 53.71%
Positive Predictive Value (*)	64.9%	59.76% to 69.65%
Negative Predictive Value (*)	71.05%	56.85% to 82.05%

Organisms seen by Gram stain yielded a sensitivity of 86.8%, specificity of 40.9%. The positive predictive value was at 64.9% and negative predictive value of 71% when used to predict positive culture results for bacterial wound infection.

Table 5: Distribution of microbial drug Sensitivity to Antibiotics as cultured on wound pus swabs of women who developed SSI at KNH between 2014 and 2020

	Antibiotic sensitive to	**Antibiotic resistant to**
E. coli 23(27.7%)	Meropenem (19= 82.6%) Amikacin (17 =73.9%) Ciprofloxacin (14=60.9%)	Ceftriaxone (15=65.2%) Cefuroxime (15=62.5%) Ampicillin (12=51.2%) Augmentin (10=43.1%) Cefepime (10=43.1%)
staph aureus16(19.3%)	Gentamicin (12=75%) Levofloxacin (10=62.5%) Vancomycin (7=43.8%)	Benzyl penicillin/Ampicillin (11=68.8%)
Klebsiella pneumoniae10(12.0%)	Meropenem (8=80.0%%) Ciprofloxacin (7=70.0%)	Cefuroxime (7=70.0%) Cefepime (5=50%) Ceftriaxone (5=50%) Ampicillin (5=50%)
Acinetobacter 9(10.8%)	Gentamicin/amikacin (5=55.6%)	Cefepime (9=100%) Ceftriaxone (9=100%) Meropenem (9=100%) Augmentine (6=66.7%)
coliform bacilli 9(10.8%)	Ceftriaxone (6=66.7%) Imipenem/meropenem (6=66.7%)	Augmentine (6=66.7%)
coagulase negative staph8(9.6%)	Vancomycin (8=100.0%)	Penicillin (7=87.5%)
E. faecalis 4(4.8%)	Vancomycin (3=75.0%) Teicoplanin (3=75.0%)	Erythromycin (3=75.5%) Gentamicin (2=50.0%)
Others 4(4.8%)	Ceftriaxone/cefuroxime (3=75.0%) Meropenem (2=50%)	Amikacin (2=50.0%) Benzylpenicillin (2=50.0%)

***Escherechia.coli** isolates* were mostly sensitive to meropenem(82.5%) and mostly resistant to cephalosporins(62.5%).

Staphylococcus aureus isolates were most susceptible to gentamicin (75.0%)and were most resistant to benzyl penicillinampicillin (68.8%).

Klebsiella pneumonia isolates were most sensitive to meropenem(80%) and most resistant to cephalosporins(50%).

Acinectobacter bauminni isolates were most sensitive to gentamicin and amikacin(55.6%) and of note all the acinetobacter isolates were resistant to cefepime(100%), ceftriaxone(100%) and meropenem(100%), while 6 were resistant to augumentine.

Coliform bacilli isolates were mostly sensitive to ceftriaxone (66.7%) and imepenem/meropenem(66.7%),while they are mostly resistant to augumentine (66.7%)

Coagulase negative staph isolates were(100%) sensitive to vancomycin, and (87.5 %)resistant to penicillin.

E.Faecalis isolates were mostly sensitive to vancomycin(75%)and teicoplanin(75%). And mostly resistant to erythromyicin(75%).

10.0 DISCUSSION.

The socio-demo graphic characteristics of the patient didn't have any association with development of surgical site infection. This compares with a study by Kabau that showed no association between the social demographic characteristic of the patient and the type of surgical site they developed (43)

Emergency Caesarean section predisposed women more to SSI as compared to elective surgery (21). In the present study a similar observation was made. Out of 149 patients who were infected, 141(94.6%) of them had undergone emergency, while only 8(5.4%) underwent elective Caesarean section. In our study ,Premature rupture of membranes (PROM) and prolonged labour were strongly associated with development of SSI this compared to a study by Mpogoro et al that found women who laboured for more than 18 hours had 33% incident rate of SSI as compared to an incident rate of 15% among those who laboured for 12 hours or less (24)

In our study there was no significant association noted between development of SSI and anemia, HIV status ,duration of surgery and presence of diabetes , this was contrast with several studies that were showing a significant association of SSI and increasing maternal age, anemia, prolonged preoperative hospital stay, prolonged total duration of surgery and that of hospital stay, failure of timely antibiotic prophylaxis (within 30 minutes of skin incision), preexisting medical illness, and intra-operative blood transfusion(21). Of note in our study is that all the four patients who were diabetic developed deep SSI.

In our study most of the SSI developed within two weeks postoperative 121(81.2%) and 28(18.7%) developed after day 15 postoperative. This is similar to finding by Kabau that found Consequently, all the SSI that developed after discharge did so within two weeks post-discharge. Most of the surgical site infections 92.7 %(n=38) developed within 14 days after the CS while only 7.3% (n=3) of the infections developed by the 3rd day after the caesarean delivery. This also compared to a study by Alfaouzan et al(44) in Kuwait that showed 74.3% of SSI developed in the first 15 days post operatively and 25.7% developed after 15 days.

Superficial surgical site infections constituted the majority of the SSIs in our study at 79(53%) and 70(47%) for deep SSI this is comparable to multicenter study done in three African countries where 93 % of SSI were superficial (45).

In our findings organisms seen by Gram stain yielded a sensitivity of 86.8%, specificity of 40.9%. The positive predictive value was at 64.9% and negative predictive value of 71% when used to predict positive culture results for bacterial wound infection. This compared to a study by Kaplan et al. that found Organisms seen by Gram stain yielded a sensitivity of 96.6%, specificity of 88.9%, positive predictive value of 97.7% and negative predictive value of 84.2% when used to predict positive culture results for bacterial wound infection(39).

The microbial etiology of post CS SSIs has been shown to be diverse, being associated with both vaginal micro organisms such as Escherichia coli, group B streptococcus(GBS) and Enterococcus spp, or with nasopharyngeal florasuch as Staphylococcus aureus or skin flora such Staphylococcusepidermidis (39).Staphylococcus aureus has beenfound to be the most common cause of SSI post CS. Other organisms such as *Escherichia coli*, *Klebsiellaspp.*, *Pseudomonas aeruginosa*, *Enterobacter spp*, *Proteus spp* and *Enterococcus spp*, show a variable distribution pattern. However in this study; Escherichia coli was the most common isolate followed by staphylococcus aureus which is in contrast with most studies .Of note, in the current study is that E.coli isolates caused more of deep SSI at 14(60.9%) as compared to 9(39.1%) found in the superficial SSI. This also applied to Klebsiella pneumoniae causing more deep SSI 7 (70.0%) as compared to superficial SSI 3(30.0%), on the other hand staphylococcus aureus was noted to have caused more superficial infections 10(66.7%) .This was similar to a finding by Mpogoro et al(24) that showed *Staphylococcus aureus* was the most common isolate causing superficial surgical site infections while *Klebsiella pneumoniae*isolates were found in deep and organ surgical sites infections.

In our E.coli *isolates* were mostly sensitive to meropenem(82.5%) and mostly resistant to cephalosporins(62.5%).This compares to a study by Mpogoro et al(24) that showed E.coli was 100% sensitive to meropenem, and 85.7% to ciprofloxacin .while they showed a high resistance to ampicillin(100%), amoxycillin/clavulanate(93%).

Staphylococcus aureus isolates were highly sensitive to gentamicin (75%) and mostly resistant to benzyl penicillin (68%).This compared to a study by Manish et al(40), which showed staphylococcus aureus sensitivity to gentamicin was 69% , while the isolates were 86.2% resistant to benzyl penicillin .

In our study, *klebsiella pneumonae* showed high sensitivity to meropenem and ciprofloxacin at 80% and 70% respectively this was partly comparable to a study by Njoku et al (34)that found *klebsiella pneumonae* was 62.5% sensitive to ciprofloxacin but 80% resistant to meropenem. We also found that *klebisiella pneumonae* was mostly resistant to cefuroxime at 70%, and this compared with the findings by Njoku et al (34)where the same organisms were 100% resistant to cefuroxime.

In the current study, we found that *acinetobacter baumunnii*was highly sensitive to gentamycin and amikacin at 55.6% and mostly resistant to cefepime, ceftraixone and meropenem all at 100% , this was concordant with a study by Shristi et al (46)in Nepal that showed More than 90% of Acinetobacter baumannii was found to be resistant to antibiotics: ampicillin, ciprofloxacin, ceftriaxone, cefotaxime, cefoperazone, cefepime, and amoxiclav.

In our study**,** *E.Faecalis*isolates were mostly sensitive to vancomycin (75%)and teicoplanin (75%) and mostly resistant to erythromyicin(75%). This compares with a study by Komiyama et al(47)that found *E.faecalis* was 100% sensitive to vancomycin and 80.6% resistant to erythromycin.

CONCLUSIONS

Gram stain microscopy can be used as a predictor of the organism likely to be isolated on the culture, hence can be used to commence treatment as one waits for culture results. The commonest bacteria isolated in our study were *Escherichia coli, Staphylococcus spp, Klebsiella pneumoniae, Acinetobacter baumanni,coliform bacillie , coagulase negative staphyloccous and enterobacter faecalis.* Antimicrobial sensitivity results showed increased resistance to the common antibiotics routinely in use in our setup.

RECOMMENDATIONS

1. The importance of review at two weeks post-caesarean delivery should be emphasized because most SSI developed after discharge and within the first two weeks after surgery.
2. Emphasis should be put on adherence of KNH antimicrobial stewardship guidelines(38) on the prophylactic antibiotic administration in Emergency Caesarean section, which recommends 2 grams of cefalozin.

3. On admission the patient should be put on appropriate antibiotics as they are already in category 2(recent hospital admission, recent antibiotic therapy) in the stratification of the patients outlined in the KNH antibiotic stewardship guidelines(38).

LIMITATIONS

1. There is Possibility of confounding variables from referral patients as we were not able to establish if they had received antibiotics prior to referral to KNH for Caesarean section.

2. In the current study there is a possibility of confounding variables as we were not able to established if the patients had any treatment (either from a different facility or over the counter) prior to coming back to KNH for the SSI.
3. Some files had missing data as wound pus swabs, we not done routinely.

STUDY TIMELINES

	Jun 2019	Aug 2019	Sept 2019	Oct 2019	Nov 2019	Feb 2020	Mar 2020	June 2020	July 2020
Concept development	■								
Proposal development		■	■	■					
Ethical approval					■	■			
Data collection& analysis							■	■	
Results presentation, dissemination & close out									■

STUDY BUDGETS

Category/item	Cost in Ksh
Charges for KNH-UoN ERC proposal review	3,000
Research assistants @Ksh 60,000	120,000
Data entry	5,000

Statistician	50,000
Photocopying/printing and publishing	50,000
Miscellaneous	10,000
Total	**238,000**

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APPENDIX 1: DATA COLLECTION FORM

Sociodemographic Data

1. Age (years): ____________
2. Education background:
   a) Primary ☐ c) Secondary ☐
   b) College ☐ d) None ☐
3. Religion
   a) Christian ☐ c) Muslim ☐
   b) Hindu ☐ d) Others: __________
4. Employment:
   a) Employed ☐ c) Self-employed ☐
   b) Unemployed ☐
5. Marital status:
   a) Married ☐ c) Separated ☐
   b) Single ☐ d) Widowed ☐
   c) Divorced ☐

Clinical Characteristics

6. Weight (kg): ____________
7. Height (cm): ____________
8. Parity: ____________
9. History of PPH: Yes ☐ No ☐
10. History of PROM: Yes ☐ No ☐
11. HIV status: ____________

12. Diabetes status: ______________

13. Type of caesarean section: Emergency   Elective

If emergency, duration of labour ______________________________

14. Prophylactic Antibiotics administered: Yes   No

If yes, which one ____________________________

15. Duration of surgery __________________________

16. Surgical complication e.g. PPH leading to hysterectomy ____________________

17. Estimate blood loss during the CS _____________________

18. Admission characteristic: __________________________________

How many days post c/s: ______________________

19. Results of microscopy, culture and sensitivity of the pus swab from the incision site.

____

20. Management and maternal outcome _____________________

Period of hospital stay ______________________________

APPENDIX 2: ERC APPROVAL

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
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Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
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KENYATTA NATIONAL HOSPITAL
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Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/185

19th June 2020

Dr. Joan Wanja Mutahi
Reg. No.H58/7203/2017
Dept. of Obstetrics and Gynecology
School of Medicine
College of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL
APPROVED
19 JUN 2020
KNH/UoN-ERC
P. O. Box 20723 - 00202 NAIROBI

Dear Dr. Mutahi

RESEARCH PROPOSAL – POST CAESEREAN SECTION SURGICAL SITE INFECTION, MICROBIAL PATTERNS AND SENSITIVITY TO ANTIBIOTICS IN PATIENTS READMITTED AT KENYATTA NATIONAL HOSPITAL: A RETROSPECTIVE STUDY (P153/03/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 19th June 2020 – 18th June 2021.

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 serious 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. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. 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*).
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**http://www.erc.uonbi.ac.ke**

Protect to discover

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Obstetrics and Gynaecology, UoN
Supervisors: Dr. Onesmus Gachuno, Dept.of Obstetrics and Gynaecology, UoN
Prof. Joseph Karanja, Dept. of Obstetrics and Gynaecology, UoN

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POST CAESAREAN SECTION SURGICAL SITE INFECTION, MICROBIAL PATTERNS AND SENSITIVITY TO ANTIBIOTICS AMONG WOMEN WHO DELIVERED AT KENYATTA NATIONAL HOSPITAL BETWEEN 2014 AND 2020. *By Dr. Joan Wanja Mutahi: Obstetrics and Gynaecolgy, (Medicine)*

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