ANTIBIOTIC PRESCRIPTION PATTERN AND MATERNAL SEPSIS: A COMPARATIVE ASSESSMENT AMONG WOMEN WHO UNDERWENT EMERGENCY CESAREAN DELIVERY BEFORE AND AFTER THE INITIATION OF FREE MATERNITY SERVICES AT THE KENYATTA NATIONAL HOSPITAL

A Dissertation Submitted in Partial Fulfillment for the Degree of

Masters of Medicine in Obstetrics and Gynecology,

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DECLARATION

This thesis was undertaken in part fulfillment of the Masters of Medicine in Obstetrics and Gynecology from the University of Nairobi and is my original work and has not been undertaken and presented in any other university for award of a degree.

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DEDICATION

To Saint **Josemaría Escrivá de Balaguer y Albás** who has been my inspiration as I strived for professional excellence in the middle of the world.
To my wife, **Pauline Adera Akinyi Opuodho-Lagat,**who has been the rock of my life, source of inspiration and support in the course of my residency program.

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ABBREVIATIONS

CD	Cesarean Delivery
CDC	The United States Centers for Disease Control and Prevention
FMS	Free Maternity Services
GAS	Group A Streptococcus
GLOSS	theGlobal Maternal Sepsis Study
HIC	High Income Countries
KNH	Kenyatta National Hospital
KNH/UoN-ERC	Kenyatta National Hospital/University of Nairobi Ethics and Research Committee
LMIC	Low and Middle-Income Countries
MTRH	Moi Teaching and Referral Hospital, Eldoret
PACU	Post Anesthesia Care Unit
SHO ObsGyn	Senior House Office Obstetrics and Gynecology
SSIs	Surgical Site Infections
UK	United Kingdom
UTI	Urinary Tract Infections
WHO	World Health Organization

OPERATIONAL DEFINITIONS

Free Maternal Services: Is a government of Kenya's policy introduced in 1st of June 2013 and whose scope was waiver of user fees for all expectant mothers in the antenatal period and during delivery (whether vaginal or cesarean).

Emergency Cesarean Section: unplanned/intrapartum cesarean delivery

Maternal Post-Operative Sepsis-infection that occurs after emergency cesarean section.

Vulnerable populations in healthcareare patients who are racial or ethnic minorities, children, elderly, socioeconomically disadvantaged, underinsured or those with certain medical conditions. In the study, it refers to teen pregnancies, the unemployed/ the poor/uninsured and those with minimal or lower level of education i.e. primary and below. Members of vulnerable populations often have health conditions that are exacerbated by unnecessarily inadequate healthcare(1).

Maternal sepsis definition: Maternal sepsis is a life-threatening condition defined as organ dysfunction resulting from infection during pregnancy, childbirth, post-abortion, or postpartum period. Features of organ dysfunction: arterial hypoxemia; acute oliguria (for at least 2 hoursdespite adequate fluid resuscitation); creatinine rise; coagulation abnormalities; ileus (absent bowel sounds); thrombocytopenia and/or hyperbilirubinemia.

Before Free Maternity Services – For purposes of the study refers to this period: January-December2012

After Free Maternity Services – For purposes of the study refers to this period: January-December2015.

ABSTRACT

INTRODUCTION:In a health system, change of user fees alters access and coverage of services and hence utilization of health services. The introduction of free maternity services in Kenya is such a policy. There is need to assess the impact of such healthcare policy on the incidence of maternal sepsis (a proxy indicator of quality of care) and utilization of services.

BROAD OBJECTIVE:This was to compare the antibiotic prescription pattern and the incidence of maternal sepsis among women who underwent emergency cesarean delivery before and after the initiation of free maternity services and followed up for 6 weeks after delivery at KNH?

MAIN OUTCOME MEASURES: incidence of maternal sepsis and antibiotic prescription pattern

METHODOLOGY

STUDY DESIGN:a comparative retrospective study

STUDY SITE:Kenyatta National Hospital

STUDY POPULATION- All patients whose gestation was ≥34 weeks and underwent emergency cesarean delivery at KNH general maternity unitbefore and after the initiation of free maternity services.

RESULTS:There was increased utilization of services by vulnerable populations: patients aged ≤19 years, patients with primary level of education,and the unemployedwhose p-values were **0.023,0.017** and **0.032**respectively.

There was no significant change in the incidence of maternal sepsis, 0.4% before and 0.2% after FMS, p-value 0.584 despite increase in the population of women being attended to.

Therewas a significant increasein antibiotic prescription pattern intraoperative: inthe use of amoxycillin-clavulinic acid 1.2g and IV ceftriaxone 1g whose p-value was **<0.001** for both

groups and an increase in theuse of postoperative: in the use of PO amoxycillin-clavulinic acid 625mgandPO amoxycillin-clavulinic acid 1g whose p-values was **<0.001** for both groups. Therewas a significant increase inthe documentation of antibiotic prescriptionafter FMS p-value was **<0.001.**

Conclusion:

Theintroduction of free maternity services led to increased utilization ofservices by the vulnerable populations and a significant increase in the intraoperative and postoperative antibiotic use. In spite of the higher cesarean section numbers after FMS, there was no significant change in sepsis rates. There was a variable antibiotic prescription pattern in both before and after FMS.

Recommendations:

There is need to standardize the antibioticuse during cesarean births because different regimes are in use in both periods. There is need to conduct prospective study to determine the incidence ofmaternal sepsis after emergency cesarean section using the strict diagnostic criteria.

KEY WORDS:**Emergency Cesarean Section, Maternal Sepsis, Free Maternity Services,Vulnerable Populations**

CHAPTER ONE: INTRODUCTION AND LITERATURE REVIEW

1.0 Introduction

Antenatal, intrapartum and postnatal infections are among the four leading direct causes of maternal morbidity and mortality worldwide, accounting for about one tenth of the global burden of maternal deaths (2). Various definitions and terms have been proposed for childbirth-related infections, but none are used universally. Maternal sepsis, genital tract sepsis, puerperal fever, puerperal sepsis and puerperal infection are common terms used synonymously inthe literature without clarity in their definitions.

Maternal sepsis is a life-threatening condition defined as organ dysfunction resulting from infection during pregnancy, childbirth, post-abortion or postpartum period. Identification criteria for maternal sepsis cases should be based on the presence of suspected or confirmed infection plus signs of mild to moderate organ dysfunction (e.g. tachycardia, low blood pressure, tachypnea, altered mental status, reduced urinary output).

Maternal sepsis pauses a great challenge since it’s a heterogeneous condition with different signs and symptoms making it difficult to diagnose in pregnancy. When it becomes evident it might be already severe. Maternal antenatal, intrapartum and postpartum physiologic changes further mask early diagnosis.

1.1:Literature Review

In the last two decades, approaches to reduce maternal mortality have focused on clinical interventions and health system strengthening. This impact is more pronounced in cases of maternal sepsis, where availability of adequate infrastructure, general hygiene, rational use of antibiotics and conducive post-operative environment are key. Government and international policies on the implementation of health-related programs can therefore have an influence on the maternal and neonatal sepsis.

Emergency compared with elective cesarean deliveries are more prone to sepsis (endometritis and surgical site infections) because of the accompanying inherent risk factors. Consequently, with a significant increase in number of emergency cesarean sections without commensurate increase in resources (human and pharmaceutical), its hypothesized that there is significant increase in maternal morbidity and mortality contributed by postpartum maternal infections.

In 2013, there was a policy brief by the President of the Republic of Kenya that all government hospitals were towaive user fees for the pregnant mothers seeking antenatal and delivery services (vaginal or cesarean deliveries). The respective hospitals would subsequently claim standardized fee per service rendered per patient. The free maternity services initiative resulted in influx of patients with net increase in deliveries.

In essence, there were possible incidences of compromised infection prevention and control measures with the increase in overall number of cesarean deliveries. The free maternity services have increased facility delivery but has resulted in: anecdotal poor facility fetal and maternal outcomes (increase in still births, birth asphyxia and uterine rapture for previous sections); possible increase in cesarean rate, overcrowding in facilities without proportional increased in all

carder of staffs and supplies; and early discharge the women who choose to or the staff are under pressure to create more space for additional patients.

In general, the etiology of puerperal infections is understudied and appropriateness of intervention is unproven(3). The response to maternal sepsis has been poor because there are no new innovations, no new drugs and protocols and this might explain the stagnation in reduction in the overall maternal sepsis rate(3)

Despite a downward trend in most countries, maternal sepsis is still an important direct cause of maternal morbidity and mortality (3,4). The burden is skewed to the low and middle-income countries (LMIC) (3).

Maternal sepsis is the direct cause of eleven percent of maternal deaths (35,000) per annum.The rest of the percentage is explained by other causes that evolve into sepsis then resulting into deaths. For instance, severe obstetric (antepartum or postpartum) hemorrhage causes shock which in turn necessitate blood transfusion and may result in bacterial translocation, setting up a cascade of infection, sepsis and finally death.

Hypertensive disorders in pregnancy (such as chronic hypertension, preeclampsia with severe features or eclampsia can be complicated by stroke (ischemic and/or hemorrhagic) which in turn predispose to aspiration pneumonia that can result in maternal death (2). A2014 WHO systematic analysis gives a detailed analysis of the global and regional trends in maternal deaths and the proportion of deaths attributable to maternal sepsis (2).

Long-term disabilities such as chronic pelvic pain, fallopian tube blockage and secondary infertility can occur. Additionally, peripartum maternal infections impact on newborn morbidity and mortality (5) while infection-related morbidities and prolonged hospitalization interfere with mother–infant bonding postnatally.

The risk factors for maternal sepsis that were identified by the confidential enquiries into maternal deaths in the UK (4)include obesity, impaired glucose tolerance / diabetes, Impaired immunity, immunosuppressant medication, anemia, vaginal discharge, history of pelvic infection, amniocentesis and other invasive procedures, cervical cerclage, prolonged spontaneous rupture of membranes, vaginal trauma, caesarean section, wound hematoma, retained products of conception, GAS infection in close contacts / family members, black or minority ethnic group origin.

The incidence of post postpartum infection varies globally, regionally, locally and from institution to institution depending on variability in the presence or absence of risk factors and on appropriate use of prophylactic antibiotics among other sepsis bundles. It accounts for 9.7% of maternal mortality (6). A study by Goitom in Kenyatta National Hospital found puerperal sepsis rates of 18.9% to 40.6% among patients receiving cefuroxime and ampicillin respectively, in both emergency and elective caesarean sections. The overall post-caesarean wound infection rate of 19% at Kiambu District Hospital for both elective and emergency caesarean section(7).

1.1.1: Aetiology of Maternal Infections

Thelocal spread of colonized bacteria is the most common etiology for postpartum infection following vaginal delivery or cesarean delivery. There are many extra genital tracts causes of maternal infection. Mastitis may lead to the development of breast abscesses,(8)necrotizing fasciitis, and toxic shock syndrome,(4,9)urinary tract infection (in form of cystisis and/or acute pyelonephritis, respiratory tract infections (pharyngitis, tonsillitis, rhinitis and/or pneumonia), skin and soft-tissue infection (especially at the intravenous cannulae or injection sites and caesarean or episiotomy wounds), gastroenteritis and infections related to regional anesthesia

(spinal abscess). Bacterial meningitis though rare can cause maternal sepsis. Postpartum infections consist of endometritis, postsurgical wound infections(SSIs), perineal cellulitis (secondary to perineal tears or episiotomies), mastitis, respiratory complications from anesthesia, infected retained products of conception, urinary tract infections (UTIs) in form of cystitis and/ or pyelonephritis, and septic pelvic phlebitis.

Globally, the predominant organisms causing surgical site infections (SSIs) after clean procedures are skin microbiome: streptococcal species, Staphylococcus aureus, and coagulase-negative staphylococci (10). In a UK study, major pathogens causing postpartum maternal infection in the puerperium are: Group A streptococcus (GAS)-Streptococcus pyogenes, Escherichia coli, Staphylococcus aureus, Streptococcus pneumoniae, methicillin-resistant S. aureus (MRSA), Clostridium septicum and Morganella morganii(4).

In clean-contaminated procedures, the predominant organisms are: skin flora, plus gram-negative rods and enterococci. When the surgical procedure involves a viscus, the pathogens reflect the endogenous flora of the viscus or nearby mucosal surface; such infections are typically polymicrobial (11). S. aureus was the most common pathogen, causing 22 percent of SSIs during this time period. Methicillin-resistant S. aureus (MRSA) infections were associated were higher mortality rates, longer hospital stays, and higher costs (12). Fungal infections are on the rise (13). Exogenous sources of infection include: contamination of the surgical site by organisms from the operating room environment or personnel; anal, vaginal, or nasopharyngeal carriage of group A streptococci by operating room personnel has been implicated as a cause of several SSI outbreaks (14); Carriage of gram-negative organisms on the hands has been shown to be greater among surgical personnel with artificial nails (15). Rarely, outbreaks or clusters of surgical site infections caused by unusual pathogens have been traced to contaminated dressings, bandages,

irrigants, or disinfection solutions. The goal of antimicrobial prophylaxis is to prevent postpartum maternal infection by reducing the burden of microorganisms at the surgical site during the operative procedure (16).

1.1.2: Role of Antibiotics in Prevention of Maternal Infections

There is evidence to support the use of prophylactic antibiotics for a number of procedures in obstetrics. Therefore, appropriate guidance for health care professionals and policy-makers on the need for antibiotics – and the type of antibiotic regimens – for the prevention and treatment of maternal infections would align with the WHO strategy on infection prevention and treatment and, ultimately, improve maternal and newborn outcomes (17).

Systematic reviews have demonstrated that the routine administration of prophylactic antibiotic reduces the incidence of maternal sepsis. It has further demonstrated that there is no significant difference in: single verses multiple doses and in narrow spectrum verses broad spectrum prophylactic antibiotics with reference to postpartum maternal infections (i.e. post-cesarean). At KNH, there is no consistent protocol for the administration of antibiotic prophylaxis to patients who are undergoing emergency or elective cesarean delivery. A variable preoperative and post-operative prescriptions patterns are in use in the facility. The patterns are as varied as the number of prescribers despite the WHO recommendations 18.0 and 18.2 based on systematic reviews of multiple clinical trials in both high income countries (HIC) and low and middle income countries (Kenya, Rwanda, Zimbabwe, Tunisia, Sudan And South Africa) (18).

An ideal antimicrobial prophylaxis should prevent SSI, prevent related morbidity and mortality, reduce duration and cost of healthcare, cause no adverse drug effects, and have no adverse effect for the microbial flora of the patient or the hospital (19). The antimicrobial agent should be active against the pathogens that contaminate the surgical site, administered in an appropriate dose and at an appropriate time to ensure adequate serum and tissue concentrations during the

period of potential contamination, and administered for the shortest effective period to minimize adverse effects, emergence of resistance, and cost (18,20,21) Consequently, antimicrobial selection for prophylaxis is based on cost, safety, pharmacokinetic profile, and bactericidal activity.Many antibiotic types, dosing schedules, and routes of administration have been investigated.

Cefazolin is the most widely studied antimicrobial agent with proven efficacy for antimicrobial prophylaxis; hence a drug of choice for many procedures (22). Cefazolin's duration of action, spectrum of activity against organisms commonly encountered in cesarean delivery, reasonable safety, and low cost makes it desirable. Its use in KNH is variable due to erratic supplies and variable prescription pattern among surgeons, obstetricians & gynecologists, anesthetists and anesthesiologist.

Patients with history of penicillin intolerance manifesting as an uncomplicated skin rash may be treated with a cephalosporin; allergic cross-reactions between penicillin and cephalosporins are infrequent except in patients with severe IgE-mediated reactions to penicillin and thus cephalosporins should be avoided. Alternatives to cephalosporins are intravenous vancomycin (15 to 20 mg/kg) or clindamycin (600 to 900 mg).

Antibiotic prophylaxis should be administered in doses sufficient to achieve adequate serum and tissue drug levels for the interval during which the surgical site is open. It is acceptable to dose antimicrobials based on standardized doses for safety, efficacy, and convenience. The serum and tissue concentrations of some drugs administered to obese patients differ from those in non-obese patients for a number of reasons: pharmacokinetic variability related to the lipophilicity of the administered drug (23).

There are limited data for determining the optimal approach to antimicrobial dosing for obese patients (24) Doubling the normal dose of cephalosporins may produce similar concentrations in obese patients to those achieved with standard doses in non-obese patients, with relatively low cost and favorable safety profile (25). The American Society of Health-System Pharmacists through its 2013 guidelines recommend the administration of a minimum 2 g dose and administration of 3 g for patients ≥120 kg (20).

To optimize adequate drug tissue levels at the time of initial incision, preoperative antibiotics should be administered within the 60 minutes prior to skin incision (20,26). The antibiotic half-life is key in making a choice (27); The timing, duration, and intra-operative re-dosing of antimicrobial prophylaxis and risk of SSI has been well studied. (28,29)

Procedures that exceed two half-lives of the drug and with excessive blood loss (>1500 mL) necessitate repeat intraoperative doses (20). The dosing interval is measured from the time of the preoperative dose (not from the beginning of the procedure). No re-dosing in renal insufficiency. To reduce the risk for development of antimicrobial resistance redosing post wound closure is unnecessary (30). Re-dosing beyond surgical time is capped at 24 hours postoperatively (20,26).

1.2: Conceptual Framework

1.2.1:Conceptual Framework-Narrative

User fees for health care in low income countries often try to remedy inequalities in healthcare utilization by putting in place safety nets in the form of exemptions and waivers. Free maternity services / policy brings into play the WHO health systems framework: **systems building blocks** (service delivery, health workforce, HMIS, access to essential medicines, financing and leadership/governance) that **alter access, coverage, quality and safety** of care to impact on **outcomes** (improved health [level and equity], responsiveness, social and financial risk protection and improved efficiency).

Various factors influence the development of maternal sepsis such as sociodemographic characteristics, obstetric/patient's characteristics, perioperative interventions and universal infection prevention measures at the community, individual or facility level.

1.2.2: Conceptual Framework-Diagram

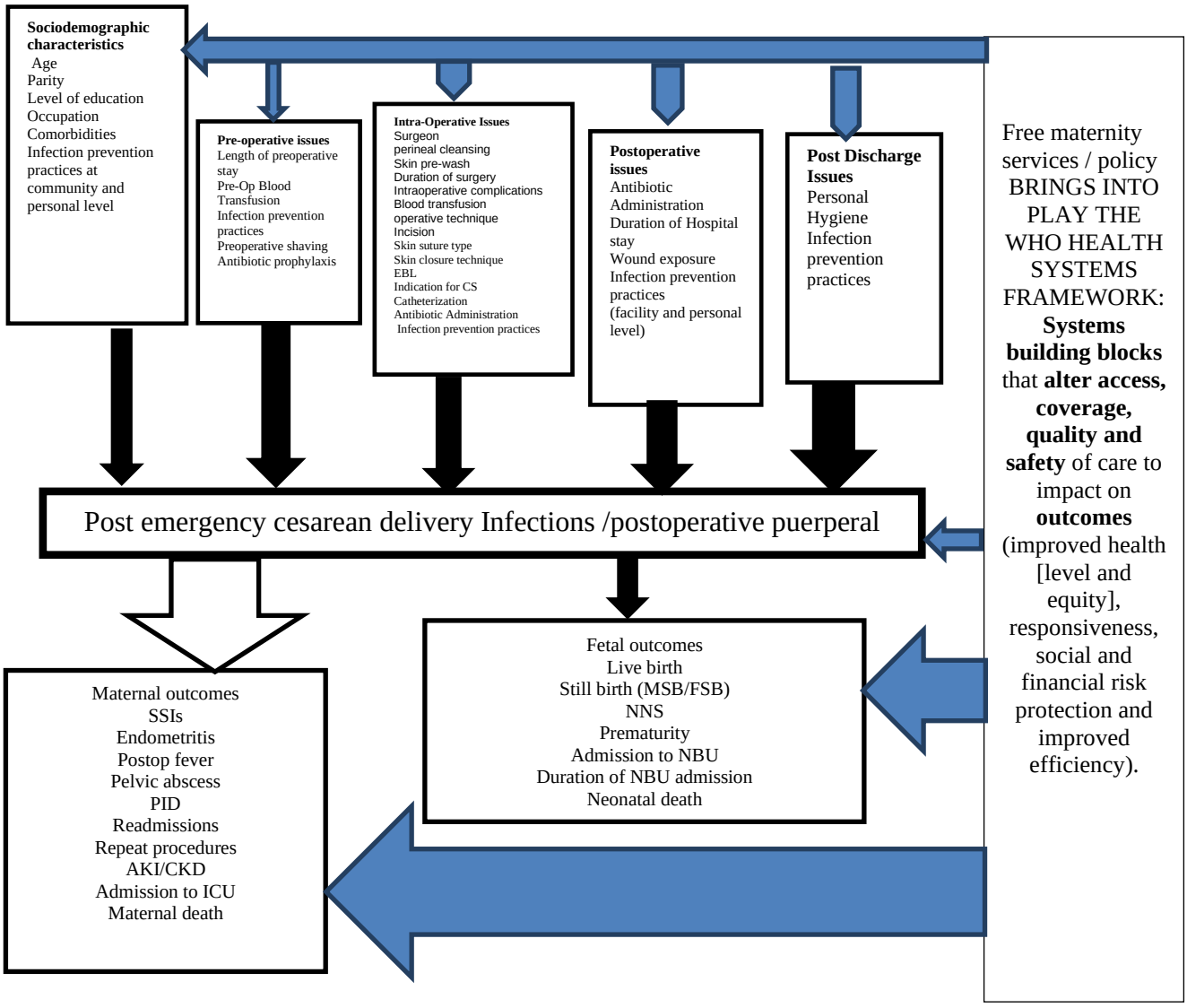

Figure 1.1: Conceptual Framework-Diagram

1.3: Study Justification

Maternal sepsis is one of the three major direct causes of maternal morbidity and mortality in LMIC, hence a proxy for assessing the impact of any obstetric care intervention. It accounts for a significant global regional and local burden of maternal deaths that is skewed to the LMIC. The free maternity intervention increased uptake of reproductive services. The demand outstripped the available resources. The KNH-Health Information Department routine statistics indicate that there was an overall increase in admissions and emergency cesarean deliveries, which is the single most important risk factor for post-operative post-partum maternal infection.

Itis postulated that an increase in volumes resultin sub-optimization of various components of sepsis bundle (infection prevention and antibiotic prophylaxis) resulting in increase in maternal sepsis(31) Infection prevention consists of provision of functional water and sanitation services, and hand hygiene measures. Overcrowding in low and middle-income countries compromises facility and hand hygiene due pressure on infrastructure, staffing and reduced compliance to infection prevention and control by both patients and healthcare workers.

No formal quantitative studies have been conducted to compare antibiotic prescription pattern and the incidence of postpartum maternal infection among patients who underwent emergency cesarean delivery before and after the initiation of free maternity services. The study was documenting the antibiotic prescription pattern before and after free maternity services so as to assess its compliance to the current body of evidence on rational use of antibiotics.

1.4: Research Question

What is the pattern of antibiotic prescriptions and the incidence of maternal sepsis among women who underwent emergency cesarean delivery before (2012: January- December) and after (2015: January- December) the initiation of free maternity services and followed up for 6 weeks after delivery at KNH?

1.5: Broad Objective

This was to comparethe antibiotic prescription pattern and the incidence of maternal sepsis among women who underwent emergency cesarean delivery **before (January- December 2012)**and **after (January- December 2015)** the initiation of free maternity services and followed up for 6 weeks after delivery at KNH.

1.6: Specific Objectives

Among women who had emergency cesarean section, before and after free maternity services, and were followed up for 6 weeks after delivery at KNH, to determine:

1. The **sociodemographic characteristics**
2. The **incidence** of **maternal sepsis**
3. The pattern of antibiotic prescriptions in the**Preoperative, intraoperative and post-operative** periods.

CHAPTER TWO: METHODOLOGY

2.1: Study Design

A comparative retrospective study

2.2: Study Site and Setting

Kenyatta National Hospital (KNH) is a National Teaching and referral Hospital located in Nairobi, Kenya. It offers comprehensive reproductive health services. It is the main public tertiary referral facility that doubles upas a teaching hospital for college of health sciences, University of Nairobi.

The maternity unit is run under the reproductive health division. It is organized into inpatient and outpatient services. The inpatients services consist of the three antenatal wards (GFB, GFA, 1A), Labor ward and two maternity theatres and ward 1D that handles some postnatal complications. The outpatient services that are offered at clinic 66 and Clinic 18 are: High Risk Clinic (on Fridays), Antenatal clinic (on Tuesday, Wednesday and Thursday), acute obstetrics and gynecology care (casualty room 8- runs 24/7/365), Postnatal Clinic (on Fridays) and the maternal fetal Unit Clinic (on Mondays). All other departments are available 24/7 for multidisciplinary acute care and 8am-5pm for Non-acute care of Reproductive Health patients. The reproductive health services are primarily by seventy-five years one, two, three and four SHO ObsGyn with the help of fifty-six Consultants/specialist drawn from KNH and UoN departments of obstetrics and gynecology (as of October 2017), nursing officers and other support departments.

Once an emergency cesarean delivery has been prescribed a series of events are triggered. In the labor ward, the decision is documented, patient is informed, an informed consent is sought and documented, sample for blood works are taken (Hemogram, Renal function test and Grouping and cross matching), a standard preoperative check list is duly filled, theatre team is informed and next available space checked. The patient is gowned and any uterotonics (Oxytocin) stopped

and necessary preoperative fluids administered. Many infection prevention and controlled practices are adhered to. No shaving and catherization is done in the ward, a patient gowned, excessive secretions are cleared

Variable perioperative antibiotic prescription patterns (parenteral ceftriaxone, amoxycillin-clavulinic acid, cefazolin, cefuroxime, ampicillin ± metronidazole and/or other are administered either by anesthetist/ anesthesiologist or the primary nurse. Variable postoperative antibiotics (parenteral ceftriaxone, amoxycillin-clavulinic acid, cefuroxime, meropenem, ampicillin ± metronidazole or oral amoxycillin-clavulinic acid, cefixime, cefuroxime, meropenem ± metronidazole all of which are of variable duration) are administered in the postnatal wards or acute care unit where the patient lands in KNH (ICU, Renal, Labor ward Floor-acute room). There is also a variable antibiotic prescription pattern on discharge.

Postoperative care consists of observation for a period of 30minutes in post anesthesia care unit (PACU), one to two hours in labor ward and three days in postnatal wards. The residents allocated conducts a daily ward with a once weekly major ward round presided over by the lead consultants and specialists. Upon discharge, all post-operative patients are scheduledfor two reviewvisits in weektwo (first visit) and week four-six (second visit) in the post-natal clinic (PNC–Fridays). Additional follow up(s)were carried out whenever necessary. As rule most patients would not have any further visits unless there are complications that require prolonged follow up such as acute/chronic kidney injury, postoperative maternal infections and/or sepsis, preeclampsia with or without severe features, eclampsia, cardiac disease in pregnancy, chronic diabetes or gestation diabetes, systemic lupus erythromatosus, thyroid disease or puerperal psychosis. These high-risk patients had a different discharge protocol.

Rate of maternal sepsis and the pattern of antibiotic prescription and use before and after FMS is unknown. There was no policy on peri-cesarean section antibiotic prescription before FMS. A policy on peri-cesarean section antibiotic prescription after FMS was initiated in January 2018.

2.3: Study Population

All patients with a gestation of ≥34 weeks who had emergency cesarean delivery at KNH general maternity unitbefore FMS (January- December2012) and after FMS (January-December2015)the initiation offree maternity services.

2.4: Sample Size Determination

The prevalence of postpartum maternal infection in a study by Wanjohi in 1989 before free maternity service was 13.3% and study by Kabau in 2014 after free maternity service at the KNH was 22.3%(32). Therefore, using the sample size formula for two proportions formulatedKelsey and colleagues in 1996.

$$\boldsymbol{n_1 = \frac{\left(Z_{\propto/2} + Z_{1-\beta}\right)^2 p(1-p)(r+1)}{r(p_0 - p_1)^2}}$$

And

$$\boldsymbol{n_2 = rn_1}$$

Where,

n_1= number of those who underwent caesarean section before (January- December2012) free maternity service

n_2= number of those who underwent caesarean section after (January- December2015) free maternity service

$Z_{\propto/2}$= standard normal deviate for two-tailed test corresponding to 95% CI i.e. 0.05

$Z_{1-\beta}$= standard normal deviate corresponding to power level of 80% i.e. 0.842

r = ratio of those women that underwent caesarean section before and after free maternity service i.e. 1

p_0 = proportion of postpartum maternal infection before free maternity service at the Kenyatta National Hospital i.e. 0.133

p_1= proportion of postpartum maternal infection after free maternity service at the Kenyatta National Hospital i.e. 0.223

$$\boldsymbol{p = \frac{p_0 + rp_1}{r + 1}}$$

$$\boldsymbol{p = \frac{0.133 + (1\,x\,0.223)}{1 + 1} = 0.178}$$

$$\boldsymbol{n_1 = \frac{(1.96 + 0.842)^2 0.178(1 - 0.178)(1 + 1)}{1(0.133 - 0.223)^2} = 284}$$

Therefore,

$$\boldsymbol{n_2 = 1x284 = 284}$$

The study therefore required to review at least 284 women that underwent caesarean section before FMS (January-December 2012) and at least 284 women after FMS (January- December 2015).

Table 1.1: Preliminary data on emergency cesarean sections done before and after free maternity services

Month/ Years	2010	2012	2013	2014	2015	2016	2017
January	-	-	311	372	458	470	51
February	255	250	257	326	412	451	28
March	275	293	292	-	478	538	167
April	281	287	298	392	480	558	415
May	277	335	380	380	559	495	514
June	320	399	354	377	577	492	577
July	276	243	319	387	488	484	756
August	308	279	332	388	535	527	625
September	315	192	323	347	591	686	643
October	-	284	391	387	444	682	658
November	310	240	222	462	451	500	-
December	314	320	374	446	495	160	-
Cesarean sections done per annum	**293**	**3122**	**3853**	**4264**	**5968**	**6043**	**4434**

(**Source:** KNH-Health Information Department. Data last accessed on 11th November 2017).

Note that, in the months that had gaps, emergency cesarean delivery data wasn't available, but total (both Emergency & Elective) cesarean deliveries were provided. All the data for year 2011 was not available. The FMS policy was initiated in June 2013. In September 2013, the figures dropped due to the health care workers' strike. From December 2016 to March 2017, the figures dropped again due to a hundred days doctors' strike. This data represented all general maternity unit deliveries and excluded Ward 1C (private wing). The files that meet the inclusion criteria were used to fill data extraction form. Based on data in table 1.1, the 2015 population was chosen as a representative population for after free maternity services because it had complete data.

March 2014 data was not available, so 2014 could not be used as year representative of post FMS era. The FMS policy was initiated in June 2013.The period of data collection was from June 2018 to October 2018.

2.6 Study Enrollment and Recruitment

Inclusion criteria

All womenwith a gestational age of ≥34 weeks who underwent emergency cesarean delivery at KNH general maternity unit beforeFMS (January- December 2012)and after FMS (January-December 2015).

Exclusion criteria

Women with sepsis at the time of cesarean section and/or were on treatment for it.

2.7: Data variables

See Annex 4

2.8: Ethical Considerations

Ethical clearance was sought from the University of Nairobi Obstetrics and Gynecology department and the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee. Since it was a comparative retrospective study,a waiver of patient written consent was sought and obtained. The patients' records were coded and patient's identifiers (name, inpatient number) were omitted to maintain confidentiality. The information obtainedremained confidential and wasnot used for any other purpose other than that of the study. Case files were reviewed in the KNH registry/health information department in accordance with its' laid down rules and regulations.

The data extractions sheets and the primary data were kept under lock and key in desk/locker by the data collection assistant until hander over to the principal investigator whoassumed full custody of the documents till data entry to excel sheets was completed. The data was to be kept

for a period of one year or until when the data entry to SPSS by statistician as completed, whichever came earlier. The excel sheets and other soft copies were kept in password protected computers, gadgets and storage devices. Study findings were to be disseminated to the KNH/UON-ERC, KNH administration and the University of Nairobi- Department of Obstetrics and Gynecology.

2.9: Data Collection Procedures

A systematic random sampling for twelve months before FMS (January to December 2012) and twelve months afterFMS (January to December 2015) was used. Files that met the inclusion criteria were identified and data extracted and filled into a pre-coded data extraction tool as captured in the appendix (Annex 2).

2.10: Data Management

The study data was collected with the use of a pre-coded questionnaire with the aid of four research assistants who were trained on the study protocol. Identifying features such as names of the women meeting the inclusion criteria were not captured for confidentiality purposes. Thereafter, data was entered into the Statistical Package for Social Sciences (Version 21, Chicago-Illinois). Regular checks on the data capture and entry process were performed to ensure accuracy of the data collected and entered. The data was protected with the use of a password which was accessible to the principal investigator and the research assistant. Continuous backup of the data was done by use of flash disks/hard drives and cloud. At completion of the study all data collected via the pre-coded instrument was shredded.

2.11: Data Analysis

Patient characteristics, preoperative and intraoperative issues, antibiotic prescription pattern, and incidence of maternal sepsis and data that contain continuous data were analyzed and summarized as means and standard deviation while those that capture categorical data were

analyzed and displayed by use of frequencies and proportions. P-values, Odds Ratios and 95% confidence intervals (CI) were calculated where applicable. A P value <0.05 was considered to be statistically significant.

2.12: The Study Limitations

The major limitationof this study was the incompleteness of data from the study files.

CHAPTER THREE: STUDY RESULTS

Out of a 3122 patient files before and 5,968 patient files after FMS, a systematic sampling procedure was used to identify 700 patient records before and 700 patient records after the introduction of free maternity services using a sampling ratio of 1:1. By using a study protocol of inclusion and exclusion criteria, all the patient records that met the inclusion criteria in either arms had its data extracted by use of pre-coded data extraction tool annexed in the appendix. This chapter presents the results for 1126 patients who underwent emergency Caesarian section at the Kenyatta National Hospital, before (493) and after (633) FMS.

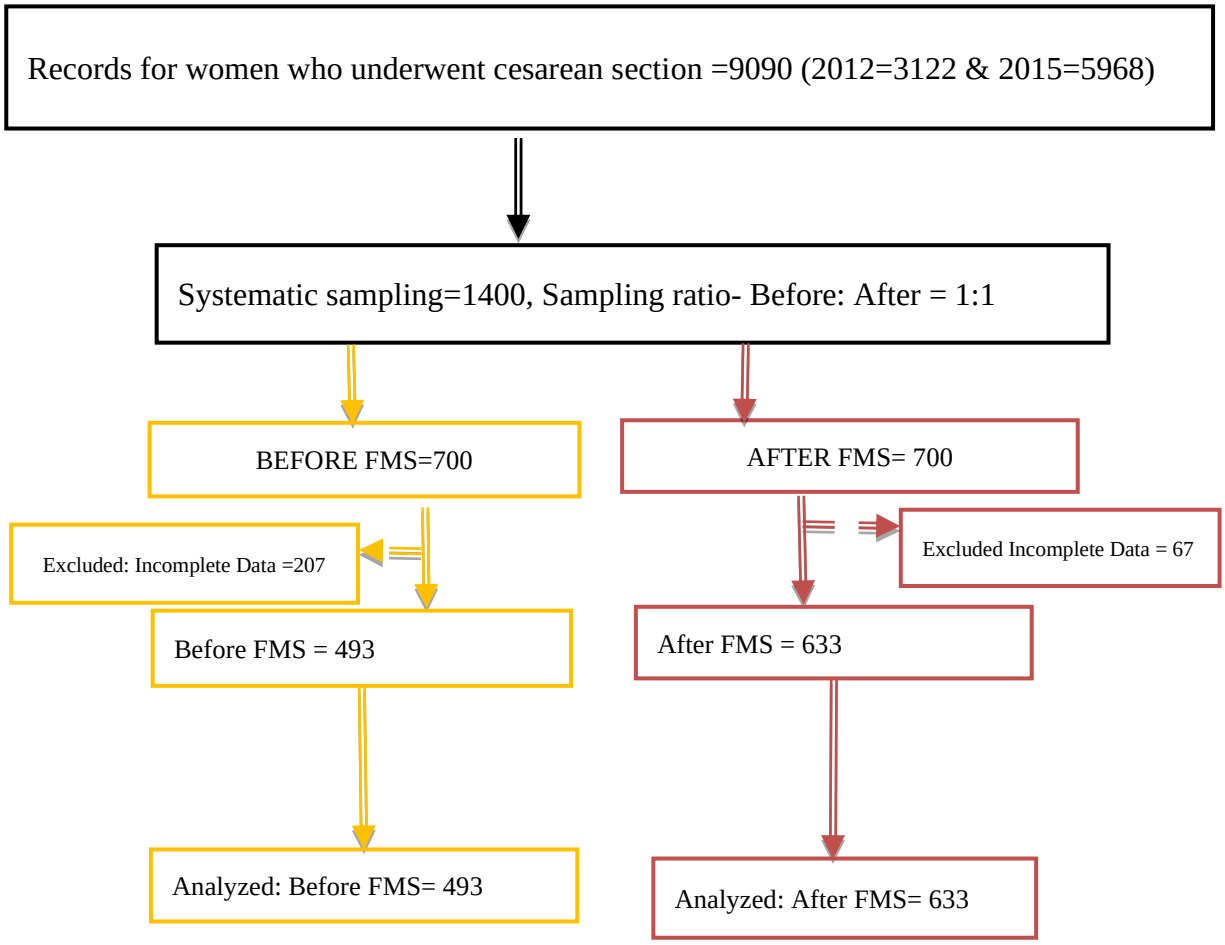

Figure 3.1 Study Flow Chart

Table 3.1:Sociodemographic characteristics of women who underwent emergency cesarean section before and after free maternity services (N=1126).

		BEFORE FMS 2012 (n=493)	**AFTER FMS 2015** (n=633)	**OR 95%CI**	**P-value**
Age		**Frequency (%)**	**Frequency (%)**		
	≤19	**13 (3)**	**34 (5)**	**0.5 (0.2-0.9)**	**0.023**
	20-24	111 (23)	148 (23)	0.9 (0.7-1.3)	0.732
	25-39	363 (74)	439 (69)	1.2 (0.9-1.6)	0.116
	≥40	6 (1)	12 (2)	0.6 (0.2-1.7)	0.368
Level of Education	**Primary**	**88 (18)**	**150 (24)**	**0.7 (0.5-0.9)**	**0.017**
	Secondary	212 (43)	255 (40)	1.1 (0.8-1.4)	0.358
	Tertiary	138 (28)	180 (28)	0.9 (0.7-1.3)	0.87
	Unknown	55 (11)	48 (8)	1.5 (1.0-2.3)	0.039
Marital status	Married	412 (84)	536 (85)	0.9 (0.7-1.3)	0.614
	Single	54 (11)	83 (13)	0.8 (0.6-1.2)	0.272
	Unknown	27 (6)	14(2)	2.6 (1.3-4.9)	0.004
Occupation	Salaried-Employed	90 (18)	112 (18)	1.0 (0.7-1.4)	0.807
	Self-employed	138 (28)	168 (27)	1.1 (0.8-1.4)	0.587
	Unemployed	**206 (42)**	**305 (48)**	**0.8 (0.6-0.9)**	**0.032**
	Unknown	**59 (12)**	**48 (8)**	**1.7 (1.1-2.5)**	**0.013**
Religion	Christian	217 (97)	296 (98)	0.7 (0.3-2.1)	0.565
	Muslim	7 (3)	7 (2)		
Parity	Primigravida	328 (67)	407 (64)	1.1 (0.9-1.4)	0.435
	Multigravida	165 (34)	226 (36)		
Gestation	Preterm: 34-36 weeks	57 (12)	66 (10)	1.1 (0.8-1.6)	0.545
	Early term: 37-38 weeks	160 (33)	182 (29)	1.2 (0.9-1.5)	0.18
	Full term: 39-40 weeks	204 (41)	283 (45)	0.9 (0.7-1.1)	0.263
	Late term: 41 weeks	45 (9)	58 (9)	0.9 (0.7-1.5)	0.984
	Postterm: ≥42 weeks	27 (6)	44 (7)	0.8 (0.5-1.3)	0.313

There was a significant increase in utilization of services by vulnerable populations after the initiation of free maternity services: among patients aged ≤19 years, patients with primary level of education, and the unemployed whose p-values were 0.023,0.017 and 0.032 respectively.

Table 3.2: Means ages, gestation and number of antenatal visits of women who underwent emergency cesarean section before and after free maternity services (N=1126).

Group Statistics

Year Group		n	Mean	Std. Deviation	Std. Error Mean
Age	Before FMS 2012	493	28.38	5.224	.235
	After FMS 2015	633	27.78	5.509	.219
Gestation	Before FMS 2012	493	38.71	1.881	.085
	After FMS 2015	633	38.92	1.846	.073
Number of ANC Visits	Before FMS 2012	493	3.43	1.544	.070
	After FMS 2015	633	3.93	1.720	.068

Table 3.3: Obstetric characteristics of women who underwent emergency cesarean section before and after free maternity services (N=1126).

Obstetric characteristics		**BEFORE FMS 2012** (n=493)	**AFTER FMS 2015**(n=633)	**OR 95%CI**	**P-value**
		Frequency (%)	Frequency (%)	OR (95% CI)	P-Value
Name of facility where ANC was attended	KNH	250 (51)	330 (52)	0.9 (0.7-1.2)	0.636
	Non-KNH	243 (49)	303 (48)		
Number of ANC visits	**≤4 visits**	**395 (80)**	**437 (69)**	**1.8 (1.4-2.4)**	**<0.001**
	>4 visits	98 (20)	196 (31)		
Family planning options	**Non-LARCs**	**111 (24)**	**188 (31)**	**0.7 (0.5-0.9)**	**0.005**
	None	**342 (73)**	**383 (64)**	**1.5 (1.2-1.9)**	**0.002**
	Unknown	24 (5)	34 (5)	0.9 (0.5-1.5)	
Number of vaginal examinations done at the time of cesarean delivery	>4	87 (18)	141 (22)	0.7 (0.6-1.0)	0.055
	≤4	406 (82)	492 (78)		
Labor initiation	**Induced**	**61 (12)**	**111 (18)**	**0.7 (0.5-0.9)**	**0.017**
	Spontaneous	432 (88)	522 (83)		
State of membranes at cesarean section	**Intact**	**301 (61)**	**325 (51)**	**1.5 (1.2-1.9)**	**0.001**
	Raptured	161 (33)	233 (37)	0.8 (0.7 -1.1)	0.147
	Unknown	31 (6)	75 (12)	0.5 (0.3-0.8)	0.002
Location postoperatively and/or at discharge	Ward-GFA	184 (37)	222 (35)	1.1 (0.9-1.4)	0.435
	Ward-GF B	171 (35)	211 (33)	1.1 (0.8-1.4)	0.634
	Ward-1A	133 (27)	182 (29)	0.9 (0.7-1.2)	0.511
	Ward-1D	4 (1)	18 (3)	0.3 (0.1-0.8)	0.015
Any postnatal visits(s)?	Yes	230 (47)	290 (46)	1.0 (0.8-1.3)	0.779
	No	263 (53)	343 (54)		

There was a significant decrease in the proportion of women having ≤4 antenatal visitsafter FMS p-value =**<0.001.** There were more women who came for induction of labor after FMS p-value= **0.017.**Women were less likely to have intact membranes at the time of cesarean section after FMS p-value= **0.001.**

Table 3.4: Incidence of maternal sepsis among women who underwent emergency cesarean section before and after free maternity services (N=1126).

		BEFORE FMS	**AFTER FMS**	**OR(95%CI)**	**P-Value**
		Frequency (%)	Frequency (%)		
Was there postpartum maternal sepsis?	Yes	2 (0.4)	1 (0.2)	2.6 (0.2-28.5)	0.584
	No	491 (99.6)	632 (99.8)		
	Total (N)	493 (100)	633 (100)		

There was no significant change in the incidence of maternal sepsis, 0.4% before FMS and 0.2% after the initiation of FMS, p-value=**0.584,** despite increase in the population of women being attended to.

Table 3.5: Preoperative and intraoperative antibiotic prescription pattern among women who underwent emergency cesarean section before and after free maternity services (N=1126).

		BEFORE FMS (n=493)	**AFTER FMS (n=633)**	
		Frequency (%)	Frequency (%)	
Preoperative Antibiotic(s)	IV Amoxycillin-Clavulinic Acid 1.2	1 (0.2)	4 (0.6)	0.393
	IV Metronidazole 500mg	0 (0)	2 (0.3)	0.507
	None	492 (99.8)	628 (99.2)	0.239
Intra-operative antibiotics	**IV Amoxycillin-Clavulinic acid 1.2G**	**155 (31)**	**362 (57)**	**<0.001**
	IV Ceftriaxone 1g	**23 (5)**	**148 (23)**	**<0.001**
	None/ UNKNOWN -	**282 (57)**	**106 (17)**	**<0.001**
	IV Metronidazole500mg	34 (7)	41 (7)	0.779
	IV Ceftriaxone 2g	3 (1)	16 (3)	0.013
	IVCefuroxime 500mg	10 (2)	5 (1)	0.072
	IVCefazolin 2g	2 (0.4)	1 (0.2)	0.584
	IV Cefazolin 1g	3 (0.6)	0 (0)	0.084
Post-operative antibiotics	**PO Amoxycillin-Clavulinic acid 625mg**	**145 (29)**	**296 (47)**	**<0.001**
	IV Amoxycillin-Clavulinic acid 1.2g	209 (42)	292 (46)	0.211
	PO Amoxycillin-Clavulinic acid 1g	40 (8)	75 (12)	0.04
	Unknown- No Treatment Sheet	76 (15)	68 (11)	0.02
	PO Metronidazole 400mg	47 (10)	55 (9)	0.624
	IV Metronidazole 500mg	64 (13)	49 (8)	0.004
	IV Ceftriaxone 1mg	28 (6)	27 (4)	0.275
	PO Cefuroxime 500mg	11 (2)	23 (4)	0.173
	IV Cefuroxime 500mg	10 (2)	20 (3)	0.242
	IV Ceftriaxone 2g	12 (2)	18 (3)	0.672
	NONE	**29 (6)**	**12 (2)**	**<0.001**
	IV Cefazolin 1g	3 (0.6)	2 (0.3)	0.659
	IV Azithromycin 500 mg	3 (0.6)	2 (0.3)	0.659
	PO Cefixime 400 mg	1 (0.2)	1 (0.2)	1
	IV Cefazolin 2g	2 (0.4)	0 (0)	0.191

There was variable antibiotic use in both periods.

There was a significant increase in intraoperative antibiotic use: in the use of amoxycillin-clavulinic acid 1.2g and IV ceftriaxone 1g; p-value was **<0.001** for both groups.

There was also a significant increase in the postoperative antibiotic use: in the use of PO amoxycillin-clavulinic acid 625mg and PO amoxycillin-clavulinic acid 1g whose p-values were <**0.001** for both groups.

There was a significant increase in the documentation of antibiotic prescription after FMS, p-value was **<0.001.**

Table 3.6:Duration and pattern of post-operative antibiotic prescription among women who underwent emergency cesarean section before and after free maternity services (N=1126).

	BEFORE FMS (n=493)		**AFTER FMS (n=633)**	**OR (95%CI)**	**p-Value**
Duration of post-operative antibiotic prescribed (in days)	Days	Frequency (%)	Frequency (%)		
	5	124(44)	173(48.7)	0.8 (0.6-1.1)	0.248
	3	**140(50)**	**128(36)**	**1.8 (1.3-2.4)**	**<0.001**
	1	9(3)	26(7.3)	0.4 (0.2-0.9)	0.024
	2	7(3)	25(7)	0.3 (0.1-0.8)	0.009
	7	0(0)	2(0.6)	-	0.506
	6	0(0)	1(0.3)	-	1
	11	1(0.4)	0(0)	-	1

There was a statistically significant reduction in three-dayantibiotic prescription p-value <0.001.

Table3.7: The pattern of discharge antibiotic prescription among women who underwent emergency cesarean section before and after free maternity services (N=1126).

Discharge antibiotics	**BEFORE FMS (n=493)**	**AFTER FMS (n=633)**	**OR (95%CI)**	**p-Value**
PO Augmentin 625mg	207(42)	299(47)	0.8 (0.6-1.0)	0.079
PO Augmentin 1g	37 (8)	44 (7)	1.5 (1.2-1.9)	0.721
PO Flucloxacillin 5	3 (1)	3 (1)	1.3 (0.9-1.7)	1.000
PO Metronidazole 400mg	84 (17)	89 (14)	1.1 (0.7-1.7)	0.169
Unknown- No Discharge Summary	17 (3)	37 (6)	0.9 (0.6-1.6)	0.062
None	186 (38)	182 (29)	0.6 (0.3-1.0)	0.318
PO Cefuroxime 500mg	26 (5)	36 (6)	1.3 (0.5-3.5)	0.763
PO Azithromycin 500mg	1 (0)	1 (0)	2.7 (0.5-15.1)	1.000
PO Ampicillin/Flucloxacillin 500mg	2 (0)	5 (1)	1.3 (0.3-6.4)	0.477
PO Cefixime 400mg	8 (2)	8 (1)	0.5 (0.1-2.6)	0.614
PO Ampicillin	4 (1)	2 (0)	1.3 (0.1-20.6)	0.413

There was no significant change in the pattern ofdischarge antibiotic prescriptionsafter the initiation of free maternity services**.**

Chapter Four: Discussion, conclusion and recommendation

4.0 Discussion

The study sought to compare the antibiotic prescription pattern and the incidence of maternal sepsis among women who underwent emergency cesarean section before and after the initiation of free maternity services and followed up for 6 weeks after delivery at KNH.

The sociodemographic characteristics demonstrated that there was increased utilization of services of varying statistical significance. The significant utilization was seen among the vulnerable populations: the under 19 years (2% increase), primary level of education (6% increase) and the unemployed (4% increase) which is consistent with other studies. Gitobu (2015) demonstrated increase in facility deliveries in five counties in Kenya(33). Njuguna through analysis of the District Health Information System 2 (DHIS2) demonstrated that the number of deliveries and antenatal attendance increased in five county referral hospitals(34). Witter demonstrated overall increase in institutional deliveries in Nepal(35) and Sudan (36) Ghana's Free Maternity Services report demonstrated a doubled overall facility delivery (37).

There was no significant difference in the incidence ofmaternal sepsis among after free maternity services.This sepsis rate closely mirrors WHO SSI rates that ranges from 3% to 15% worldwide. Maternal sepsis rates are lower than the SSI rates (38).However, the numbers were too few to allow further detailed analysis. This is because of thisstudy used Gloss(39) and WHO (2016) strict criteria in the diagnosis of what maternal sepsis is.The incidence rate was lower in contrast to what Bonetfound in the Gloss study using the same strict criteria that found maternal sepsis (Infectionwith organ failure) at 3-5%(40). The difference is explained by the prospective nature of the Gloss study. It is likely that more data was captured and more patients were not lost to

follow up. To the best of availableknowledge, no other studies have used similar strict criteria for diagnosis of maternal sepsis

There was a significant change in the use of intraoperative antibiotics and of postoperative antibiotics. For the intraoperative antibiotics, there was a significant increase in the use of intravenous amoxicillin-clavulanic acid and ceftriaxone after FMS. This was accompanied by reduction in undocumented prescriptions. This is consistent with what was found by Tippawan (Thailand) who found a 71% post cesarean intraoperative prescription after removal of user fees which was close to KNH's in 2015 that stood at 83%. Postoperatively, there was a significant increase in the use of oral amoxicillin-clavulanic acid 625mg/1g after FMS compared to before. After FMS there was significant reduction in non-prescription of antibioticsand a significant improvement of documentation of antibiotic prescriptions.

There was no significant difference in the pattern of antibioticprescriptions on discharge. This is similar to what Aiken demonstratedin Thika where there was a predominant post cesarean antibiotic prescription before the intervention(41,42). However, the antibiotic prescriptions pattern is not in keeping with the intrapartum cesarean delivery antibiotic prescription recommendation level I generated from systematic reviews(43).

Like other reviews, the study suggests that reducing or removing user fees increases the utilization of certain healthcare services. However, other studies suggest that such a change may have unintended consequences on utilization of preventive services and service quality. The introduction or increasing fees can have a negative impact on health services utilization, although when implemented with quality improvements the interventions could be beneficial(44).

4.1 Conclusion

The introduction of free maternity services led to increased utilization of services by the vulnerable populations and a significant increase in the intraoperative and postoperative antibiotic use. In spite of the higher cesarean section numbers after FMS, there was no significant change in sepsis rates. There was a variable antibiotic prescription pattern in both before and after FMS.

4.2 Recommendations

There is need to standardize the antibiotic use during cesarean births because different regimes are in use in both periods. There is need to conduct prospective study to determine the incidence ofmaternal sepsis after emergency cesarean section using the strict diagnostic criteria.

There is need to align KNH's antibiotic prescriptions to the existing body of evidence as captured in the cesarean antibiotic protocol launchedin January 2018.

There is need for adoption of the current WHO (2016) definition of maternal sepsis as a case definitionand a prospective study to determine the incidence of maternal sepsis among women who undergoemergency cesarean section using the strict diagnostic criteria recently validate by the Gloss study and used in this study.

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Annex 1: Approval Letter From KNH-UON ERC

29 MAY 2018

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Ref: KNH-ERC/A/192

May 29, 2018

Dr. Lagat Moses Kipchumba
Reg. No.H58/74642/2014
Dept. of Obs/Gynae
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Kabinga

RESEARCH PROPOSAL – THE ANTIBIOTIC PRESCRIPTION PATTERN AND THE INCIDENCE OF MATERNAL SEPSIS AMONG WOMEN WHO UNDERWENT EMERGENCY CESAREAN DELIVERY BEFORE (2012: JANUARY -DECEMBER) AND AFTER (2015: JANUARY-DECEMBER) THE INITIATION OF FREE MATERNITY SERVICES AND FOLLOWED UP FOR 6 WEEKS AFTER DELIVERY AT K.N.H **(P740/12/2017)**

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 from 29th May 2018 – 28th May 2019.

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) 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) 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.

Protect to discover

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director, CS, KNH
The Chairperson, KNH-UON ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept.of Obs/Gynae, UoN
Supervisors: Dr. F.X.Odawa, Dr. Rose Kosgei

Annex 2: Data Extraction Tool/ Form

Form Serial Number:	
Patients Initials:	**Patient IP#.**

1. Age: years and or Date of Birth:
2. PARITY
3. Gestation (weeks)
4. LEVEL OF EDUCATION: a. NONE b. PRIMARY c. SECONDARY d. TERTIARY e. UNKNOWN
5. Primary origin before labor ward (circle): Ward- GFA, GFB, 1A, /Home /Referral: Yes/ No
6. Occupation (as documented): Specify: 1. Unemployed 2. Housewife 3. Self-employed 3. Salaried employment 4. Other: Specify: …...
7. Religion: 1. Catholic 2. Muslim 3. Protestant 4. Atheist 5. Traditional 6. Other …. 7. Unknown.
8. Weight: ……/None KG; HEIGHT: ……/None M.; BMI: ……/KG/M^2
9. Antenatal care: -ANC profile: Hb: ……. G/dL, Blood Group: ABO Rhesus: Positive/Negative
10. Contraceptive use: Any usage documented?

Contraceptive Type	Duration of Use	Reason for Cessation.	Any complication
COC Pills (Y/N)			
CIC (Y/N)			
DEPO (Y/N)			
NFP (Y/N)			
IUCD (Y/N)			
Implants (Y/N)			
Others: Specify …….			

11. HIV: (Circle)UNKNOWN/NEG/POS
    11.1.1. If Positive: OnHAART: YES/NO
12. Length of preoperative stay (diagnosis to cutting): …….. Hours/Minutes.
    12.1. Date and time when Cesarean Section was prescribed: DD/MM/YYYY/Time.

12.2. Date and time when Cesarean Section was performed: DD/MM/YEAR/Time

13. ANEMIA

13.1. PREOPERATIVE HB-……. G/dL.

13.2. Perioperative transfusion

14. Coexistent infection at a remote body site

14.1. URTI: Pharyngitis, Tonsilitis (Yes /No/Unknown)

14.2. LRTI: Pneumonia, Bronchiolitis, (Yes /No/Unknown)

14.3. Cervicitis/Vaginitis (Yes /No/Unknown)

14.4. UTI (cystitis/Pyelonephritis) (Yes /No/Unknown)

14.5. Cellulitis

15. Operative issues: preoperative issues

15.1.1. Preoperative antibiotics

15.1.2. Intra Operative antibiotics

15.1.3. Postoperative antibiotics

15.1.4. Discharge Medications

16. Operative issues: Intraoperative issues

16.1. Duration of surgery (minutes): 0-30 MINUTES 2. 30-60 MINUTES 3. >60 Minutes.

16.2. Intraoperative Complications/Additional surgeries done (laparotomy/Hysterectomy, Lynch, Gut Injury, Ureteric Injury, Bladder Injury other):1. No 2. Yes: Specify.

16.3. Blood transfusion: Yes/No) 2. Transfusion Type (Whole Blood, Packed RBCs, Platelets, FFP)

16.4. Type of surgeon: 1. Resident 2. Consultant/Specialist 3. MO-Intern 4.RCO RH.

16.5. Estimated blood loss: 1. <500 mL; 2. 500-1000 mL; 3. 100-1500 mL; 4.>1500mL

16.6. Indication for Cesarean delivery

17. Post-operative issues

17.1. Post-Operative Medication-As prescribed by the surgeon (see Post-operative notes and treatment sheet).

17.1.1. Antibiotics (Choice, Dose, Route, Duration).

Antibiotic	Dose	Route of administration	Duration

17.1.2. Analgesia (Choice, Dose, Route, Duration).

Antibiotic	Dose	Route of administration	Duration

17.1.3. Others (Choice, Dose, Route, Duration).

Antibiotic	Dose	Route of administration	Duration

17.2. Wound exposure: 1. Day 1, 2. Day 2, 3. Day 3, 4. >Day 3, 4. Unknown

17.3. Postoperative Complications/need for repeat procedures: 1. Laparotomy/Hysterectomy, Lynch, Gut Injury repair, Ureteric Injury repair, Bladder Injury Repair) 2. Evacuation of clots. 3. Re-suturing of the incision. 4. Other(s) Specify….

17.4. Hospital stays

17.5. Discharge medication (document as indicated on discharge notes or Discharge sheet).

18. Maternal Re-admission (YES/NO)

19. MATERNAL NEED FOR ADDITIONAL PROCEDURES. (YES/NO)

19.1. TAH/LAPARATOMY/COLOSTOMY/Secondary RESUTURING/Other – specify-

20. MATERNAL SEPSIS (Yes or NO)

Maternal sepsis definition: Maternal sepsis is a life-threatening condition defined as organ dysfunction resulting from infection during pregnancy, childbirth, post-abortion, or postpartum period. Features of Organ dysfunction:

- Arterial hypoxemia ($PaO_2/FIO_2 < 300$)

- Acute oliguria (urine output <0.5 mL/kg/hr.for at least 2hr despite adequate fluid resuscitation).
- Creatinine rise >0.5 mg/dL or 44.2micromol/L
- Coagulation abnormalities (INR >1.5 or aPTT >60 s)
- Ileus (absent bowel sounds)
- Thrombocytopenia (platelet count <100,000/mL)
- Hyperbilirubinemia (plasma total bilirubin > 4 mg/dl or 70 mmol/L)

Annex 3: Results Dissemination Plan

Results were presented in UoN, CHS, SoM, department of obstetrics and gynecology results presentation forum and a printed dissertation book was handed for internal marking.

Copy of the final book shall be handed in to the division ofobstetrics and gynecology KNH-research department, the school for school of postgraduate studies. We due guidance, a manuscript shallbe developed and handed in for publication.

Annex 4: Data Variables

Data variables as per objectives and sources of data						
Objective	**Exposure variable**	**Outcome variable**	**Sources ofData**	**Before FMS**	**AfterFMS**	**DIFFERENCE**
Sociodemographic Characteristics	Age Parity Level of Education Primary Secondary Tertiary Missing Data Weight Height BMI Comorbidities (Health of The Surgical Patient) Chronic DM Gestational DM SLE Anemia Thyroid Diseases (Hypo/Hyper/Subclinical) HIV Genital Warts Chronic HTN Gestational HTN Pre-Eclampsia with Severe Features or Without Severe Features Eclampsia CKD Length of Preoperative Stay (Diagnosis to Cutting) Perioperative Transfusion Preexisting Infections or Preexisting organ failure		Patient file Nursing Cardex Interdepartmental consultations ANC card/ Booklet			
Operative issues: preoperative issues	Mean Body Temperature Skin Antisepsis Preoperative Shaving (Hair Removal) Surgical Blade Clippers Antimicrobial Prophylaxis					

Operative issues: Intraoperative issues	Preoperative perineal cleansing with Iodine Yes /no/not documented Skin pre-wash with chlorhexidine Yes /no/not documented Duration of surgery (minutes) Intraoperative Complications/Additional surgeries done (laparotomy/Hysterectomy, Lynch, other) Blood transfusion (Yes/No) Transfusion Type (Whole Blood, Packed RBCs, Platelets, FFP) the operative technique Incision SUMI Pfannestiel/ transverse Skin Suture type Monofilament Braided Skin Closure Subcuticular Stables Unknown Type of surgeon Resident Consultant/Specialist Intern RCO RH. Major Breach of aseptic technique during surgery Yes /no/not documented Estimated blood loss <500 mL 500-1000 mL 100-1500 mL >1500mL Indication for Cesarean delivery Maternal Feto-maternal					

	wound exposure day1 day 2 day 3 >day 3 Postoperative Complications/need for repeat procedures laparotomy evacuation of clots Hospital stays					
The antibiotic prescription pattern	type of antibiotic given Preoperative Intraoperative Postoperative Discharge Variable Combination					
Incidence of maternal infections and sepsis	Type of maternal infection SSI superficial Deep Time sepsis occurred (Postoperative day X) Medication given as treatment	Incidence of postpartum maternal	Labor ward register Theatre register Postnatal ward register Nursing Cardex Patient file /records HMIS coding			