PATTERNS OF PERIOPERATIVE ANTIBIOTIC SURGICAL PROPHYLAXIS AMONG SURGICAL PATIENTS UNDERGOING SURGERY IN K.N.H THEATRES

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STUDENT'S DECLARATION

I, **Sheila Nyakio Gitau,** do hereby declare that this dissertation is my original work and has not been previously submitted to any institution for examination or otherwise.

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LIST OF ABBREVIATIONS

SAP-	Surgical Antibiotic prophylaxis
SSI-	Surgical Site Infection
HAI-	Health-care Associated Infections
KNH-	Kenyatta National Hospital
UoN-	University of Nairobi
NICE-	National Institute of Health Care Excellence
ASHP-	American Society of Health-System Pharmacists
SHEA-	Society for Healthcare Epidemiology of America
IDSA-	Infectious Diseases Society of America
RCPA-	Royal College of Physicians of Ireland
HPS-	Health Protection Scotland,

DEFINITION OF TERMS

SAP- Surgical antibiotic prophylaxis is the administration of a short course of an antimicrobial agent prior to surgery to prevent surgical site infection.

SSI- Surgical site infection is defined as a proliferation of pathogenic microorganisms which develops in an incision site either within the skin and subcutaneous fat (superficial) and muscular facial layers (deep) or in an organ or cavity within 30 days after operation.

HAI- Health-care associated infection, also referred to as nosocomial or hospital acquired infection, is defined as an infection that occurs in a patient during the process of care in a hospital or other health-care facility, which was not manifest or incubating at the time of admission. This includes infections that develop in the hospital or any other setting where patients receive health care and may appear even after discharge.

Antibiotics- Also known as antimicrobials and are medications that are used to destroy or slow the growth of bacteria.

MIC- Minimum Inhibitory Concentration is defined as the lowest concentration of a drug that will inhibit the visible growth of a microorganism.

ABSTRACT

Background: Surgical antibiotic prophylaxis is one of the main principles in reducing postoperative surgical site infection. Choice of antibiotic prophylaxis is best tailored to the type of surgical wound and risk of postoperative infection based on the causative organism. Guidelines were developed to encourage rational antibiotic use and to reduce risk of antibiotic over use which leads to increased hospital costs and promotes antibiotic resistance.

Broad Objective: This study sought to determine the patterns of perioperative antibiotic surgical prophylaxis among surgical patients in KNH theatres.

Study Design: Descriptive cross-sectional study.

Methodology: Patients undergoing surgery, who were not already on antibiotic treatment, were recruited into the study through consecutive sampling. The patients' data on choice of antibiotic, time of administration relative to the time to surgical incision, timing and duration of postoperative administration, was collected intraoperatively. The data was then compared against available KNH and WHO surgical antibiotic guidelines. Patients were reviewed postoperatively to assess for surgical site infection.

Data Analysis: Data was analyzed with the statistical package for social sciences. Socio-demographic and clinical characteristics were summarized and presented as means with standard deviations, and interquartile ranges where applicable. The timing and duration of prophylactic antibiotic use was presented as means with standard deviations. Adherence to KNH protocol and incidence of surgical site infection was presented as proportions.

Results: We enrolled 402 patients in the study. The choice of intraoperative antibiotic was appropriate in 29% of patients in accordance with the KNH and WHO guidelines. Ceftriaxone was the most frequently prescribed antibiotic intraoperatively. Amoxicillin/clavulanic acid was the most frequently prescribed antibiotic post-operatively. Majority of the patients received antibiotics within 30 minutes of the surgical incision. Antibiotic dosages varied depending on the age of the patient. 11.4% of patients received antibiotics for a maximum of 24 hours. 11.7% of patients did not receive antibiotics postoperatively. The choice of postoperative antibiotic was appropriate in 7% of patients, according to KNH and WHO guidelines. The antibiotic dose was appropriate in 21.4% vs 4.2% of patients according to KNH and WHO guidelines respectively. The timing of antibiotic administration was appropriate in 84.6% and 86.1% in accordance with KNH and WHO guidelines respectively. Only 3/109 (2.75%) of patients received a required repeat dose of antibiotics. 23.1% of patients got appropriate duration of antibiotic prophylaxis according to KNH and WHO guidelines. The rate of surgical site infection was at 11%. Clean wounds were associated with reduced risk of SSI's p=0.001.

Conclusion: Patients got varied antibiotics for surgical prophylaxes that were not in accordance to the recommendations in the KNH or WHO guidelines. Timing of antibiotic prophylaxis was appropriate in majority of the patients. The choice, dose and duration of surgical antibiotic prophylaxis was found to be varied and outside the existing guidelines (KNH, WHO).

1.0 CHAPTER ONE: INTRODUCTION

1.1 Background

Patients who undergo surgical procedures are at increased risk of developing an infection postoperatively due to breach of the protective skin barrier with a surgical instrument. Many strategies have been implemented to prevent surgical site infection postoperatively. Antibiotics use is one of the cornerstone strategies in preventing healthcare associated infections (HAIs) across the world. They are used prophylactically to prevent surgical site infections (SSIs), known to affect up to a third of all surgical patients, in middle and low income countries [1] Nosocomial infections account for significant health care costs and psychological stress to the patient and relatives [2].

Inappropriate antibiotic use contributes to increased healthcare costs and the emergence of multidrug resistant bacteria, which are a public health dilemma [3]. Antibiotic prescription guidelines have been widely used in an effort to reduce antibiotic over-prescription and encourage appropriate prescription based on local bacterial patterns. [4] Several studies have shown poor compliance to guidelines in surgical patients contributes to increased length of hospital admission and added health treatment costs. [5-12].

Perioperative surgical antibiotic prophylaxis is a widely accepted practice found in many local and international guidelines [4,13,15-17]. Adherence to local antibiotic prescription guidelines has been shown to reduce SSI rates. [16,18] However, compliance to guidelines has been very poor [19,20] with studies in Australia showing up to 40% of antibiotics prescribed are inappropriate [12].

Antibiotics should be given before a surgical incision is made to obtain optimal tissue drug concentration, based on the pharmacokinetics of the drug. The timing of drug administration has been studied widely and data from high level evidence suggests it to be within 120 minutes prior to skin incision [4,12,13,15, 21-23].

Surgical site infections have been documented up to 30 to 90 days after surgery [25]. Infections cause significant morbidity ranging from local inflammation to severe systemic infection and even death. Evidence shows that up to 40-60% of surgical site infections are preventable. [20, 26]

This study looked at the type of antibiotic, timing, dose and duration of antibiotics use in the perioperative period. The aim was to encourage appropriate and timely antibiotic use which reduces antibiotic overuse and incidence of surgical site infections. By reducing antibiotic over prescriptions, we can reduce the incidence of antibiotic associated adverse drug events and also reduce healthcare costs. The results of this study shall be shared with the KNH Antimicrobial Stewardship Committee which formulates policy on antibiotic prescription.

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2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Antibiotic Prophylaxis

Surgical antibiotic prophylaxis can be defined as the administration of an antibiotic for a short duration of time before surgery to prevent surgical site infection. [27,28]. For antibiotics to be effective, drug tissue concentrations must be above the minimum inhibitory concentration (MIC) for bacterial killing, prior to contamination of the wound through skin incision, and maintained throughout the procedure [29]. Surgical wounds are at a particular risk of infection through direct microbial contamination during surgery. Microorganisms may come from the patient through skin contaminants which then enter the wound. The environment around the patient including clothing and beddings may also be a source of contamination. Once the patient in the operating room, the operating staff, the theatre, hospital equipment maybe the source of micro-organisms[30].

The surgical team at the Kenyatta National hospital are responsible for administering the antibiotics perioperatively. The surgical team comprises of the anesthesia provider the surgeon and the nursing staff. Antibiotics are prescribed preoperatively in the wards or intraoperatively by the surgical team. It is not clear who prescribes the antibiotics. It is not recommended to continue antimicrobials after the surgical wound is closed, in clean and clean- contaminated procedures [4,5,13,16,30]

Antibiotic prophylaxis in surgery is effective in preventing surgical SSIs in clean surgical procedures (hernia repair, cardiac surgery, lower limb, caesarean sections) [30]. Tamma et al. 2017 found that 20% of patients suffered at least one antibiotic associated adverse drug event, among hospitalized patients who received antibiotic prophylaxis. The adverse events were increased prevalence of antimicrobial resistant bacteria and infections caused by Clostridium difficile [3]. Antibiotics should therefore only be prescribed when recommended.

The National Institute for health and care excellence(NICE) in 2008 developed clinical guidelines, where they recommended that antibiotics given for prophylaxis, should not be given as standard practice for clean, non-prosthetic and uncomplicated surgery because when used, the risk of adverse events such as *Clostridium difficile*-associated diseases, antibiotic hypersensitivity and drug resistance were increased. [3,15,27]

Procedures that require antibiotic prophylaxis include surgery on infected or dirty wounds, contaminated wounds, clean-contaminated wounds or surgery that involves the placement of a prosthesis or implant. [3,30] Appropriate SAP practices encompass the use the right,

antimicrobial for the right indication, the right dose, right route, right timing of administration and for the correct duration. [27]

There are local and international guidelines on correct antibiotic prophylaxis for different surgical procedures. The Centre for Disease Control Guidelines are the most commonly used worldwide. The Kenyatta National Hospital Antimicrobial Stewardship Committee in 2018, developed guidelines for antibiotic use, both prophylactically and empirically. They recommended that surgical patients should not receive antibiotics, unless indicated. In order to determine if antibiotics are prescribed appropriately, we shall compare prescriptions to the standard, which are the available local antibiotic guidelines. The KNH guidelines do not cove where guidelines are not available, we shall consider the WHO guidelines (See appendix II).

Antibiotics administered intravenously for prophylaxis before a caesarean incision reduced the risk of SSI when compared to administration after neonatal umbilical cord clamping [30]. SAP in infants and children follows guidelines based on adult studies due to a paucity of studies done in this population. Drug dosing should be adjusted for weight in this population and in the obese. [4,29,58,59].

2.2 The Kenyatta National Hospital Surgical Antibiotic guidelines

Procedure	Antibiotic	Dosage	Level of evidence
Emergency orelective caesarean section (no labour, no rupture of membranes)	Cefazolin IV 15 to60 mins prior to skin incision Penicillin allergy: Clindamycin or Erythromycin	1-2g IV 900mg IV 500mg IV	I-A
Vacuum delivery	Non recommended	N/A	II-1C
Manual removal placenta	Non recommended	N/A	III-L
Repair third or fourth degree laceration	Cefazolin/cefuroxime/cefotetan	1-2g IV	I-B
Cervical cerclage	Non recommended	N/A	II-3C
Postpartum D&C	Non recommended	N/A	No evidence
Need for broader spectrum antibiotics: • Prolonged labor (>24hrs) • Prolonged rupture of membranes (>24hrs) • Multiple number of vaginal examinations (>5 examinations) • Post partum hemorrhage (PPH) or anemia • Difficult or prolonged surgery due to adherence of placenta or numerous adhesions.	Cefazolin + Azithromycin	1-2gm IV 500mg IV	
Chorioamnionitis Treat for 5 days	Amoxicillin/clavulanic acid or Ceftriaxone + Metronidazole		

Cefazolin	Administered as deep IM, IV injection or IV Infusion ADULT 1 g as a single dose at induction of anaesthesia, or after cord clamping in caeserian section, repeated if necessary if surgery lasts more than 3 hours CHILD: 25mg/kg (maximum 1 g) as a single dose at induction of anaesthesia, repeated if necessary if surgery lasts more than 3 hours Further doses may be given every 6-8 hours post operatively for 24 hours if necessary or up to 5 days in continued risk of infection.

Source: The KNH guide to empirical antimicrobial prophylaxis, second edition 2018.

2.3 Surgical Site Infections

Surgical site infection (SSI) which is defined as the proliferation of pathogenic microorganisms developing in an incision site either within the skin and or subcutaneous fat, muscular fascial layers (deep) or in an organ or cavity within 30 days after operation [31]. SSI are associated with increased morbidity and mortality related to increased healthcare associated costs [1,2,10]

Surgical site infection rates in studies, range between 2.5% - 41.9% globally, but are almost double in developing countries [10,32]. Mortality rates in developing countries, that are attributable to patients with history of anesthesia exposure, are almost 10 times in developing countries, compared to those in developed countries [10,33]. This is explained by the fact that all patients undergoing surgical procedures do so under some form of anesthesia for pain control. SSI rates in developing countries were found in a meta-analysis of international studies, to have a cumulative incidence of 0.4 to 30.9 per 100 patients, 1.2 to 23.6 per 100 surgical procedures, and 11.8 per 100 patients, pooled cumulative incidence [10,32,34]. In the perioperative patient outcomes study by Biccard et al 2017, it was found that 20% of patients undergoing caesarean sections in Africa develop surgical site infections contributing to maternal and infant morbidity. In Africa, patients are twice as likely to die following surgery although they are younger and healthier compared to those in developed countries [34].

Surgical site infections are the second commonest nosocomial infection, at 21.8% in the United States and causing a significant financial burden with up to 400,000 added in-hospital days and up-to 10 billion dollars in healthcare costs annually [2]. This is thought to be an underestimation of the disease burden as about half of the reported cases are reported after discharge from hospital [35]. Patients developing surgical site infections have increased re-admissions, and mortality rates that are 2 to 3-fold higher. The European point prevalence study 2011 found SSI to be the second commonest hospital acquired infection (HAI). [9] According to the NICE 2009 guidelines, between 2% - 5% of all patients undergoing surgery, develop SSIs. [15]. A survey in 2006 by Smyth et al, reported that of the 8% of patients who develop HAIs, 14% were surgical site infections [36]. A report in 2004 estimated that healthcare costs due to SSI were approximately € 1.47-19.1 billion in Europe. The estimated additional 6.5 hospital days per patient, costs 3 times more than the non-infected patient [37].

Burke in the 1960s, demonstrated that use of antibiotics intraoperatively, was one of the cornerstones processes to reduce surgical site infection. Antibiotics, he found, reduced the bacterial load at the surgical site. He inoculated the dermis of guinea pigs with Penicillin-sensitive Staphylococcus aureus isolates and there after gave a single dose of penicillin. He then took cultures from the tissues and found that the lesions were similar to those inoculated with killed bacteria. When antibiotics were administered more than three hours after the surgical incision, isolates were similar to those in pigs who had not received antibiotics [38, 39]. This formed the basis of timing of antibiotic prophylaxis in many guidelines used today.

Effectiveness of antibiotic prophylaxis is dependent on achieving the minimum inhibitory concentration, (MIC) before surgical incision, when the bacterial load is highest, and maintaining these levels throughout the procedure.[24,28,38,40]. Single dose antibiotic prophylaxis is sufficient in clean orthopedic procedures not involving a prosthetic device [52]. Additional intraoperative doses are required if a procedure lasts more than four hours or one to two times the half-life of the antimicrobial, or if there is blood loss of more than 1500 mls. [4,17,29,30].

Additional prophylactic antibiotic doses after the surgical incision is closed in theatre are not recommended in clean and clean contaminated procedures even if a drain is left in situ [4, 30] The available evidence in literature does not to support prolonged use of antibiotics due to the presence of surgical drains or catheters beyond 48 hours, which has been shown to increase the risk of adverse drug events. [4,13,16,29,30].

2.4 Timing of Antibiotic Prophylaxis

Studies that were carried out to determine the optimum timing of antibiotics prophylaxis, have demonstrated antimicrobial tissue levels must be optimum before surgical incision [38,40]. The current WHO guidelines 2018, on prevention of SSI's recommendation on administration on surgical antibiotic prophylaxis is administration within 120 minutes prior to the surgical incision. This is similar to recommendations by the European and American guidelines. In North America, the Society for Healthcare Epidemiology of America (SHEA), the American Society of Health-System Pharmacist (ASHP), and the Infectious Diseases Society of America (IDSA) together with Royal College of Physicians of Ireland (RCPA) and the Health Protection in Scotland, came up with clinical guidelines that recommend administration of antibiotics within 60 minutes prior to incision [4,41,42,43].

The Global Guidelines for Prevention of Surgical Site infections 2016, recommend antibiotic administration within 120 minutes of surgical incision. This is based on a meta-analysis of all data on optimal timing of antibiotic prophylaxis, which found no added benefit of prevention of surgical site infections between 0 and 60 minutes of incision. They however found significant harm if antimicrobials were given 120 minutes before the incision OR 5.26;95% C.I. 3.29-8.39 [44]

In a meta-analysis conducted by de Jonge et al 2017 involving 54,552 patients, they conclusively reported that SAP should be given within 120 minutes before surgical incision. SSI increased to almost double when prophylactic antibiotics were administered after the surgical incision was made (OR:1.89; 95%CI: [1.05-3.40]). The risk of SSI was 5 times more when SAP was given more than 120 minutes before surgical skin incision, (OR 5.26; 95%CI: [3.29-8.39]).

Studies have been carried out comparing SAPs given 75, 60 or 30 minutes before surgical incision, but all showed no added benefit of reduced SSI risk. [22,24,26,40]

The maximum recommended duration of postoperative antibiotic prophylaxis is 24hrs, with a single intraoperative dose being sufficient for clean and clean contaminated wounds [4,29]

The WHO surgical checklist requires that the antibiotic is given by the anesthesia provider before the surgical incision is made. Postoperative antibiotics are not recommended unless treating an active infection. [5,12,29,30]. Choice of antibiotic should be influenced by local surveillance data on causative organisms from wound cultures in the specific procedures, and by the relative costs of available drugs. For majority of clean and clean contaminated procedures, the microorganisms identified are Staphylococcus aureus and coagulase negative Staphylococcus species, which are skin commensals [40] Elamenya in 2014 found staphylococcus aureus as the commonest causative agent at 82%, for SSIs in pediatric surgical patients [60]. Miima 2016 found Escherichia Coli as the commonest organism causing SSI in surgical patients undergoing laparotomy [61]. Cefazolin is the recommended antimicrobial for most surgical procedures. [4,17,30].

Gastrointestinal surgical procedures involve different microorganism such as Enterobacteriaceae and enteric anaerobic bacteria such as Bacillus fragilis. Administration of antimicrobials which are effective against gram-negative and anaerobic bacteria as well as in mechanical bowel preparation are necessary interventions.[4,29,30] Antibiotics such as vancomycin and the fluoroquinolones should be given within 60- 120 minutes before making the surgical incision [46].

High quality evidence from systematic reviews on AMP in caesarean section demonstrated that a once only intravenous dose of prophylactic antibiotic dose should be administered before the surgical incision based on pharmacokinetic properties. It should be given within 60 minutes in electives and emergency surgeries [30,48,49,50]. Recommendations from clinical guidelines are re-dosing should be done intraoperatively in procedures lasting more than 3-4 hours, severe burns or massive blood loss, more than 1500 mls. [29,30].

A meta-analysis of 45 randomized control trials comparing antibiotic prophylaxis single dose versus multiple doses across all surgical fields found no added benefit in continuing antibiotics after closure of a surgical wound. [13]. SAP is not recommended for clean non-prosthetic and uncomplicated surgery. The use of local antimicrobial formulary and consideration of the possible adverse effects, should guide the choice of antibiotic. In surgery requiring a tourniquet, evidence suggest giving antibiotics before application of tourniquet. [13,46]

The most important elements in appropriate surgical antibiotic prophylaxis, encompass using the correct drug for the correct indication, and using it through the right route for the recommended duration of time at the right dose at the right time. [4,12, 29,30]

The principles of SAP include starting appropriate antimicrobial prophylaxis based on the bacterial flora most commonly known to cause infection postoperatively, with a narrow antibacterial spectrum, cheap, most efficacious, least toxic and easily administered at the right time, dose, duration, and for the right indication. Antimicrobial use should be reviewed often as microbial patterns change, and they should never be used to cover for poor surgical technique. Broad spectrum antimicrobials that are used for severe infections are discouraged for prophylaxis. [29]

2.5 Wound Classification

Wounds are generally classified according to their potential risk of developing infection, based on the extent of skin contamination preoperatively. There are many classification methods used but the most widely used is the Center for Disease Control Clinical classification.

Table 1: Wound Classification

Class I ***Clean***	A surgical wound that shows no signs of infection or inflammation. The uninfected genitourinary, alimentary, genital and respiratory system should not have been breached during surgery. Clean wounds are primarily closed and, if required, closed drainage left in situ. Incisional wounds for operations for non-penetrating (blunt) trauma should be included in this category if they meet the criteria.
Class II ***Clean-contaminated***	An operative surgical wound in which the genital. respiratory, alimentary, or urinary tracts are entered under controlled conditions but do not contain unusual amount of contamination. Surgical wounds for operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, if there is no evidence of infection or a major break in technique is encountered.
Class III ***Contaminated***	Fresh wounds in which the skin breach is encountered accidentally. These include operations with major breaks in sterility for example open cardiac massage or gross spillage from the gastrointestinal tract, and incisions in which acute, non-purulent inflammation is encountered.
Class IV ***Dirty-infected***	Old trauma related wounds which contain devitalized tissue or those that have existing clinical infection or perforated viscera. This suggests that the organisms causing postoperative infection were present in the operative field before the operation.

http://www.cdc.gov/hicpac/SSI/table7-8-9-10-SSI.html Adapted from CDC 2017 guidelines

SAP has become the standard of care for contaminated, clean-contaminated surgeries and for surgeries involving insertion of artificial devices [13,23]. Most parenteral antibiotics are usually given at induction of anesthesia.

2.6 Current Guidelines for Antibiotic Prophylaxis of Surgical Wounds

There are many international guidelines on SAPs such as the WHO 2018 and the CDC 2017 guidelines. They are based on high level evidence from meta-analysis of studies on different surgical procedures. The recommendation on antibiotic prophylaxis is guided by the organisms most commonly associated with SSIs in specific surgical procedures. The multidisciplinary Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery was developed as a combined endorsement by the Infectious Disease Society of America (IDSA), American Society of Health-System Pharmacists (ASHP), and the Surgical Infection Society (SIS) and the Society for Healthcare Epidemiology of America (SHEA). From these guidelines, they recommended a single agent most often a beta-lactam antibiotic for most surgical procedures [4]. This formed the basis of the WHO 2016 antibiotic prophylaxis guideline. For the guideline, see appendix II

2.7 Classification of SSI

Surgical site infection is defined as an infection of skin, or cavity or organ that occurs within 30 to 90 days of a surgical procedure. This is due to proliferation of microorganisms in the surgical would leading to signs and symptoms of infection such as redness, swelling, heat, pain and sometimes accompanied by signs of systemic infection such as raised white cell counts [44,46]. Wounds can be classified as superficial or deep depending on the tissues involved.

A surgical procedure by definition is one that is clean and does not show any signs of inflammation. The major organ systems; genital, respiratory, alimentary and the urinary tract that is not infected, should not have been encountered during the surgery. A surgical procedure is clean-contaminated if genital, alimentary respiratory or non-infected urinary tract are entered. Surgical operations that involve oropharynx, biliary tract, appendix and vagina are considered clean-contaminated procedures. Procedures are considered dirty-infected procedures when they have devitalized tissues with associated clinical signs of infection, as is seen in old traumatic wounds.

Conditions other than the mentioned ones were considered as contaminated cases. Prophylactic antibiotics are required for all clean-contaminated procedures and for some specific clean procedures. For example, when a prosthesis is used in joint or vascular surgeries especially in the presence of certain conditions. These risk factors include: malnutrition, obesity, irradiation history, diabetes mellitus, use of immunosuppressant

therapy or smoking. Dirty or contaminated procedures which are being treated with antibiotics are not considered as prophylaxis.

Local data from KNH suggested that a single high dose prophylactic antibiotic in emergency and elective caesarean sections surgeries reduced the incidence of puerperal sepsis. Macharia et al in 2017 determined that among patients undergoing elective caesarean section, single dose antibiotics prophylaxis was as effective as multiple dosing regimen in preventing puerperal sepsis [47]

Opanga Sylvia found an incidence of 21% of surgical site infection among neurosurgical patients undergoing elective or emergency surgery with dirty or contaminated wounds. The most commonly used antibiotics were cephalosporins. She found that systemic antimicrobial prophylaxis was very effective in reducing surgical site infections in patients undergoing craniotomy for subdural hematoma for evacuation. Njiru et al determined that patients undergoing clean craniotomy had a 7.5% incidence of surgical site infection. The most common causative organisms for surgical site infection were staphylococcus aureus and Pseudomonas aeruginosa which were resistant penicillins, erythromycin and cefuroxime, ceftazidime, piperacillin-tazobactam respectively. [53]

Nyambada et al conducted a study on single dose of flucloxacillin in clean major surgical procedures and had an incidence of 1% of postoperative surgical site infections. Regoiorri et al in a randomized control trial compared single intravenous dose ampicillin versus multiple doses of ampicillin and metronidazole in patients having herniorrhaphy or ectopic pregnancy surgeries or hysterectomies. They found a relative risk reduction of 86% for SSIs, with ampicillin in herniorrhaphy and ectopic pregnancies. The average duration of hospital stay was reduced in all patients getting antibiotics compared to those not getting any antibiotics [48]

2.8 Study Justification

There is evidence that intraoperative surgical prophylaxis prevents surgical site infection, if given before skin incision. Hospital guidelines were in place to reduce antibiotic use and antibiotic associated adverse events. There were no local studies to show if the guidelines were being adhered to. The timing of the antibiotic prophylaxis was recommended within 120 minutes before surgical incision. Post-operative antibiotics have been found to be ineffective in preventing surgical site infections, if the colonization of the tissue at incision site occurs more than 3 hours before first dose of antibiotic. It is not known what antibiotics are being given intraoperatively and when they are given. It is not known if the choice of

antibiotic prophylaxis is related to the cadre of the surgical team. In KNH, there is an antibiotic protocol in place. It is not clear if it is adhered to. This study looked at identifying the trends in antibiotic use and to assess whether the choice, dose, timing and duration of use was appropriate. The outcomes of this study were to help improve compliance to protocol use and possibly help in formulation of a protocol for management of surgical site infections in KNH. This would lead to reduced hospital costs, duration of stay for the patients, SSI risks and adverse effects associated with antibiotics.

2.9 Study Objectives

2.9.1 Main Objective

To determine patterns of prophylactic surgical antibiotic use among surgical patients in KNH.

2.9.2 Specific Objectives:

a) To determine the choice and timing of antibiotic prescribed

b) To determine the dose and repeat dosing of antibiotic

c) To determine duration of prophylactic antibiotic use.

d) To determine the incidence of surgical site infection among surgical patients who receive prophylactic antibiotics within 30 days of surgery

3.0 CHAPTER THREE: METHODOLOGY

3.1 Study Design

This was a descriptive cross-sectional observational study.

3.2 Study Population

All patients seeking services in all KNH theatres for elective or emergency surgery.

3.3 Study Site

The study was carried out at the main, minor and satellite theaters of the Kenyatta National Hospital. Patients were followed up in the wards postoperatively.

3.4 Sampling Technique

The sampling technique was consecutive sampling.

3.5 Sample Size

Sample size was calculated using Fisher's formula:

n=(Z^2 x P(1-P))/d^2

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P = expected true proportion (estimated at 42%, from a cross-sectional study conducted by Alavi SM. et al (2014) looking at antibiotics use pattern for surgical prophylaxis site infection in different surgical wards, found that 42% of patients received appropriate prophylactic antibiotics.)

d = desired precision (0.05)

A Sample size of 374 participants was required for the study.

3.6 Eligibility Criteria

All patients scheduled for surgery in KNH theatres who are not already on antibiotics treatment.

3.7 Inclusion Criteria

All patients undergoing surgery at KNH theatres

Patients not already on antibiotics preoperatively

All patients who give consent for inclusion in the study

3.8 Exclusion Criteria

All patients who are already on antibiotic treatment for other diseases

Patients already on antibiotics for 24hrs shall be considered to be on empiric treatment and excluded from the study.

All patients who decline to give consent for inclusion in the study.

3.9 Study Procedure

The study included all patients seeking surgical services in KNH theatres. All patients were recruited at the theater receiving areas after a preoperative review was done and patient confirmed for surgery. For all patients below 18 years, assent was obtained from self or consent from the guardian preoperatively. Patients had their weights measured at the receiving area after recruitment and this information was entered in the data collection tool. All general surgical, orthopedic, pediatric, neurosurgical and gynecology patients were included in the study when they gave consent or next of kin gave consent, and they were not on antibiotics before surgery.

A questionnaire was filled by a research assistants who was present during the surgical procedure. They indicated the bio-demographic data of all patients recruited into the study. They also indicated the level of training of antibiotic prescriber i.e. qualified anesthesiologist, registered clinical officer, resident or diploma student in training. They indicated what antibiotic was prescribed, dose and time it was administered, timing of the surgical incision, if dose was repeated and the reason. The type of surgical procedure and the postoperative antibiotic choice and duration was also indicated.

That information was obtained from the treatment sheet when the patient was in the post anesthesia care unit. The type of wound was defined; clean, clean-contaminated or dirty. The wound classification was determined intraoperatively by the research assistants and recorded in the questionnaires. They were trained on use the wound classification chart which was attached to the questionnaire for easy reference. When this data was not captured in the data collection tool, the surgeon who performed the operation was asked to classify the wound based on the attached wound classification. When not able to get this data, these patients were excluded from the study.

Patients were followed up for up at day 5 and 30 postoperatively either in the ward or at home. Complications of surgical site infection or drug reaction if any, were noted. All patients contacts or contact of next of kin were included in the data collection tool. A follow up at 30 days after the procedure was made in person for patients still in the ward, or by a

phone call after discharge. Patients who were already discharged and developed SSI's were requested to come back to KNH for treatment, or go to their nearest health facility for medical treatment.

The role of the research assistants was to collect data using the data collection tool. Two research assistants were recruited to assist in data collection. They were registered clinical officers working in KNH, who were trained on the study protocol, ethical issues, confidentiality and data collection procedure. The research assistants were formally trained on the study methodology and how to use the data collection tool. Once the patients were recruited by the principal investigator, the research assistants accompanied the patient into the operating theatre and using a structured questionnaire, collected data from the anesthesia provider intraoperatively. They alone collected the data to prevent reporting bias. They were blinded to the outcomes of interest. They were responsible for keeping the questionnaires confidential.

They were also trained on how to use the data collection tool to collect data intraoperatively. They followed up patients postoperatively to look for signs of surgical site infections. They maintained patient confidentiality according to the UoN/ERC guidelines. All data collection tools were stored under lock and key, at all times.

3.10 Data Management and Analysis

All questionnaires were coded, entered and managed in the Microsoft Access 2013 database designed for the study. Data was checked for completeness prior to entry and analysis with the use of Statistical package for Social Sciences version 21. Any wound that appeared infected post operatively was considered a positive outcome for surgical site infection. This data was analyzed and reported as a proportion of the total number of patients in the study. The timing and duration of prophylactic antibiotic use was analyzed and presented as means with standard deviation. Adherence to KNH protocol and incidence of surgical site infection was analyzed and presented as proportions. Adherence to KNH protocol was analyzed by comparing what prophylactic antibiotics were prescribed and administered compared to what should have been prescribed according to the KNH protocol. This data was presented as proportions. The proportion of patients who had the correct antibiotic prescriptions was compared against the total population of patients in the study. Demographic and clinical characteristics was analyzed and presented as means with standard deviation and interquartile ranges where applicable. Data was kept under lock and key for the duration the duration of the study. At the end of the study, the raw data was destroyed; the hard copies by paper

shredding, and soft copies by formatting and deleting from all storage devices including computers, flash discs and hard drives. This is in accordance with the UoN/ERC guidelines.

3.11 Ethical Consideration

The researcher obtained approval from the UON ethics and research committee to conduct the study. All patients signed an informed consent form after an explanation of the study objectives. Participation was on a voluntary basis and withdrawal from the study was allowed at any time. This was an observational study and was not harmful to the patients participating in the study. Participants' anonymity was ensured throughout the study where all patients were coded. The costs of the study were not transferred to the patients participating in the study. Any patient noted to have developed signs of surgical site infection were commenced on treatment without delay. A pre-anesthetic assessment was conducted by the anesthesia provider on all consenting patients. The results of this study were presented to the KNH and UON departments of anesthesia.

4.0 CHAPTER FOUR: RESEARCH FINDINGS

4.1 Introduction

The main objective of the study was to determine patterns of prophylactic surgical antibiotic use among surgical patients in KNH. The study site was the main and satellite theatres at Kenyatta National Hospital. After study protocol approval by the KNH-UON Ethics and Research Committee, 402 patients were enrolled into the study.

4.2 Patient Characteristics

This section describes the patient characteristics who received treatment at the Kenyatta National Hospital. Means and standard deviations are presented as Mean (SD) where applicable.

Table 1: Patient characteristics

The characteristics of the patients is as shown by the table below.

Table 2: Patient Characteristics

	Frequency n (%)
Age (years)	
<18	67 (16.7)
18-35	152 (37.9)
36-45	69 (17.2)
46-65	86 (21.4)
>65	27 (6.7)
Gender	
Male	231 (57.5)
Female	171 (42.5)

There were more male patients (57.5%) compared to the female patients. Majority of the patients were aged between 18-35years. The mean age of the patients was 35.9 (SD=18.3) years, while the median age was 35.0 (IQR=25) years.

Table 3: Baseline data

Cadre prescribing	
Consultant Anesthesiologist	41 (10.2)
Registered clinical officer	36 (9.0)
Registrar	277 (68.9)
Clinical officer in training	48 (11.9)
Type of surgery	
Emergency	114 (28.4)
Elective	288 (71.6)
Patient existing comorbidity	
Yes	120 (29.9)
No	282 (70.1)
Type of wound	
Clean	266 (66.2)
Clean contaminated	136 (33.8)

Residents in training or registrars were the main antibiotic prescribers at 68.9%, followed by clinical officers in training at 11.9%. Majority of the surgical cases were elective cases at 71.6% compared to emergency cases at 28.4%. Patients with preexisting medical conditions constituted 29.9% of all the patients with 70.1% having no comorbidities. Most of the patients had clean wounds 66.2% and those with clean contaminated wounds were at 33.8%.

Table 4:Co-morbid Conditions

	N	**Percent of Patients (N=115)**
Hypertension	28	24.6%
Diabetes	9	7.9%
HIV	4	3.5%
Malignancy	39	34.2%
Renal disease	6	5.3%
Congenital anomalies	4	3.5%
Previous surgery	38	33.3%
Obesity	1	0.9%

The most common comorbidity was malignancy at 34.2% followed by previous surgery at 33.3% and hypertension 24.6%. Diabetes only constituted 7.9% of the cases with 9 patients.

Table 5 :Co-morbidity and wound type

N=115	Clean	Contaminated	Total
Hypertension	25 (33.8)	3 (7.3)	28
Diabetes	6 (8.1)	3 (7.3)	9
HIV	4 (5.4)	1 (2.4)	4
Malignancy	26 (35.1)	13 (31.7)	39
Renal disease	6 (8.1)	0 (0.0)	6
Congenital anomalies	0 (0.0)	4 (9.8)	4
Previous surgery	18 (24.3)	20 (48.8)	38
Obesity	1 (1.4)	0 (0.0)	1
	74	**41**	

Table 6: Comorbidity and wound type

	Clean	Contaminated	Total	p-value
Comorbidity Present	74 (27.8)	41 (30.1)	115 (28.6)	0.625
Comorbidity Absent	192 (72.2)	95 (69.9)	287 (71.4)	

Table 7: Case Distribution per Specialty

	Frequency	Percent
Cardiothoracic Surgery	12	3.0
ENT Surgery	37	9.2
General Surgery	122	30.3
Maxillofacial Surgery	6	1.5
Multidisciplinary Team	5	1.2
Neurosurgery	20	5.0
Obstetrics/Gynecology	63	15.7
Orthopedics	71	17.7
Pediatrics Surgery	14	3.5
Plastic Surgery	12	3.0
Urology	40	10.0
Total	**402**	**100.0**

The surgical cases were distributed across all surgical specialties. General surgery had majority of the cases at 30.3%, followed by Orthopedics surgery at 17.7% and obstetrics and gynecology at 15.7%.

Table 8: Preoperative hospital stay before surgery

	Frequency	Percent
Less than 1 day	5	1.2
1 day	137	34.1
2-6 days	132	32.8
7 days	29	7.2
8-14 days	39	9.7
15-21 days	21	5.2
22-28 days	5	1.2
Above 29 days	34	8.5
Total	**402**	**100.0**

The mean preoperative hospital stay before surgery was 9.4 (SD=21.4) days, while the median was 3.0 (6.0) days. The minimum was less than a day, and the maximum observed length was 240 days.

4.3 Choice of Antibiotic

This section presents the results on the antibiotics administered both intraoperatively and postoperatively.

Table 9: Choice of Antibiotic prescribed intraoperatively

	Frequency	Percent
Amoxicillin/Clavulanic	61	15.2
Cefazolin	115	28.6
Ceftazidime	2	.5
Ceftriaxone	164	40.8
Cefuroxime	52	12.9
Meropenem	1	.2
Metronidazole	1	.2
None	5	1.2
Not indicated	1	.2
Total	**402**	**100.0**

The most frequently prescribed antibiotic for surgical prophylaxis intraoperatively was ceftriaxone at 40.8%, followed by cefazolin at 28.6%. Amoxicillin/clavulanic acid was given in15.2% of all patients. Five patients (1.2%) did not receive SAP. The rest of the patients got varied antibiotics as seen. (table 6). The Kenyatta National Hospital and the WHO guidelines recommend cefazolin for SAP, therefore, 29% of patients got the appropriate antibiotic for Surgical Antibiotic Prophylaxis intraoperatively.

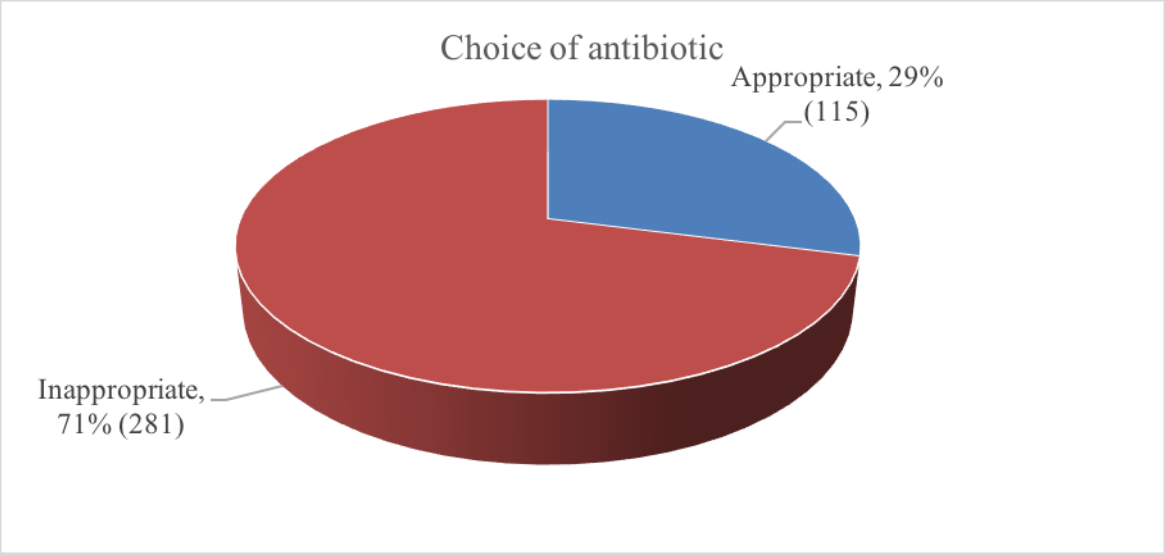

Figure 1 : Choice of antibiotic intraoperatively

Table 10: Intraoperative antibiotic choice per specialty

	Amoxicillin/Clavulanic	Cefazolin	Ceftazidime	Ceftriaxone	Cefuroxime	Meropenem	Metronidazole	None	Not indicated	Total
Cardiothoracic Surgery	4	3		4			1			**12**
ENT Surgery	2	4		26	4			1		**37**
General Surgery	25	40	2	42	13					**122**
Maxillofacial Surgery	2			3	1					**6**
Multidisciplinary Team		1		2	1			1		**5**
Neurosurgery		1		13	4			2		**20**
Obstetrics/Gynecology	10	30		20	2				1	**63**
Orthopedics	6	20		30	13	1		1		**71**
Pediatric Surgery	2	5		3	4					**14**
Plastic Surgery	1	5		5	1					**12**
Urology	9	6		16	9					**40**
	61	**115**	**2**	**164**	**52**	**1**	**1**	**5**	**1**	**402**

In majority of the surgical disciplines, the most frequently prescribed antibiotic for prophylaxis was ceftriaxone. In pediatric surgery, 5/14 and obstetrics and gynecology, 30/63 received cefazolin for intraoperative prophylaxis. Among plastic surgical patients, there were equal proportions of patients who received cefazolin and ceftriaxone.

Table 11: Prescriber of Antibiotics

	Cadre of health care professional prescribing antibiotics				Total
	Consultant Anesthesiologist	Registered clinical officer	Registrar	Clinical officer in training	
Amoxicillin/Clavulanic	5	3	46	7	**61**
Cefazolin	9	14	78	14	**115**
Ceftazidime	0	0	2	0	**2**
Ceftriaxone	20	15	107	22	**164**
Cefuroxime	7	3	37	5	**52**
Meropenem	0	0	1	0	**1**
Metronidazole	0	0	1	0	**1**
None	0	1	4	0	**5**
Not indicated	0	0	1	0	**1**
Total	41	36	277	48	**402**

Most of the intraoperative antibiotics were prescribed by the registrars (277/402), followed by clinical officers in training 48/402. Ceftriaxone was the most frequently prescribed antibiotic by all cadres of health care providers. Cefazolin was most frequently prescribed by registrars 78/115, followed by registered clinical officers and clinical officers in training both with 14/115 and finally consultants at 9/115.

4.4 Post-Operative Antibiotic Prescribed

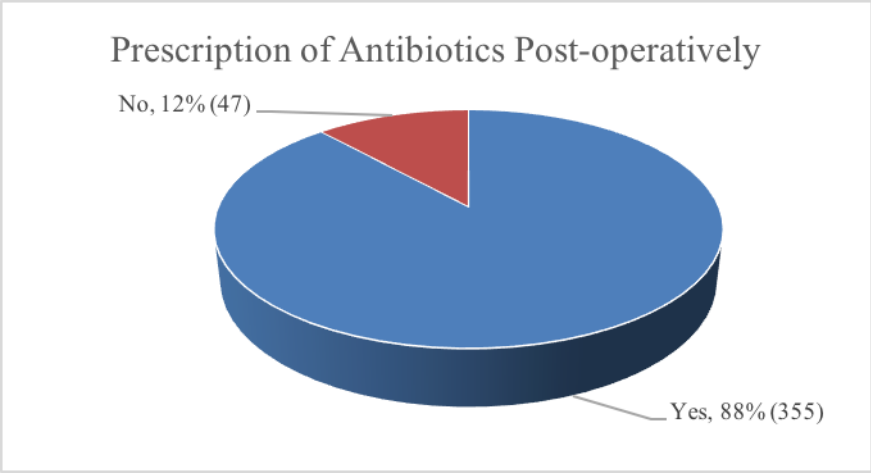

Figure 2: Prescription of Antibiotics Post-operatively

Most patients received antibiotics postoperatively at 88%, against 12% who did not. The postoperative antibiotics were prescribed by the surgeons in the respective surgical disciplines.

Table 12:Antibiotics Prescribed Post-operatively (n=355)

	Frequency n (%)
Amikacin	1 (0.3)
Amoxicillin/Clavulanic acid	147 (41.4)
Cefaclor	1 (0.3)
Cefazolin	24 (6.8)
Ceftazidime	4 (1.1)
Ceftriaxone	86 (24.2)
Cefuroxime	69 (19.4)
Ciprofloxacin	2 (0.6)
Clindamycin	2 (0.6)
Flucloxacillin	6 (1.7)
Levofloxacin	5 (1.4)
Meropenem	1 (0.3)
Metronidazole	6 (1.7)
Piperacillin	1 (0.3)
Total	355 (100.0)

The most frequently prescribed antibiotic postoperatively was amoxicillin/clavulanic acid 41.4%. Ceftriaxone was prescribed for 24.2% of patients and cefuroxime for 19.4% of patients. A total of 24 patients (6.8%) were given Cefazolin for antibiotic prophylaxis post-operatively. According to the KNH and WHO antibiotic prescription guidelines for SAP, the drug of choice for postoperative surgical antibiotic prophylaxis is Cefazolin. Only 6.8% of patients got Cefazolin post-operatively.

The most frequent prescribers of postoperative antibiotics were the obstetrics and gynecology department, 61/63, followed by the general surgeons, 104/122, orthopedics 63/71, urology 36/40 and neurosurgery 19/20. The most frequently prescribed antibiotic was amoxicillin/clavulanic acid at 86.9% by obstetrics and gynecology department, followed by cefuroxime by neurosurgery department at 52.6%.

Table 13: Postoperative antibiotic choice per specialty

	Amikacin	Amoxicillin/Clavulanic acid	Cefaclor	Cefazolin	Ceftazidime	Ceftriaxone	Cefuroxime	Ciprofloxacin	Clindamycin	Flucloxacillin	Levofloxacin	Meropenem	Metronidazole	Piperacillin	Total
Cardiothoracic Surgery		2 (16.7)		1 (8.3)		3 (25)	3 (25)					1 (8.3)	2 (16.7)		12
ENT Surgery		23 (76.7)	1 (3.3)			1 (3.3)	4 (13.3)			1 (3.3)					30
General Surgery		36 (34.6)		4 (3.8)	2 (1.9)	39 (37.5)	17 (16.3)			2 (1.9)	1 (1)		2 (1.9)	1 (1)	104
Maxillofacial Surgery		4 (80)				1 (20)									5
MDT		1 (20)		1 (20)		3 (60)									5
Neurosurgery		2 (10.5)		1 (5.3)		6 (31.6)	10 (52.6)								19
Obstetrics/Gynecology		53 (86.9)		2 (3.3)		5 (8.2)				1 (1.6)					61
Orthopedics	1 (1.6)	9 (14.1)		15 (23.4)		9 (14.1)	28 (43.8)		1 (1.6)				1 (1.6)		64
Pediatric Surgery		4 (40)			1 (10)	4 (40)				1 (10)					10
Plastic Surgery		6 (66.7)				1 (11.1)	1 (11.1)			1 (11.1)					9
Urology		7 (19.4)			1 (2.8)	14 (38.9)	6 (16.7)	2 (5.6)	1 (2.8)		4 (11.1)		1 (2.8)		36
	1	147	1	24	4	86	69	2	2	6	5	1	6	1	355

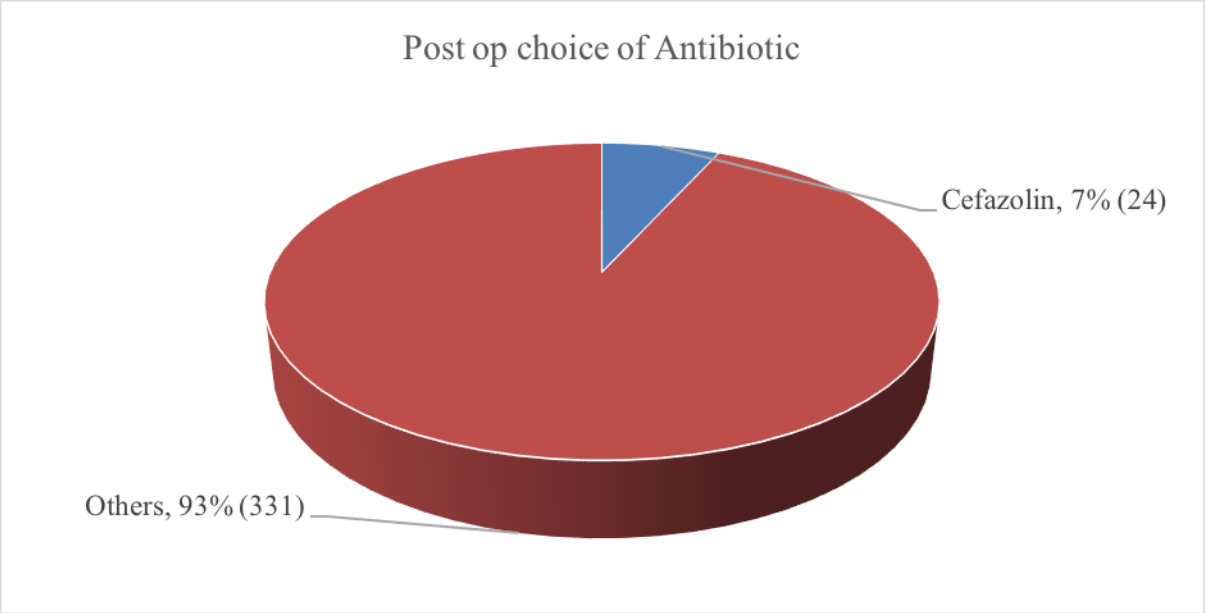

Figure 3: Choice of antibiotic post-operatively

7% of all surgical patients received the appropriate antibiotic postoperatively.

4.5 Timing of Antibiotic Administration

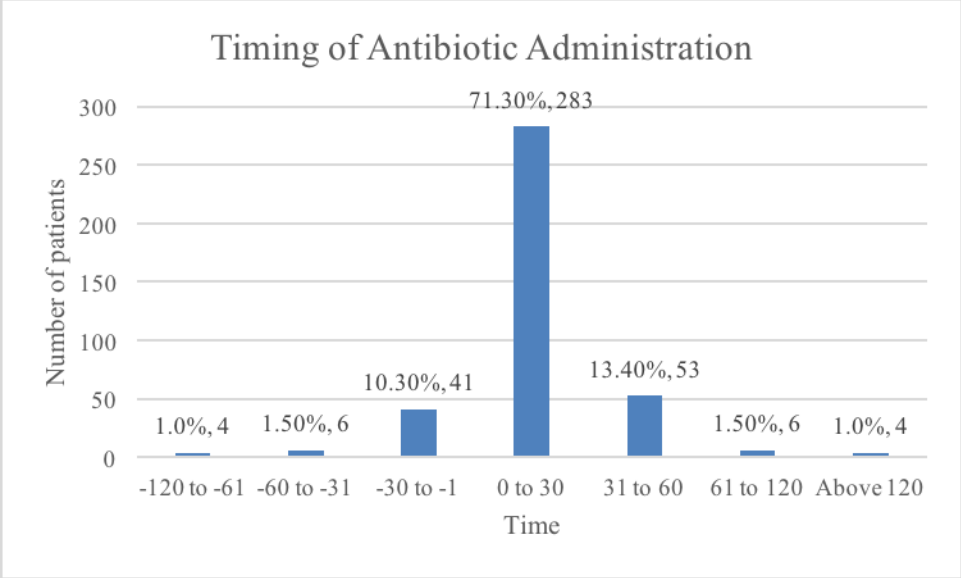

Figure 4: Timing of antibiotic prescription

Antibiotics were given within 30 minutes before the surgical incision was made in majority of the patients at 71.3%. 13.4 % of patients received antibiotics between 30-60 minutes. Four patients got antibiotics more than 120 minutes before the surgical incision was made, while four others got antibiotics more than 120 minutes after the surgical incision was made. These 8 patients did not have appropriate antibiotic cover as they were outside the appropriate antibiotic prophylaxis window of 120 minutes.

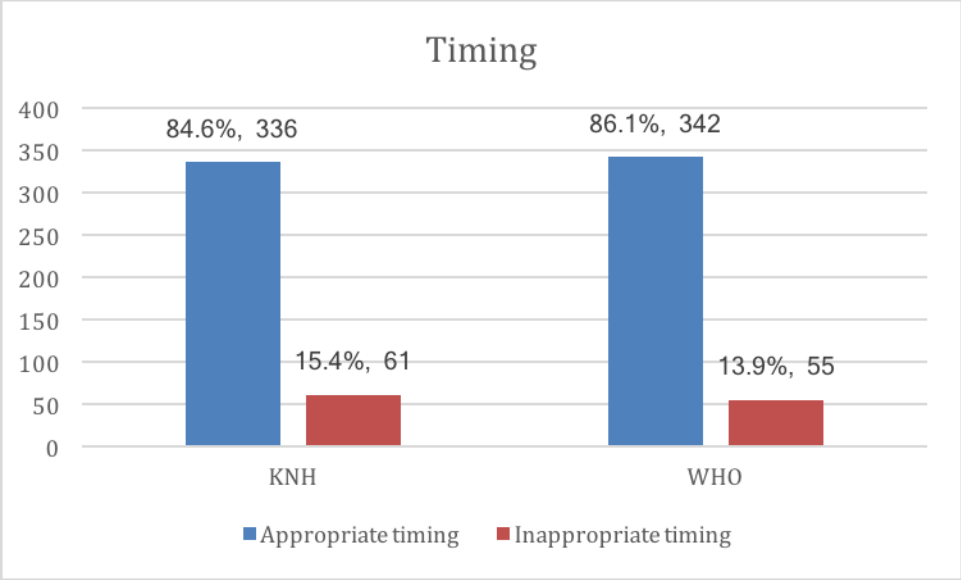

Figure 5: Timing of Antibiotic Prescribed

The timing of antibiotic prophylaxis was compared to the KNH and WHO recommendations of 60 mins and 120 minutes before the surgical incision. 84.6% of patients received antibiotics within the time stipulated in the KNH guidelines. 86.1% of patients received antibiotic at the appropriate time according to WHO recommendations.

4.6 Dose of Antibiotic

Antibiotic doses varied depending on the antibiotic chosen and age of the patient.

Table 14: Dose of Antibiotics (Adults)

	Adult (18+ years)
Amoxicillin/Clavulanic acid 1.2gm	52
Amoxicillin/Clavulanic acid 600mg	1
Cefazolin 2gm	19
Cefazolin 1.5gm	10
Cefazolin 1gm	66
Ceftriaxone 2gm	34
Ceftriaxone 1.5gm	3
Ceftriaxone 1.2gm	2
Ceftriaxone 1gm	99
Ceftriaxone 750mg	1
Cefuroxime 2gm	1
Cefuroxime 1.5gm	22
Cefuroxime 1gm	3
Cefuroxime 750mg	14
Meropenem 1gm	1
Metronidazole 80mg	1
None	4
	333

Table 15: Doses of Antibiotics in mg/kg bwt (Pediatrics)

	Antibiotic choice					Total
	Amoxicillin/Clavulanic	Cefazolin	Ceftazidime	Ceftriaxone	Cefuroxime	
<15	0	1	0	0	0	1
16-24	0	5	0	7	2	14
25-29	2	6	0	6	4	18
30-34	0	1	0	1	1	3
35-44	1	2	0	3	2	8
45-54	1	4	2	5	3	15
55-59	2	1	0	2	0	5
Total	6	20	2	24	12	64

Table 16: Pediatric Antibiotic Dose in mg/kg bwt

	Frequency	Percent
<15	1	1.6
16-24	14	21.9
25-29	18	28.1
30-34	3	4.7
35-44	8	12.5
45-54	15	23.4
55-59	5	7.8
Total	64	100.0

Majority of patients were given ceftriaxone intraoperatively. We assessed the antibiotic doses that were given among adult and pediatric patients separately. Cefazolin was the recommended antibiotic or prophylaxis according to KNH and WHO guidelines. The appropriate dose of Cefazolin for adult patients intraoperatively, is 1g/dose and 2g/dose according to KNH and WHO respectively. Among pediatric patients, the KNH recommendation is 25mg/kg/dose while WHO recommendation is 30mg/kg/dose. A summary of all the Cefazolin doses are shown in tables 17 and 18.

Table 17: Dose of Cefazolin (Adults)

	Adult (18+ years)
Cefazolin 2gm	19
Cefazolin 1.5gm	10
Cefazolin 1gm	66
Total	95

Table 18:Dose of Cefazolin (Peadiatrics)

Mg/kg bwt	Frequency	Percent
14.0	1	5.0
16.0	1	5.0
18.4	1	5.0
20.0	1	5.0
20.4	1	5.0
24.0	1	5.0
25.0	4	20.0
25.8	1	5.0
29.0	1	5.0
30.0	1	5.0
40.0	1	5.0
43.7	1	5.0
45.0	1	5.0
46.0	1	5.0
47.0	1	5.0
50.0	1	5.0
56.0	1	5.0
Total	20	100.0

Majority of the adult patients were given cefazolin at 1mg dose while majority of the pediatric patients were given 25-29 mg/kg bwt of Cefazolin.

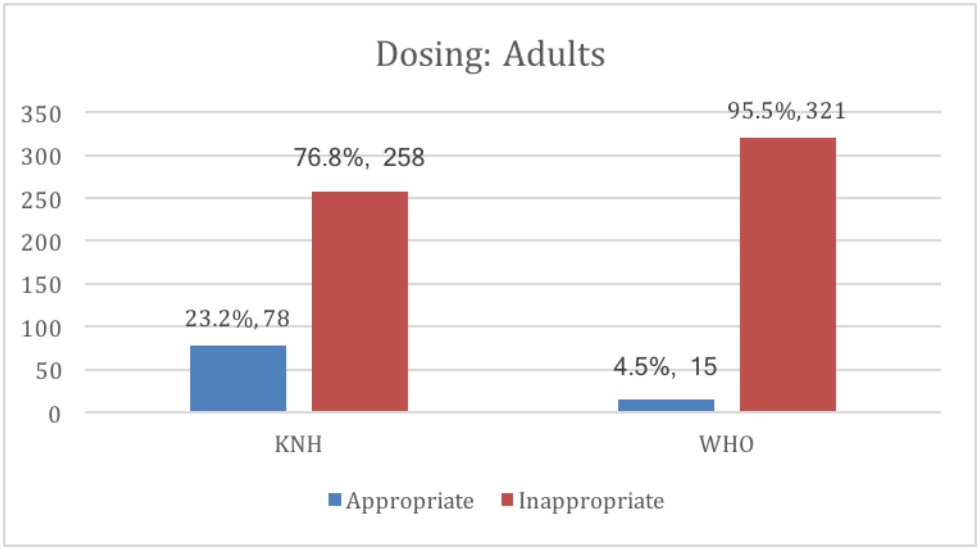

Figure 6: Dose of Antibiotic (Cefazolin) among adults

23.2% of all adult patients got appropriate antibiotic dose according to KNH protocol while 4.5% were appropriate, according to WHO protocol.

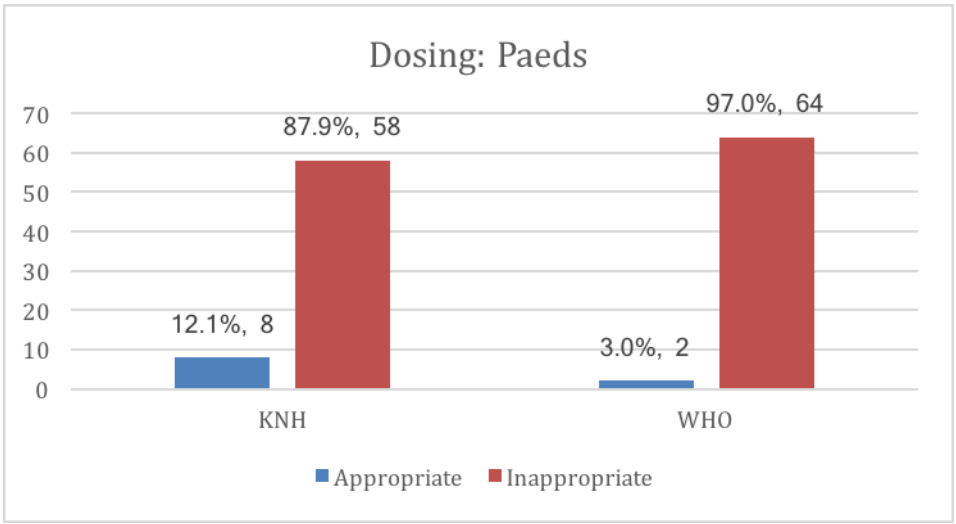

Figure 7: Dose of antibiotic (Cefazolin) among Pediatrics

Among the pediatric patients, 12.1% received appropriate dosing according to KNH guidelines while 3.0% received appropriate dosing according to WHO guidelines

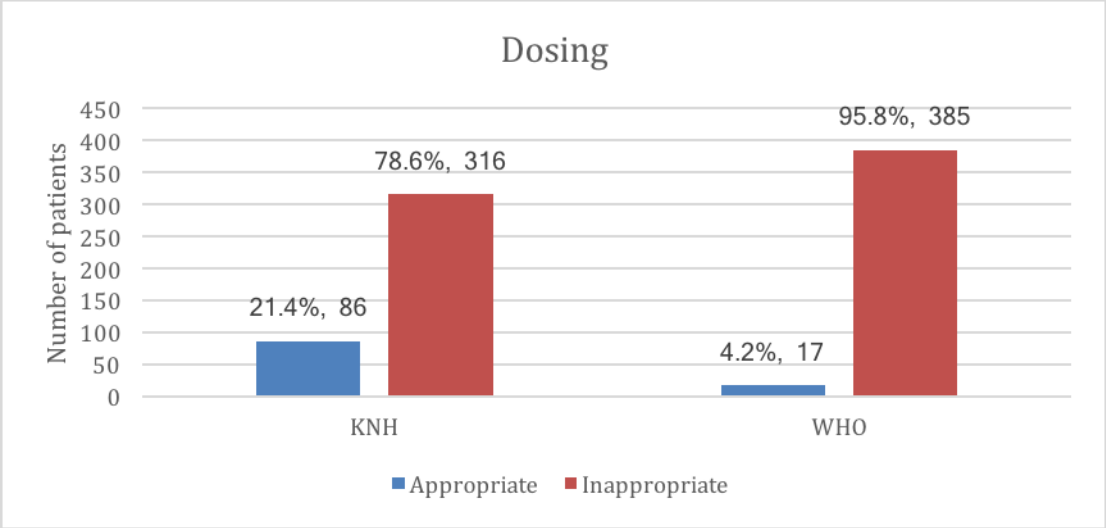

Figure 8: Appropriate dose of Antibiotics

Overall, appropriate antibiotic dose was found in 21.4% and 4.2% of patients according to KNH and WHO guidelines respectively.

4.7 Repeat Dose of Antibiotic (Cefazolin)

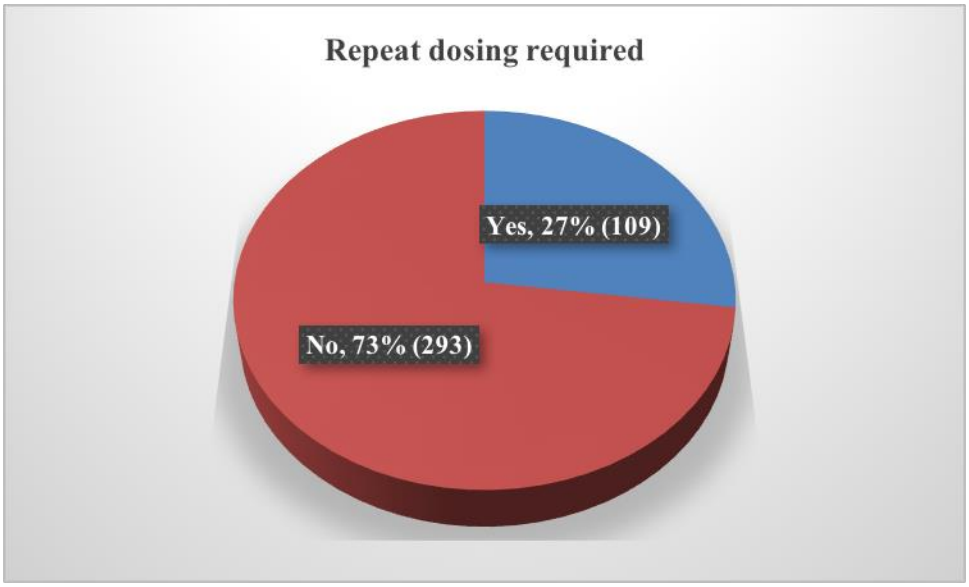

Figure 9:Repeat dose required

109 patients (27%) undergoing surgery required a repeat dose of prophylactic antibiotics intraoperatively according to the guidelines. Only 3 of these patients received a repeat dose of antibiotic intraoperatively.

4.8 Duration of Prophylactic Antibiotic Use

The data on duration of antibiotics was analyzed against the recommended guidelines, i.e. KNH and WHO.

Table 19: Duration of Prophylactic Antibiotic Use (all antibiotics)

	Frequency n (%)
Up to 24 hours	46 (11.4)
Beyond 24 hours	309 (76.9)
None given	47 (11.7)

11.4% of patients received antibiotics for up to 24hrs postoperatively. 76.9% of patients received antibiotics for more than 48hrs, while 11.7% of the patients did not receive prophylactic antibiotics postoperatively. 23.1% of all patients got antibiotic prophylaxis for the appropriate duration. Three patients received cefazolin for 24hrs while twenty-two patients received cefazolin for more than 24hrs.

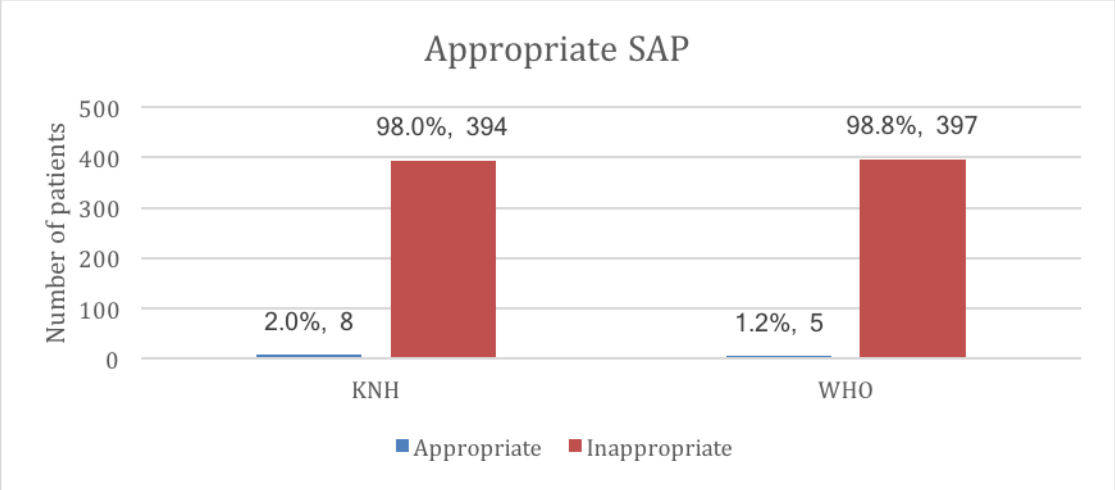

Figure 10: Appropriate Surgical Antibiotic Prophylaxis

2.0% and 1.2% of the patients received appropriate perioperative SAP for choice, timing, dose and duration according to KNH protocol and WHO recommendation, respectively.

4.9 Surgical Site Infection

This section presents the results of the incidence of surgical site infection among surgical patients, occurring within 30 days of surgery.

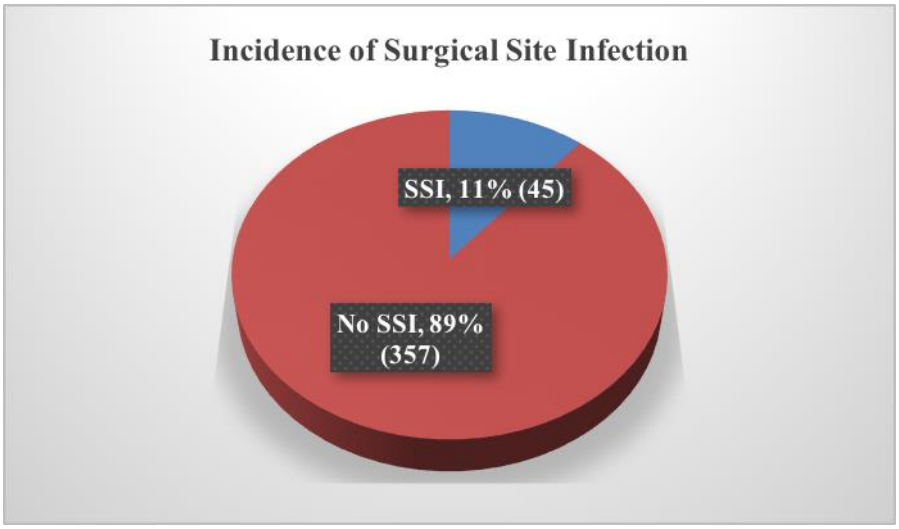

Figure 11: Incidence of surgical site infection

Surgical site infections were noted in 11% of the patients.

Table 20:Surgical Site Infections

	SSI (n=45)	No SSI (n=357)	Total	p-value
Age				
<18	6 (9)	61 (91)	67	0.520
18-35	15 (9.9)	137 (90.1)	152	0.502
36-45	13 (18.8)	56 (81.2)	69	0.028
46-65	8 (9.3)	78 (90.7)	86	0.525
>65	3 (11.1)	24 (88.9)	27	0.985
Gender				
Male	27 (11.7)	204 (88.3)	231	0.715
Female	18 (10.5)	153 (89.5)	171	
Specialty				
Cardiothoracic Surgery	4 (33.3)	8 (66.7)	12	0.035
ENT Surgery	4 (10.8)	33 (89.2)	37	0.938
General Surgery	9 (7.4)	113 (92.6)	122	0.109
Maxillofacial Surgery	1 (16.7)	5 (83.3)	6	0.512
MDT	1 (20)	4 (80)	5	0.530
Neurosurgery	1 (5)	19 (95)	20	0.713
Obstetrics/Gynecology	7 (11.1)	56 (88.9)	63	0.982
Orthopedics	11 (15.5)	60 (84.5)	71	0.205
Pediatric Surgery	0 (0)	14 (100)	14	0.383
Plastic Surgery	3 (25)	9 (75)	12	0.140
Urology	4 (10)	36 (90)	40	0.801
Comorbidity				
Present	15 (13)	100 (87)	115	0.457
Absent	30 (10.5)	257 (89.5)	287	
Wound type				
Clean	20 (7.5)	246 (92.5)	266	0.001
Contaminated	25 (18.4)	111 (81.6)	136	
Duration of hospital stay				
Less than 1 day	0 (0)	5 (100)	5	1.000
1 day	13 (9.5)	124 (90.5)	137	0.436
2-6 days	18 (13.6)	114 (86.4)	132	0.278
7 days	1 (3.4)	28 (96.6)	29	0.229
8-14 days	4 (10.3)	35 (89.7)	39	1.000
15-21 days	2 (9.5)	19 (90.5)	21	1.000
22-28 days	1 (20)	4 (80)	5	0.449
29 days and above	6 (17.6)	28 (82.4)	34	0.249

Most of the patients who developed SSI's were between 18-35 years of age, though not statistically significant (p=0.502). The proportion of male patients who developed SSI's was 11.6% while among the among female patients was 10.5%. This was however not statistically significant, p=0.715. Infections were highest among cardiothoracic surgery patients at 33.3% but not statistically significant compared to infections among the rest of the surgical

disciplines. Among the pediatric surgery patients, no SSI was reported. 13% of patients who developed SSI's had comorbidities, while 10.5% of patients with SSI's did not have comorbidities. 7.5% of patients who developed SSI's had clean wounds and this was statistically significant p=0.001.

Table 21:Co-morbidities and SSI

N=115	SSI	No SSI	Total
Hypertension	4 (14.2)	24 (85.7)	28
Diabetes	0 (0)	9 (100)	9
HIV	0 (0)	5 (100)	5
Malignancy	4 (26.7)	35 (35)	39
Renal disease	0 (0)	6 (6)	6
Congenital anomalies	1 (6.7)	3 (3)	4
Previous surgery	7 (46.7)	31 (31)	38
Obesity	0 (0)	1 (1)	1
	15	100	

Patients who had previous surgery were found to have the highest number of SSI at 18.4%. This suggests that having previous surgical exposure was a risk factor for developing a surgical site infection. Patients who had a malignancy contributed 26.7% of total SSI's cases. Patients with HIV, diabetes did not record any SSI's. Patients who were admitted and had surgery the same day did not record any surgical site infection however this was not statistically significant, p=1.000. 40% of the patients who developed SSI's, were in the hospital preoperatively for between 2-6 days.

Table 22:Antibiotics dose prescribed in relation to SSI

	SSI	No SSI	Total
Amoxicillin/Clavulanic acid 1.2gm	6 (13.3)	50 (14)	56 (13.9)
Amoxicillin/Clavulanic acid 600mg	1 (2.2)	2 (0.6)	3 (0.7)
Amoxicillin/Clavulanic acid 500mg	0 (0)	1 (0.3)	1 (0.2)
Amoxicillin/Clavulanic acid 320mg	0 (0)	1 (0.3)	1 (0.2)
Cefazolin 2gm	1 (2.2)	19 (5.3)	20 (5)
Cefazolin 1.5gm	1 (2.2)	9 (2.5)	10 (2.5)
Cefazolin 1gm	7 (15.6)	62 (17.4)	69 (17.2)
Cefazolin 750mg	0 (0)	2 (0.6)	2 (0.5)
Cefazolin 720mg	0 (0)	1 (0.3)	1 (0.2)
Cefazolin 625mg	0 (0)	1 (0.3)	1 (0.2)
Cefazolin 600mg	0 (0)	1 (0.3)	1 (0.2)
Cefazolin 550mg	0 (0)	1 (0.3)	1 (0.2)
Cefazolin 500mg	0 (0)	1 (0.3)	1 (0.2)
Cefazolin 450mg	0 (0)	1 (0.3)	1 (0.2)
Cefazolin 425mg	0 (0)	1 (0.3)	1 (0.2)
Cefazolin 400mg	0 (0)	1 (0.3)	1 (0.2)
Cefazolin 350mg	0 (0)	1 (0.3)	1 (0.2)
Cefazolin 258gm	0 (0)	1 (0.3)	1 (0.2)
Cefazolin 250mg	0 (0)	2 (0.6)	2 (0.5)
Cefazolin 225mg	0 (0)	1 (0.3)	1 (0.2)
Cefazolin 75mg	0 (0)	1 (0.3)	1 (0.2)
Ceftazidime 350mg	0 (0)	2 (0.6)	2 (0.5)
Ceftriaxone 2gm	5 (11.1)	29 (8.1)	33 (8.4)
Ceftriaxone 1.5gm	0 (0)	3 (0.8)	3 (0.7)
Ceftriaxone 1.2gm	0 (0)	3 (0.8)	3 (0.7)
Ceftriaxone 1gm	15 (33.3)	102 (28.6)	117 (29.1)
Ceftriaxone 800mg	0 (0)	1 (0.3)	1 (0.2)
Ceftriaxone 750mg	0 (0)	1 (0.3)	1 (0.2)
Ceftriaxone 700mg	1 (2.2)	0 (0)	1 (0.2)
Ceftriaxone 500mg	0 (0)	1 (0.3)	1 (0.2)
Ceftriaxone 300mg	1 (2.2)	0 (0)	1 (0.2)
Ceftriaxone 155gm	0 (0)	1 (0.3)	1 (0.2)
Ceftriaxone 150mg	0 (0)	1 (0.3)	1 (0.2)
Cefuroxime 2gm	1 (2.2)	0 (0)	1 (0.2)
Cefuroxime 1.5gm	4 (8.9)	19 (5.3)	23 (5.7)
Cefuroxime 1gm	1 (2.2)	3 (0.8)	4 (1)
Cefuroxime 950mg	0 (0)	1 (0.3)	1 (0.2)
Cefuroxime 750mg	0 (0)	16 (4.5)	16 (4)
Cefuroxime 575mg	0 (0)	1 (0.3)	1 (0.2)
Cefuroxime 500mg	0 (0)	1 (0.3)	1 (0.2)
Cefuroxime 350mg	0 (0)	2 (0.6)	2 (0.5)
Cefuroxime 225mg	1 (2.2)	0 (0)	1 (0.2)
Cefuroxime 200mg	0 (0)	1 (0.3)	1 (0.2)
Cefuroxime 180mg	0 (0)	1 (0.3)	1 (0.2)
Meropenem 1gm	0 (0)	1 (0.3)	1 (0.2)
Metronidazole 80mg	0 (0)	1 (0.3)	1 (0.2)
None	0 (0)	5 (1.4)	5 (1.2)

33.3% of patients who developed SSI's received Ceftriaxone 1 gram for antibiotic prophylaxis. 15.6% of patients who received cefazolin 1 gram, developed SSI.

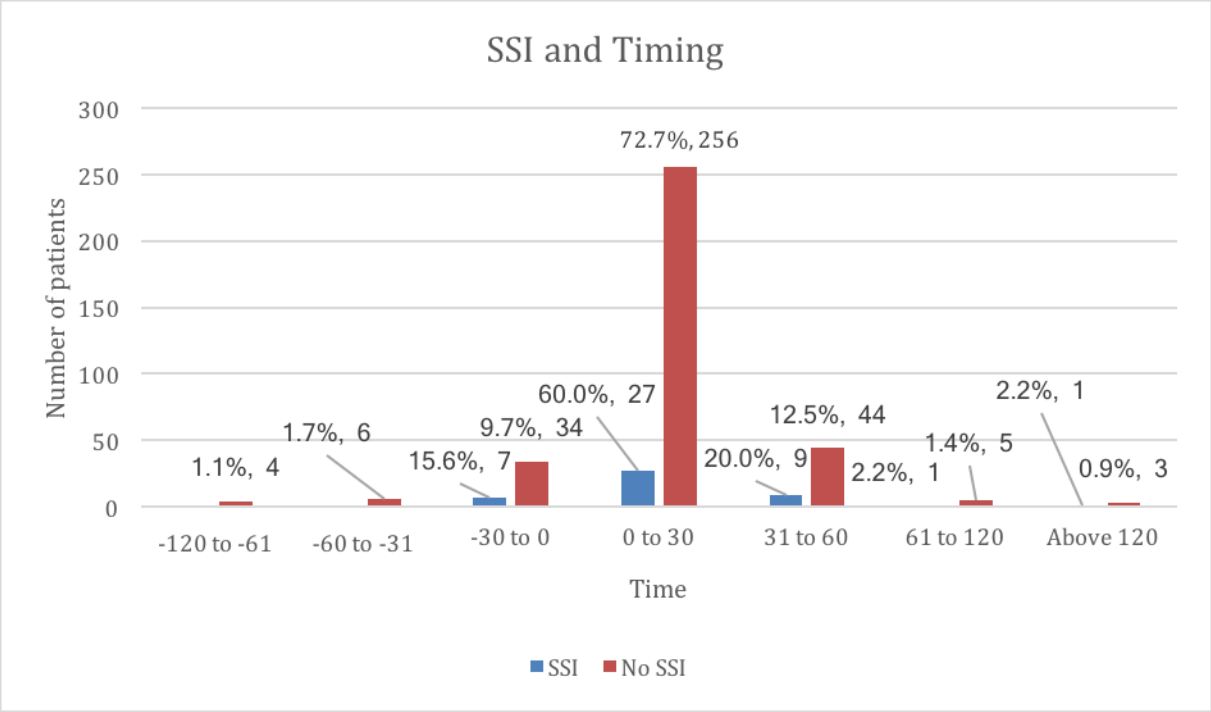

Figure 12: SSI and Timing

27/256 (10.5%) of all patients who developed SSI's received antibiotics within 30 minutes of the surgical incision while 9/44 (20.4%) of the patients received antibiotics within 60 minutes of the surgical incision.

5.0 CHAPTER FIVE: DISCUSSION

The objective of this study was to determine the patterns of antibiotic prophylaxis. We found that 40.8% of patients received ceftriaxone intraoperatively and 41.4% received amoxicillin/Clavulanic postoperatively. 28.6% received of patients Cefazolin at 28.6% and 7% intraoperatively and postoperatively respectively. The antibiotics were given within 30 minutes in in 71.3% of the patients. Among adult patients Cefazolin was given at 1mg doses while among pediatric patients most were given between 25-29mg kg bwt doses. Majority of antibiotics were given for more than 48hrs.Perioperative surgical antibiotic prophylaxis was appropriate for choice, timing, dose and duration of in 2% of the patients according to KNH guidelines. The incidence of surgical site infections was 11%.

There is a paucity of local data on patterns of antibiotic prescriptions among surgical patients. Momanyi et al 2019 conducted a point prevalence on antibiotic prescription patterns in KNH and found that majority of surgical patients on SAP were on treatment for more than one day and ceftriaxone was the most frequently prescribed antibiotic for surgical prophylaxis. [63] This is similar to the findings in our study where ceftriaxone was used intraoperatively and antibiotics were given for too long postoperatively. Momanyi found 9.6 % of patients did not receive postoperative antibiotics while we found 12%. Opanga et al 2017 looked at effectiveness of antimicrobial prophylaxis among neurosurgical patients [64].

They found that the most frequently prescribed antibiotic for surgical prophylaxis was ceftriaxone at 78%, similar to our neurosurgical patients at 65%. They found that patients were on antibiotic prophylaxis for between 1 to 3 days, and ceftriaxone use was associated with the risk of SSI though not statistically significant. In our study ceftriaxone was the most frequently prescribed intraoperative antibiotic at 40.8%, similar to Alemkere at 84% and Opanga S 78%. Odame 2016 also found Ceftriaxone as the most commonly used antibiotic in KNH at 79.8% [65]. This shows a declining use in ceftriaxone for SAP. The change could be attributed to the KHN SAP guidelines which were introduced in 2018.

There were more male than female patients recruited into this study at 57.5% similar to Alemkere et al 2018, 58.8% male participants [20]. Alemkere found that the male gender was associated with inappropriate preoperative antibiotics, AOR 3.10 95% CI 1.07-3.98. The mean age of patients in our study was 35.9 years. The mean number of in hospital days before surgery was 9.4. Majority of patients were from general surgery department at 30.3%. Majority of cases in our study were elective cases at 71.6%. Most of the surgical cases in our

study had clean wounds 66.2%. Majority of the patients had no comorbidities at 70.1% similar to Momanyi et al 2019.

Cefazolin was given in 28.6% of patients, despite it being the antibiotic of choice according to KNH and WHO guidelines. This is much lower than in Alemkere, at 61% and Australian Commission on safety guidelines, 69% [20,12]. In the 2016 Surgical National Antimicrobial Prescription survey, they found that when guidelines were available, they were less likely to be followed. 41% of intraoperative and 62% of postoperative prescriptions were not according to guidelines. In our study 98% of our antibiotic prescriptions were not according to the KNH guidelines.

Lerano et al 2017, found 41% of patients received inappropriate intraoperative antibiotic prophylaxis where there were available guidelines, compared to 43.3% where there were no guidelines [27]. Alavi et al reported 13.2% inappropriate antibiotics in regards to choice of antibiotic. In our study 28.6% appropriate antibiotics given is a far cry from where we should be. Lerano et al found that post-operative antibiotic prescriptions were inappropriate in 62% versus 45.6%, where there were SAP guidelines versus no guidelines. This suggests that the prescribers were not familiar with the available guidelines.

The most frequently prescribed antibiotic post-operatively was amoxicillin/clavulanic acid at 41.4%. Cefazolin which is the recommended antibiotic for prophylaxis was given in only 6.8%, therefore 93.2% of patients got inappropriate antibiotic prescriptions postoperatively. The timing for SAP administration was within 60 minutes before the surgical incision in 84.6% of all the patients. The KNH antibiotic guidelines describe giving antibiotics at the induction of anesthesia. Results from our study indicate that 86.1% of our patients got antibiotics within 120 minutes of surgical incision. According to a meta-analysis by Jonge et al 2017, SAP should be within 120 minutes of a surgical incision because the rate of SSI almost doubled when antibiotics were given after the surgical incision had been made and were five time more when given 120 minutes before the incision [24].

The 2016 Surgical National Antimicrobial Prescription Survey in Australia found that 45.7% of patients got antibiotics outside the recommended time window [12]. This was the most common prescription error encountered. Bratzler DW et al 2005, found 55.7% of antibiotic prescriptions were appropriate for timing, according to the According to the WHO recommendation of 120 minutes before surgical incision [66] Only 13.9% of patients were given antibiotics outside this timing window of 120 minutes in our study, which is better than in most studies.

The recommended dose of antibiotic according to the KNH protocol is 1gram of cefazolin intraoperatively. This differs from the current WHO, CDC guidelines and Australian guidelines which recommend 2 grams. The Clinical practice guidelines and the Melbourne, therapeutic guidelines recommend a single dose of 2 grams' cefazolin where indicated. [4,12]. 21.4% of patients got cefazolin at the appropriate dose according to the KNH protocol and 4.2% according to WHO recommendation. 27% of patients who required a repeat dose of antibiotics due to long duration of surgery more than 3 hours or intraoperative blood loss of more than 1.5L. Only 3 patients received a repeat dose of antibiotic, which is unacceptable. Bratzler et al 2005 found that only 12.2% of patients received a repeat dose intraoperatively. This shows that in developing and developed countries, patients do not seem too get a repeat dose of antibiotic intraoperatively when it is required.

11.4% of patients received antibiotics according to guideline recommendation of no more than 24 hours, while 11.7% did not receive antibiotics postoperatively. Majority of antibiotics were given for more than 48 hours, at 76.9%. This is similar to Alemkere 75.8%, de Jonge, 73.7%, [20,24,]. Bratzler also found a high inappropriate duration of antibiotic use at 40.7%. This shows that majority of the practitioners do not know the recommended duration of SAP in the guidelines.

The incidence of surgical site infections in this study was 11%. This is almost similar to that found by Njiiru 2015, 7.5% and Mwita et al 2018, 9% [67,68]. Opanga et al 2017 found a much higher incidence among neurosurgical patients at 37.7%. [69]. In our study, 5% of neurosurgical patients developed a SSI. In the USA, 21.8% SSI rates have been reported [2]. Asaad et al 2016 put global SSI rates at between 2.5% to 41.9%, while data from developing countries has reported SSI between 5-10% [33,70,71]. Our SSI rates are therefore within the documented rates.

Male patients had a higher SSI rate at 11.7%, p=0.715. which not statistically significant. This could be attributed to larger numbers of male patients included in this study. Patients with clean wound had 7.5% SSI rates p=0.001 which suggests that having a clean wound was associated with a significantly reduced risk of developing a surgical site infection. 13% of patients who had a comorbidity did not develop SSI's p=0.457.

Among the patients who developed SSI's 18.4% had previous surgical intervention. Opanga 2017 also found 73% of patients who developed SSI's had surgery at least once previously. This suggests a correlation between multiple surgical exposure and SSI. Among our patients with HIV and diabetes, we did not report any SSI's. Since majority of our patients did not have comorbidities, we were not able to make an association between co-morbidities and

SSI's. 40% of the patients who developed surgical site infection were admitted in hospital for an average of 8.0 days. 33% of patients that received ceftriaxone for prophylaxis developed SSI, suggesting that inappropriate antibiotic regimen is a risk factor for developing a surgical site infection.

10.5% of patients who developed SSI's were given antibiotics within 30 minutes of the surgical incision. This suggests that this timing may be associated with an increased risk of SSI. This contrary to most studies such as de Jonge and Steinberg et al 2009 which found the lowest SSIs when patients received antibiotics within 30 minutes of incision [24,22]. The sample of patients was very small and we could not make a conclusion about timing and SSI's. There is room for further research on this.

We attempted to collect data on awareness of the protocol among the anesthesia providers. The number of response was not sufficient to collect accurate data. Majority of the anesthesia providers were unaware that KNH had a protocol on SAP. When we inquired how they chose their antibiotic of choice, the most common responses were, depending on availability in theatre or antibiotic that the patients came with from the wards. The poor adherence to guideline recommendation noted in this study could explain the higher incidence of surgical site infection noted compared to countries where guidelines are followed. It was noted in a study in Thika by Aiken et al, that by sensitizing clinicians to guidelines, over a six-week period the adherence to guidelines increased from 60% to 98% with a relative risk reduction of 0.66 for developing SSI's.

Appropriate antimicrobial prophylaxis according to KNH protocol was given to 2.0% (8) of the sample population patients and 1.2% (5) according to WHO recommendations. The data shows very poor compliance to surgical antibiotic guidelines KNH and this needs to be looked into.

5.1 Recommendations:

- Creating awareness about SAP through training workshops and continuous medical education for surgeons and anesthesia providers.
- Provide the recommended antibiotics according to the guidelines both in the operating theatres and in the surgical wards.
- Regular audits, i.e. quarterly or half yearly to assess if guidelines are being adhered to.
- More studies should be carried out on SSI to determine the factors associated with SSI and antibiotics, for example, bacterial contamination during reconstitution and administration of antibiotics.
- Encourage proper documentation of patients' ward location postoperatively to enable follow-up.
- Encourage documentation of indication of antibiotic prescription to allow the pharmacy to raise or revert to the clinician when SAPs are given for more than 24hrs.
- More studies should be done determine if use of ceftriaxone for SAP and previous surgery predispose to surgical site infection.
- Standardization of KNH guidelines dosages with those in international guidelines to enable comparison of data obtained from SAP studies to be used across regions.

5.2 Limitations

The study population was very varied. We did not have similar numbers in the groups to make any inferences on the SSI and risk factors in our study population. The number of patients with co-morbidities were not large enough to detect association with surgical site infections. Differences in dosages between KNH and WHO guidelines may be a confounder in the incidence of SSI obtained.

5.3 Conclusion

84.6% of the patients received surgical antibiotic prophylaxis within the appropriate time. 11.7% of patients did not receive antibiotics postoperatively. Clean wounds were associated with reduced risk of SSI's p=0.001. Ceftriaxone was the most frequently prescribed antibiotic intraoperatively. Amoxicillin/clavulanic acid was the most frequently prescribed antibiotic post-operatively. The choice of intraoperative antibiotic was appropriate in 29% of patients in accordance with the KNH and WHO guidelines. The choice of postoperative antibiotic was appropriate in 7% of patients, according to KNH and WHO guidelines. The antibiotic dose

was appropriate in 21.4% vs 4.2% of patients according to KNH and WHO guidelines respectively. The timing of antibiotic administration was appropriate in 84.6% and 86.1% in accordance with KNH and WHO guidelines respectively. Only 2.75% of patients received a required repeat dose of antibiotics. Majority of patients did not receive appropriate SAP for choice, dose or duration according to the guidelines.

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APPENDICES

Appendix I: Recommendations for Surgical Antibiotic Prophylaxis

"Patterns of Perioperative Antibiotic Surgical Prophylaxis among Surgical Patients Undergoing Surgery in K.N.H Theatres"

Type of Procedure	Recommended Agents[a,b]	Alternative Agents in Pts Withβ-Lactam Allergy	Strength of Evidence
Cardiac Coronary artery bypass	Cefazolin, cefuroxime	Clindamycin,[vancomycin d]	A
Cardiac device insertion procedures (e.g., pacemaker implantation)	Cefazolin, cefuroxime	Clindamycin, vancomycin	A
Ventricular assist devices	Cefazolin, cefuroxime	Clindamycin, vancomycin	C
Thoracic Noncardiac procedures, including lobectomy, pneumonectomy, lung resection, and thoracotomy	Cefazolin, ampicillin-sulbactam	Clindamycin,[d]vancomycin[d]	A
Video-assisted thoracoscopic surgery	Cefazolin, ampicillin-sulbactam	Clindamycin,[d]vancomycin[d]	C
Gastroduodenal[e]Procedures involving entry into lumen of gastrointestinal tract (bariatric, pancreaticoduodenectomy[f])	Cefazolin	Clindamycin or vancomycin + aminoglycoside[g]or aztreonam or fluoroquinolone[h–j]	A
Procedures without entry into gastrointestinal tract (antireflux, highly selective vagotomy) for high-risk patients	Cefazolin	Clindamycin or vancomycin + aminoglycoside[g]or aztreonam or fluoroquinolone[h–j]	A

Biliary tract Open procedure	Cefazolin, cefoxitin, cefotetan, ceftriaxone,[k] ampicillin-sulbactam[h]	Clindamycin or vancomycin + aminoglycoside[g]or aztreonam or fluoroquinolone[h–j]Metronidazole + aminoglycoside[g]or fluoroquinolone[h–j]	A
Laparoscopic procedure Elective, low-risk[l]	None	None	A
Elective, high-risk[l]	Cefazolin, cefoxitin, cefotetan, ceftriaxone,[k] ampicillin-sulbactam[h]	Clindamycin or vancomycin + aminoglycoside[g]or aztreonam or fluoroquinolone[h–j]Metronidazole + aminoglycoside[g]or fluoroquinolone[h–j]	A
Appendectomy for uncomplicated appendicitis	Cefoxitin, cefotetan, cefazolin + metronidazole	Clindamycin + aminoglycoside[g]or aztreonam or fluoroquinolone[h–j] Metronidazole + aminoglycoside[g]or fluoroquinolone[h–j]	A
Small intestine Nonobstructed	Cefazolin	Clindamycin + aminoglycoside[g]or aztreonam or fluoroquinolone[h–j]	C
Obstructed	Cefazolin + metronidazole, cefoxitin, cefotetan	Metronidazole + aminoglycoside[g]gor fluoroquinolone[h–j]	C
Hernia repair (hernioplasty and herniorrhaphy)	Cefazolin	Clindamycin, vancomycin	A
Colorectal[m]	Cefazolin + metronidazole, cefoxitin, cefotetan, ampicillin-sulbactam,[h] ceftriaxone +	Clindamycin + aminoglycoside[g]or aztreonam or fluoroquinolone[h–j], metronidazole + aminoglycoside[g]or	A

	metronidazole,[n] ertapenem	fluoroquinolone[h–j]	
Head and neck Clean	None	None	B
Clean with placement of prosthesis (excludes tympanostomy tubes)	Cefazolin, cefuroxime	Clindamycin[d]	C
Clean-contaminated cancer surgery	Cefazolin + metronidazole, cefuroxime + metronidazole, ampicillin-sulbactam	Clindamycin[d]	A
Other clean-contaminated procedures with the exception of tonsillectomy and functional endoscopic sinus procedures	Cefazolin + metronidazole, cefuroxime + metronidazole, ampicillin-sulbactam	Clindamycin[d]	B
Neurosurgery Elective craniotomy and cerebrospinal fluid-shunting procedures	Cefazolin	Clindamycin,[d]vancomycin[d]	A
Implantation of intrathecal pumps	Cefazolin	Clindamycin,[d]vancomycin[d]	C
Cesarean delivery	Cefazolin	Clindamycin + aminoglycoside[g]	A
Hysterectomy (vaginal or abdominal)	Cefazolin, cefotetan, cefoxitin, ampicillin-sulbactam[h]	Clindamycin or vancomycin + aminoglycoside[g]or aztreonam or fluoroquinolone[h–j]Metronidazole + aminoglycoside[g]or fluoroquinolone[h–j]	A
Ophthalmic	Topical neomycin-polymyxin B-gramicidin or fourth-generation topical fluoroquinolones (gatifloxacin or moxifloxacin) given as	None	B

	1 drop every 5–15 min for 5 doses[o]Addition of cefazolin 100 mg by subconjunctival injection or intracameral cefazolin 1–2.5 mg or cefuroxime 1 mg at the end of procedure is optional		
Orthopedic Clean operations involving hand, knee, or foot and not involving implantation of foreign materials	None	None	C
Spinal procedures with and without instrumentation	Cefazolin	Clindamycin,[d]vancomycin[d]	A
Hip fracture repair	Cefazolin	Clindamycin,[d]vancomycin[d]	A
Implantation of internal fixation devices(e.g., nails, screws, plates, wires)	Cefazolin	Clindamycin,[d]vancomycin[d]	C
Total joint replacement	Cefazolin	Clindamycin,[d]vancomycin[d]	A
Urologic Lower tract instrumentation with risk factors for infection (includes transrectal prostate biopsy)	Fluoroquinolone,[h–j]trimethoprim-sulfamethoxazole, cefazolin	Aminoglycoside[g]with or without clindamycin	A
Clean without entry into urinary tract	Cefazolin (the addition of a single dose of an aminoglycoside may be recommended for placement of prosthetic material [e.g., penile prosthesis])	Clindamycin,[d]vancomycin[d]	A
Involving implanted prosthesis	Cefazolin ± aminoglycoside,	Clindamycin ± aminoglycoside or	A

	cefazolin ± aztreonam, ampicillin-sulbactam	aztreonam, vancomycin ± aminoglycoside or aztreonam	
Clean with entry into urinary tract	Cefazolin (the addition of a single dose of an aminoglycoside may be recommended for placement of prosthetic material [e.g., penile prosthesis])	Fluoroquinolone,[h–j] aminoglycoside[g] with or without clindamycin	A
Clean-contaminated	Cefazolin + metronidazole, cefoxitin	Fluoroquinolone,[h–j] aminoglycoside[g] + metronidazole or clindamycin	A
Vascular[p]	Cefazolin	Clindamycin,[d] vancomycin[d]	A
Heart, lung, heart-lung transplantation[q] Heart transplantation[r]	Cefazolin	Clindamycin,[d] vancomycin[d]	A (based on cardiac procedures)
Lung and heart-lung transplantation[r,s]	Cefazolin	Clindamycin,[d] vancomycin[d]	A (based on cardiac procedures)
Liver transplantation[q,t]	Piperacillin-tazobactam, cefotaxime + ampicillin	Clindamycin or vancomycin + aminoglycoside[g] or aztreonam or fluoroquinolone[h–j]	B
Pancreas and pancreas-kidney transplantation[r]	Cefazolin, fluconazole (for patients at high risk of fungal infection [e.g., those with enteric drainage of the pancreas])	Clindamycin or vancomycin + aminoglycoside[g] or aztreonam or fluoroquinolone[h–j]	A
	Cefazolin	Clindamycin or vancomycin + aminoglycoside[g] or aztreonam or fluoroquinolone[h–j]	A

Plastic surgery			
Clean with risk factors or clean-contaminated	Cefazolin, ampicillin-sulbactam	Clindamycin,[d]vancomycin[d]	C

Recommended Doses and Redosing Intervals for Commonly Used Antimicrobials for Surgical Prophylaxis

Antimicrobial	Recommended Dose		Half-life in Adults With Normal Renal Function, hr[19]	Recommended Redosing Interval (From Initiation of Preoperative Dose), hr[c]
	Adults[a]	Pediatrics[b]		
Ampicillin-sulbactam	3g (ampicillin 2g/sulbactam 1 g)	50 mg/kg of the ampicillin component	0.8–1.3	2
Ampicillin	2g	50 mg/kg	1–1.9	2
Aztreonam	2g	30 mg/kg	1.3–2.4	4
Cefazolin	2 g, 3 g for pts weighing ≥120 kg	30 mg/kg	1.2–2.2	4
Cefuroxime	1.5g	50 mg/kg	1–2	4
Cefotaxime	1 g[d]	50 mg/kg	0.9–1.7	3
Cefoxitin	2 g	40 mg/kg	0.7–1.1	2

Cefotetan	2 g	40 mg/kg	2.8–4.6	6
Ceftriaxone	2 g[e]	50–75 mg/kg	5.4–10.9	NA
Ciprofloxacin[f]	400 mg	10 mg/kg	3–7	NA
Clindamycin	900 mg	10 mg/kg	2–4	6
Ertapenem	1 g	15 mg/kg	3–5	NA
Fluconazole	400 mg	6 mg/kg	30	NA
Gentamicin[g]	5 mg/kg based on dosing weight (single dose)	2.5 mg/kg based on dosing weight	2–3	NA
Levofloxacin[f]	500 mg	10 mg/kg	6–8	NA
Metronidazole	500 mg	15 mg/kg Neonates weighing <1200 g should receive a single 7.5-mg/kg dose	6–8	NA
Moxifloxacin[f]	400 mg	10 mg/kg	8–15	NA
Piperacillin-tazobactam	3.375 g	Infants 2–9 mo: 80 mg/kg of the piperacillin component Children >9 mo and ≤40 kg: 100 mg/kg of	0.7–1.2	2

		the piperacillin component		
Vancomycin	15 mg/kg	15 mg/kg	4–8	NA
Oral antibiotics for colorectal surgery prophylaxis (used in conjunction with a mechanical bowel preparation)				
Erythromycin base	1 g	20 mg/kg	0.8–3	NA
Metronidazole	1 g	15 mg/kg	6–10	NA
Neomycin	1 g	15 mg/kg	2–3 (3% absorbed under normal gastrointestinal conditions)	NA

Source: Bratzler DW, Dellinger EP, Olsen KM, et al. Clinical practice guidelines for antimicrobial prophylaxis insurgery. Am J Health Syst Pharm 2013;70:195–283.

Appendix II (a): Patient Consent Form (English)

"Patterns of Perioperative Antibiotic Surgical Prophylaxis among Surgical Patients Undergoing Surgery in K.N.H Theatres"

Informed Consent Form

This informed consent form is for patients who will undergo surgery at Kenyatta National Hospital Satellite and Main and minor theatres.

The principal investigator is Dr Sheila Gitau under supervision from Dr Anthony Gatheru and Dr George Njogu, is conducting a study looking at patterns of perioperative antibiotic surgical prophylaxis among surgical patients Kenyatta National Hospital. The study is being done under the department of Anaesthesia in the University of Nairobi.

This Informed Consent Form has two parts:

- Information Sheet (gives you information about the study)
- Certificate of consent (this is where you sign if you agree to participate)

You will be given a copy of the full Informed Assent Form

Part I: Information Sheet

I am a Student currently doing my Masters in Anaesthesia at the University of Nairobi. I am doing a study looking at the patterns of antibiotic surgical prophylaxis among patients undergoing surgery in Kenyatta National Hospital Theatres. Information given to you will help you decide whether or not you should participate in this study. You are free ask about the purpose of this study and risks and benefit to you if you participate in the study. When we have fully answered your questions to your satisfaction, you may decide if you want to participate in this study.

There may be some words that you do not understand, please ask me to explain as we go through the information. If you have questions later, you can ask them my contacts are available on this consent form.

Purpose: Why are you doing this research?

Antibiotics are given to patients undergoing surgery to prevent surgical site infections. They work best when they are given before the surgical incision is made. They should be given for the shortest duration of time to reduce the risk of unwanted drug effects. This study is being carried out to see if these practices on antibiotic usage are being followed.

Choice of participants: Why are you asking me?

We want to get some information about antibiotic use among surgical patients at KNH. There shall be 374 study participants in this study including adults and children.

Participation is voluntary: Do I have to do this?

You don't have to be in this research if you don't want to be. It's up to you. If you decide not to be in the research, it's okay and nothing changes.

I have checked with the patient and they understand that participation is voluntary…….. (signature)

Procedures: What is going to happen to me?

If you agree to participate in this study, the following things will happen:

You will be interviewed by the principal investigator in a private area where you feel comfortable answering questions. We shall ask for your personal details: name, age telephone number and measure your weight. The interview will last approximately five minutes. During the interview, we shall explain the purpose of the research study we are conducting and what information we require. The benefit of the study to you shall also be explained. The information required shall be obtained during the surgery and after surgery in the recovery area. We shall also come and see you in the ward to check on your wound on day 5 and day 30 post operatively. If you will have left the hospital. we shall call you on the telephone and ask you questions about your wound.

I have checked with the patient and they understand the procedures

……signature)

Risks: Is this bad or dangerous for me?

You will not be in any harm when you take part in this research. This is an observational study and you will be asleep throughout

I have checked with the patient and they understand the risks and discomforts

…….…….(signature)

Benefits: Is there anything good that happens to me?

There is the benefit to you that monitoring your progress after surgery will be more efficient. The information you give us might help us learn more about antibiotic surgical prophylaxis in adults and children. There is no financial gain or loss in participating in this study.

I have checked with the patient and they understand the benefits

…….. (Signature)

Reimbursements: Do I get anything for being in the research?

Unfortunately, there will be no gifts if you choose to participate in the study.

Confidentiality: Is everybody going to know about this?

We will not tell other people that you are in this research and we won't share information about you to anyone who does not work in the research study.

Information about you that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will store all paper records in a locked file cabinet. It will not be shared with or given to anyone.

Sharing the Findings: Will you tell me the results?

When we are finished with the research we will not contact you personally to give you the results but you can come find out about the research at the Department of Anaesthesia, University of Nairobi. We will be telling more people, scientists and others, about the research and what we found. We will do this by writing and sharing reports.

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

You do not have to be in this research. You do not have to be in this research. You can withdraw from the study at anytime without necessarily giving a reason. Refusal to participate in research will not affect the services you are entitled to in this health facility or any other facilities.

Who to Contact: Who can I talk to or ask questions to?

You can ask me questions now or later. I have written a number and address where you can reach us or, if you are nearby, you can come and see us. If you want to talk to someone you are at liberty to do so.

After the interview, has finished?

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you is to find out if you have developed any complications from the surgical procedure.

Choosing not to participate in study will not lead to any change in your care. There will be no interference with instructions given by the surgeon and/or the anesthesiologist about your care.

Are there any risks or harm for participating in the study?

There shall be no risk or harm to you for participating in the study. There is no financial gain or loss in participating in this study. We shall keep all information relating to you the patient as confidential as possible. This study is approved by appropriate hospital authorities before it starts. (KNH Ethics and Research Committee).

PART II: Certificate of Consent **Serial Number: _____**

I understand that this research is about finding out the patterns of antibiotic surgical prophylaxis among surgical patients undergoing surgery at K.N.H. and I will be asked a set of questions if I choose to participate in the research. Information about my treatment will also be obtained from my medical records.

I have read this information (or had the information read to me), I have asked questions which have been answered. and know that I can ask questions later if I have them.

I freely consent to taking part in the research.

OR

I do not wish to take part in the research and I have NOT signed the consent below._____ (initialled by patient)

Print name of patient _____

Signature of patient: …… Date:…….

If illiterate:

I have witnessed the accurate reading of the consent form to the patient, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness (not a parent) _____ AND Thumb print of participant

Signature of patient : …… Date:…….

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the patient understands the purpose and procedure of the study

I confirm that the patient was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this consent form has been provided to the participant.

Name of Researcher: DR SHEILA GITAU

Signature of patient: …… Date:…….

Copy provided to the participant _____(initialed by researcher)

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Sheila Gitau (Primary Researcher)

Mobile Number: +254735-805465

Email: reeesny@gmail.com

Dr Antony Gatheru

Mobile Number:+254721-654806

Email: gatherua@gmail.com.

Dr George Njogu

Mobile Number: +254722-712207

Email: njogug@gmail.com

Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

College of Health Sciences

P. O. Box 19676 00202 Nairobi

Tel. (254-020) 2726300-9 Ext 44355

E-mail: uonknh_erc@uonbi.ac.ke

Appendix II (b): Patient Consent Form (Swahili)

‘‘Ruwaza Ya Madawa Ya Antibiotiki Nayo Tumika Katatika Kuzuia Ugonjwa Wa Upasuaji Miongoni Ya Wagonjwa Wanaofanyiwa Upasuaji Katika Hospitali Ya K.N.H‘‘

Lengo: Kwa nini unafanya utafiti?

Antibiotiki zinapewa kwa wagonjwa kufanyiwa upasuaji ili kuzuia maambukizo ya tovuti ya upasuaji kwa kutumia madawa ya antibiotic kuzuia ugonjwa. Wagonjwa wanapaswa kupewa madawa kwa muda mfupi kwa kupunguza hatari ya madhara ya madawa yasiyotakiwa.

Faida:

Utafiti huu unafanywa ili kuona kama desturi hizi kwenye matumizi ya antibiotiki zinafuatiliwa.

Uchaguzi wa washiriki: kwa nini ni wewe kuniuliza mimi?

Tunataka kupata baadhi ya taarifa kuhusu matumizi ya antibiotiki miongoni mwa wagonjwa wa upasuaji katika KNH. Kutakuwa na washiri 374 wa kujifunza somo hili ikiwa ni pamoja na watu wazima na watoto.

Ushiriki ni wa hiari: natakiwa kufanya hivyo?

Haulazimishwi kuwa katika utafiti huu kama hutaki kuwa. Ukiamua wewe hutaki kuwa katika utafiti, ni sawa na hakuna mabadiliko yeyote katika matibabu kwako.

Kuwa umekubaliana na mgonjwa na wanaelewa kwamba ushiriki ni wa hiari ___ (sahihi)

Taratibu: ni kitu gani kitaenda kutendeka kwangu?

Kama unakubali kushiriki katika utafiti huu, mambo yafuatayo yatatokea: itakuwa waliohojiwa na mchunguzi mkuu katika eneo la binafsi ambapo unahisi starehe kujibu maswali. Tunaomba kwa ajili ya maelezo yako binafsi: jina, umri na nambari ya simu na kupima uzito wako. Mahojiano ya mwisho takriban dakika tano. Wakati wa mahojiano, sisi kueleza madhumuni ya utafiti tunaofanya na nini taarifa tunahitaji. Faida ya kujifunza kwako itakuwa pia kuelezwa. Taarifa inayotakiwa itakuwa kupatikana wakati upasuaji ukiendelea na baada ya upasuaji katika eneo la kupona. Sisi pia kuja na kuona katika kata kuangalia jeraha yako siku 5 na baada ya siku 30 operatively. Kama wewe utakuwa kushoto hospitali. Ndipo simu kwenye simu na kuuliza maswali kuhusu jeraha yako.

Kuwa umekubaliana na mgonjwa na anaelewa taratibu .....(saini)

Hatari: hii ni mbaya au hatari kwangu?

Hutakuwa katika madhara yoyote wakati unaweza kushiriki katika utafiti huu. Hii ni somo la utafiti na utakuwa amelala wakati wote.

Ikuwa umekubaliana na mgonjwa na wao kuelewa hatari na usumbufu .....(saini)

Faida: kuna kitu kizuri chochote kinachotokea kwangu?

Kuna faida kwako kwamba kufuatilia maendeleo yako baada ya upasuaji itakuwa na ufanisi zaidi. Maelezo unayotupa inaweza kutusaidia sisi kujifunza zaidi kuhusu kinga ya upasuaji wa antibiotiki katika watu wazima n na watoto. Hakuna faida ya kifedha au hasara katika kushiriki katika utafiti huu.

Kuwa umekubaliana na mgonjwa na wanaelewa matumizi ya faidha..... (sahihi):

Usiri: Ni kila mtu ataweza kujua kuhusu hili?

.Maelezo kukuhusu ambayo itakuwa zilizokusanywa kutoka utafiti itakuwa imeweka mbali na hapana mtu kati ya watafiti watakuwa na uwezo wa kuona. Taarifa yoyote kuhusu wewe utakuwa na idadi juu yake badala ya jina lako. Tu watafiti kujua namba yako ni nini na tunaweza kuhifadhi kumbukumbu zote za karatasi katika kikabati zilizofungwa. Ni halitatumika ubia na au kupewa kwa mtu yeyote.

Kushiriki matokeo: Je Unaweza kuniambia matokeo?

Wakati tukimaliza na utafiti si tutawasiliana na wewe binafsi kwa kukupa matokeo lakini unaweza kuja kujua kuhusu utafiti katika Idara ya unusukaputi, Chuo Kikuu cha Nairobi. Sisi itakuwa kuwa kuwaambia watu zaidi, wanasayansi na wengine, kuhusu utafiti na sisi kupatikana. Tutafanya haya kwa kuandika na kubadilishana taarifa.

Haki ya kukataa au kuondoa:

Mimi nikichagua kuwa katika utafiti, ninaweza kubadilisha akili yangu? Unahuru kuwa katika utafiti huu. Anaweza kujiondoa kutoka kusoma kwa wakati wowote bila lazima. Kuchagua kushiriki katika kujifunza si itasababisha mabadiliko yoyote katika huduma yako. Kutakuwa na hakuna kuingiliwa na maelekezo yaliyotolewa na upasuaji na/au unusukaputi kuhusu huduma yako. Tutakuwa kuweka habari zote kuhusiana na wewe mgonjwa siri kama iwezekanavyo. Utafiti huu ni kupitishwa na mamlaka ya hospitali sahihi kabla ya matengenezo. (KNH maadili na kamati y a utafiti).

SEHEMU YA II: Cheti cha kibali Namba tambulishi: .....

Mimi nimelewa kwamba utafiti huu ni kuhusu kutafuta ruwadha ya madawa ya antibiotiki inayotumika kukinga ugonjwa wa upasuaji kati ya wagonjwa wanaofanyiwa upasuaji katika hospitali K.N.H. na watatakiwa seti ya maswali kama kuchagua kushiriki katika utafiti. Maelezo kuhusu matibabu yangu itakuwa taka inayofika wote.

Sahihi ya mgonjwa: ..... **Tarehe**: .....

Kama hawajui kusoma na kuandika: nimeshuhudia usomaji sahihi wa fomu za idhini mgonjwa, na mtu binafsi imekuwa fursa ya kuuliza maswali. Mimi kuthibitisha kwamba mtu ametoa idhini uhuru

Jina la shahidi (si mzazi)

.....

Kidole gumba ya mshiriki _____

Saini ya shahidi :..... Tarehe .....

Jina la mpelelezi: DR SHEILA GITAU

Saini: ……..…… Tarehe: …….

Nakala imepewa kwake mshiriki _____(alama ya mpelelezi)

Mzazi/Mgarini amaitia saini Shahada ya Idhini:

Ndiyo_____ Hapana_____

Kwa maelezo Zaidi hata baada ya utafiti huu una uhuru wakuwasiliana na watu wafuatao kupitia anwani na numbari za simu silizoandikwa hapa chini.

Dkt Sheila Gitau
Numba ya simu: 0735805465
Barua pepe: reecesny@gmail.com

Dkt Antony Gatheru
Namba ya simu: 0721-654806
Barua pepe: gatherua@gmail.com

Dkt George Njogu
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Appendix III (a): Parental Consent Form (English)

"Patterns of Perioperative Antibiotic Surgical Prophylaxis among Surgical Patients Undergoing Surgery in K.N.H Theatres"

Informed Consent Form

This informed assent form is for parents with children below 18 years who will undergo surgery at Kenyatta National Hospital Main, Minor and Satellite theatres.

The principal investigator is Dr Sheila Gitau under supervision from Dr Anthony Gatheru and Dr George Njogu, is conducting a study looking at patterns of perioperative antibiotic surgical prophylaxis among surgical patients Kenyatta National Hospital. The study is being done under the department of Anaesthesia in the University of Nairobi.

This Informed Consentt Form has two parts:

- Information Sheet (gives you information about the study)
- Certificate of Assent (this is where you sign if you agree to participate)

You will be given a copy of the full Informed Assent Form

Part I: Information Sheet

I am a Student currently doing my Masters in Anaesthesia at the University of Nairobi. I am doing a study looking at the patterns of antibiotic surgical prophylaxis among patients undergoing surgery in Kenyatta National Hospital Theatres. Information given to you will help you decide whether or not your child should participate in this study. You are free ask about the purpose of this study and risks and benefit to you if you participate in the study. When we have fully answered your questions to your satisfaction, you may decide if you want your child to be in the study or not.

There may be some words that you do not understand, Please ask me to explain as we go through the information. If you have questions later, you can ask them my contacts are available on this parental consent form.

Purpose: Why are you doing this research?

Antibiotics are given to patients undergoing surgery to prevent surgical site infections. They work best when they are given before the surgical incision is made. They should be given for the shortest duration of time to reduce the risk of unwanted drug effects. This study is being carried out to see if these practices on antibiotic usage are being followed.

Choice of participants: Why are you asking me?

We want to get some information about antibiotic use in children and patients with impaired cognitive function. There shall be 374 study participants in this study including adults and children.

Participation is voluntary: Do I have to do this?

You don't have to be in this research if you don't want to be. It's up to you. If you decide not to be in the research, it's okay and nothing changes.

I have checked with the parent and they understand that participation is voluntary …… (signature)

Procedures: What is going to happen to my child?

If you allow us we are going to document what antibiotics are given to your child during surgery, the dose, time it is given to you relative to the start of surgery. We shall also come and see your child in the ward to check on the surgical wound on day 5 and day 30 post operatively. If you will have left the hospital, we shall call you on the telephone and ask you questions about the wound.

I have checked with the parent and they understand the procedures …… (signature)

Risks: Is this bad or dangerous for my child?

Your child will not come to any harm if they take part in this research.

I have checked with the parent and they understand the risks and discomforts ……(signature)

Benefits: Is there anything good that will happen to my child?

There is a benefit or more vigilant monitoring of your child as we follow up the patient after surgery. The information you give us might help us learn more about antibiotic surgical prophylaxis in children.

I have checked with the parents and they understand the benefits ……(Signature)

Reimbursements: Do I get anything for being in the research?

Unfortunately, there will be no gifts if you choose to participate in the study.

Confidentiality: Is everybody going to know about this?

We will not tell other people that you are in this research and we won't share information about you to anyone who does not work in the research study.

Information about you that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up. It will not be shared with or given to anyone.

Sharing the Findings: Will you tell me the results?

When we are finished with the research we will not contact you personally to give you the results but you can come find out about the research at the Department of Anaesthesia, University of Nairobi. We will be telling more people, scientists and others, about the research and what we found. We will do this by writing and sharing reports.

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

You do not have to be in this research. You can withdraw from the study at anytime without necessarily giving a reason. Refusal to participate in research will not affect the services your child is entitled to in this heath facility or any other facilities.

Who to Contact: Who can I talk to or ask questions to?

You can ask me questions now or later. I have written a number and address where you can reach us or, if you are nearby; you can come and see us. If you want to talk to someone else, you are at liberty to do so.

If you choose for your child to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Assent

Serial Number: _____

I understand that this research is about finding out the patterns of antibiotic surgical prophylaxis among surgical patients undergoing surgery at K.N.H. and I will be asked a set of questions if I choose to participate in the research. Information about my child's treatment will also be obtained from their medical records.

I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

OR

I do not wish my child to take part in the research and I have NOT signed the consent below……(initialled by parent)

:

Print name of child ……

Signature of Parent:……. Date:……..

If illiterate:

I have witnessed the accurate reading of the consent form to the parent, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness (not a parent) …….AND Thumb print of participant

Signature of witness:…… Date :…….

I have accurately read or witnessed the accurate reading of the consent form to the potential participant's parent, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of researcher: DR SHEILA GITAU

Signature of researcher:…… Date ……..

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant's parent, and to the best of my ability made sure that the parent understands the purpose and procedure of the study

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.

Name of Researcher: DR SHEILA GITAU

Signature of researcher: …… Date ……..

Copy provided to the participant …… (initialed by researcher)

Parent/Guardian has signed an informed consent: Yes_____ **No_____**

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Sheila Gitau (Primary Researcher)

Mobile Number: +254735-805465

Email: reeesny@gmail.com

Dr Antony Gatheru

Mobile Number:+254721-654806

Email: gatherua@gmail.com.

Dr George Njogu

Mobile Number: +254722-712207

Email: njogug@gmail.com

Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

College of Health Sciences

P. O. Box 19676 00202 Nairobi

Tel. (254-020) 2726300-9 Ext 44355

E-mail: uonknh_erc@uonbi.ac.ke

Appendix III (b): Parental Consent Form (Swahili)

Fomu Ya Kutiwa Saini Na Mzazi

"Ruwaza Ya Madawa Ya Antibiotiki Nayo Tumika Katatika Kuzuia Ugonjwa Wa Upasuaji Miongoni Ya Wagonjwa Wanaofanyiwa Upasuaji Katika Hospitali Ya K.N.H"

Fomu Ya Idhini

Maelezo:

Fomu fomu hii niya idhini kwa ajili ya watoto wote wagonjwa wenye umri wa chini ya miaka kumi na nane watakaofanyiwa upasuaji katika hospitali kuu ya Taifa ya Kenyatta katika chumba zote za upasuaji.. Mchunguzi mkuu ni Dr Sheila Gitau chini ya usimamizi kutoka Dr Anthony Gatheru na Dr George Njogu, anaendesha utafiti kuangalia ruwaza ya madawa ya kuzuia ugonjwa wa upasuaji miongoni mwa upasuaji wa wagonjwa katika hospitali ya Taifa ya Kenyatta. Utafiti utafanyika chini ya Idara ya unusukaputi katika Chuo Kikuu cha Nairobi.

Fomu ya kutiwa saini na mzazi wa mtoto:

Hi fomu ya kutiwa saini na wazazi wa watoto ina sehemu mbili:

- Sehemu ya Maelezo (kukuelezea zaidi kuhusu utafiti)
- Shahada ya Kutiwa saini na watoto (sahihi ikiwa umekubali kujihusisha na utafiti huu)

Utapewa nakala ya maalezo ya utafiti huu.

Sehemu Ya Kwanza: Maelezo

Mimi ni mwanafunzi katika chuo kikuu cha Nairobi nikisomea shahada kuu katika Unusukaputi katika Chuo Kikuu ya Nairobi. Mimi ninafanya utafiti kuangalia ruwadha ya madawa yanayo kinga ugonjwa wa upasuaji miongoni mwa wagonjwa kufanyiwa upasuaji katika hospitali ya taifa ya kenyatta.

Nia

Taarifa uliyopewa ni yako wewe itakusaidia kuamua au unapaswa kushiriki katika utafiti huu. Uko huru kuuliza kuhusu madhumuni ya somo hili na hatari na faida kwa mtoto kama akishiriki katika utafiti. Wakati ukisikia kikamilifu nimekajibu maswali yako ameshiba, unaweza kuamua kama unataka kushiriki katika utafiti huu. Kama inaweza kuwa baadhi ya maneno ambayo haukuelewa, tafadhali Niulize ni kueleza kama tunaenda kupitia taarifa. Kama una maswali baadaye, Unaweza kuwauliza Wawasiliani wangu zinapatikana kwenye fomu hii ya kibali.

Hatari

Hakuna hatari yoyote itakayotarajiwa utakaposhiriki utafiti huu.

Nimethibitisha kuwa mtoto ameelewa ya kwamba hakuna hatari yoyote ile itayomkabili …….(saini)

Faida ya utafiti

Utafiti huu utasaidia kuboresha maisha ya watoto wetu na matibabu yao.

Nimethibitisha kuwa mzazi ameelewa faida ya utafiti _____ (saini)

Waanaoalikwa kujihusisha na utafiti

Mtafiti anawakaribisha watoto wote wagonjwa wote watakaofanyiwa upasuaji wa kutoa findo katika Hospitali ya Taifa Ya Kenyatta .

Kushiriki

Kushiriki utafiti huu utakuwa kwa njia ya kujitolea na kwa hivyo hakuna malipo yoyote atakayolipwa mshiriki wa utafiti huu. Iwapo hungependa kushiriki, uamuzi huu hautaathiri kwa njia yoyote matibabu yako au utakavyiohudumiwa.

Nimethibitisha kuwa mtoto ameelewa ya kwamba kujihusisha na hii utafiti ni kwa njia ya kujitolea _____ (saini)

Maelezo kuhusu mchakato

Iwapo utakubali mtoto kushiriki utapewa fomu ya kujaza iliyo na seti ya maswali hasa kuhusu hali ya afya ya watoto hawa na idadi ya nyakati za kulazwa hospitalini kwa muda wa mwaka moja.sababu ya kulazwa. Maelezo zaidi pia yatatolewa kwenye file yako kliniki ili kuboresha utafiti.

Nimethibitisha kuwa mtoto ameelewa maelezo kuhusu mchakato

……(saini)

Wakati utakaotumika

Kwa ujumla,utafiti huu utachukua siku sitini(60).Kwa wakati huu,tutahitaji dakika kumi na tan tu kujaza fomu na kuchukua maelezo mengine yatakayohitajika

Usiri

Matokeo ya utafiti huu yatawekwa siri wala hayatapatiwa mtu yeyote asiyehusika na utafiti huu. zaidi ya hayo badala ya jina la mtoto, numbari zitatumiwa kutambuliwa watoto hawa.Matokeo yatazungumziwa na idara ya afya ya watoto pekee wala sio mtu mwingine.

Haki ya kutoshiriki

Kushiriki kwa utafiti huu ni kwa kujitolea na iwapo hungependa kushiriki,uoamuzi wako utaheshimiwa na pia hautathiri kwa njia yoyote matibabu yako. Bali utaendelea kupokea matibabu na huduma ya hospitali hii kama hapo awali.

Pendekezo hili limeangaliwa na kuidhinishwa na Idara ya nusu kaputi ya Chuo kikuu cha Nairobi na kamiti ya maadili ya utafiti katika hospitali ya Kenyatta inayohakikisha kuwa haki za wanaoshiriki utafiti wowote inchini,zinazingatiwa .

Iwapo utakuwa na swali lolote kumbuka una uhuru kuuliza.

SEHEMU YA II: Shahada ya Kutiwa Saini na mzazi

Nambari Maalum:_____

Nimesoma maaelezo yote ya utafiti huu au nimesomewa maaelezo haya na nimekuwa na fursa ya kuuliza maswali ambayo yamejibiwa kadri na matarajio yangu kwa njia ya kuridhisha.Kwahio ningependa kupeana saini langu na pia kujitolea kushiriki kwa utafiti huu .

Nakubali kujihusisha na utafiti huu.

AMA

Si kubali mtoto wangu ashiriki katika utafiti huu na sijatia saini lolote._____ (alama ya mzazi)

Mzazi akikubali:

Jina la mtoto: _____

Saini la mzazi: _____

Tarehe:_____

Iwapo mzazu hawezi akasoma:

Nimeona na ninaweza thibitisha ya kwamba mzazi amesomewa yaliyo kwenye hii fomu ya kutiwa saini na mzazi wa mtoto na ameweza kuuliza maswali atakayo. Na thibitisha ya kwamba mzazi amekubali kwa hiari yake kushirikiana na hii utafiti.

Jina la shahidi mzazi): _____

Alama ya Kidole ya Mzazi

Saini la shahidi:…… Tarehe: ……..

Nememsomea ama nimeona na ninaweza thibitisha ya kwamba mzazi amesomewa yaliyo kwenye hii fomu ya kutiwa saini na mzazi, na mwenyewe ameweza kuuliza maswali atakayo. Na thibitisha ya kwamba mzazi amekubali kwa hiari yake mtoto wake kushirikiana na huu utafiti.

Jina la mpelelezi: Dr. Sheila Gitau

Saini la shahidi:…… Tarehe: ……..

Nakala imepewa kwake mzazi wa mshiriki _____(alama ya mpelelezi)

Mzazi/Mgarini amaitia saini Shahada ya Idhini :

Ndiyo_____ Hapana_____

Kwa maelezo Zaidi hata baada ya utafiti huu una uhuru wakuwasiliana na watu wafuatao kupitia anwani na numbari za simu silizoandikwa hapa chini.

Dkt Sheila Gitau

Numba ya simu: 0735805465

Barua pepe: reecesny@gmail.com

Dkt Antony Gatheru

Namba ya simu: 0721-654806

Barua pepe: gatherua@gmail.com

Dkt George Njogu

Namba ya simu: 0722-712207

Barua pepe: njogug@gmail.com

Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

College of Health Sciences

P. O. Box 19676 00202 Nairobi

Simu. (254-020) 2726300-9 Ext 44355

Barua pepe: uonknh_erc@uonbi.ac.ke

Appendix IV (a): Assent Form (English)

"Patterns of perioperative antibiotic surgical prophylaxis among surgical patients undergoing surgery in K.N.H theatre"

Informed Assent Form

This informed assent form is for children above 7 years or cognitively impaired persons who will undergo surgery at Kenyatta National Hospital Satellite and Main theatres.

The principal investigator is **Dr Sheila Gitau** under supervision from **Dr Anthony Gatheru** and Dr George Njogu, is conducting a study looking at patterns of perioperative antibiotic surgical prophylaxis among surgical patients Kenyatta National Hospital. The study is being done under the department of Anaesthesia in the University of Nairobi.

This Informed Assent Form has two parts:

- **Information Sheet (gives you information about the study)**
- **Certificate of Assent (this is where you sign if you agree to participate)**

You will be given a copy of the full Informed Assent Form

Part I: Information Sheet

I am a Student currently doing my Masters in Anaesthesia at the University of Nairobi. I am doing a study looking at the patterns of antibiotic surgical prophylaxis among patients undergoing surgery in Kenyatta National Hospital Theatres. Information given to you will help you decide whether or not you should participate in this study. You are free ask about the purpose of this study and risks and benefit to you if you participate in the study. When we have fully answered your questions to your satisfaction, you may decide if you want to participate in this study.

There may be some words that you do not understand, Please ask me to explain as we go through the information. If you have questions later, you can ask them my contacts are available on this assent form.

Purpose: Why are you doing this research?

Antibiotics are given to patients undergoing surgery to prevent surgical site infections. They work best when they are given before the surgical incision is made. They should be given for the shortest duration of time to reduce the risk of unwanted drug effects. This study is being carried out to see if these practices on antibiotic usage are being followed.

Choice of participants: Why are you asking me?

We want to get some information about antibiotic use in children and patients with impaired cognitive function. There shall be 374 study participants in this study including adults and children.

Participation is voluntary: Do I have to do this?

You don't have to be in this research if you don't want to be. It's up to you. If you decide not to be in the research, it's okay and nothing changes.

I have checked with the child and they understand that participation is voluntary ……. (signature)

Procedures: What is going to happen to me?

If you allow us we are going to document what antibiotic you get during surgery, the dose, time it is given to you relative to the start of surgery. We shall also come and see you in the ward to check on your wound on day 5 and day 30 post operatively. If you will have left the hospital. we shall call you on the telephone and ask you questions about your wound.

I have checked with the child and they understand the procedures ……..(signature)

Risks: Is this bad or dangerous for me?

You will not be in any harm when you take part in this research.

I have checked with the child and they understand the risks and discomforts ……...(signature)

Benefits: Is there anything good that happens to me?

Nothing might happen to you, but the information you give us might help us learn more about antibiotic surgical prophylaxis in children.

I have checked with the child and they understand the benefits …… (Signature)

Reimbursements: Do I get anything for being in the research?

Unfortunately there will be no gifts if you choose to participate in the study.

Confidentiality: Is everybody going to know about this?

We will not tell other people that you are in this research and we won't share information about you to anyone who does not work in the research study.

Information about you that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up. It will not be shared with or given to anyone.

Sharing the Findings: Will you tell me the results?

When we are finished with the research we will not contact you personally to give you the results but you can come find out about the research at the Department of Anaesthesia, University of Nairobi. We will be telling more people, scientists and others, about the research and what we found. We will do this by writing and sharing reports.

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

You do not have to be in this research. No one will be mad or disappointed with you if you say no. It's your choice. You can think about it and tell us later if you want. You can say "yes" now and change your mind later and it will still be okay.

Who to Contact: Who can I talk to or ask questions to?

You can ask me questions now or later. I have written a number and address where you can reach us or, if you are nearby, you can come and see us. If you want to talk to someone else that you know like your teacher or doctor or auntie, that's okay too.

If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Assent

Serial Number: _____

I understand that this research is about finding out the patterns of antibiotic surgical prophylaxis among surgical patients undergoing surgery at K.N.H. and I will be asked a set of questions if I choose to participate in the research. Information about my treatment will also be obtained from my medical records

I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.
I agree to take part in the research.

OR

I do not wish to take part in the research and I have <u>NOT</u> signed the assent below._____ (initialled by child/minor)

<u>Only if child assents:</u>
Print name of child _____
Signature of child: _____
Date:_____

If illiterate:
I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.
Print name of witness (not a parent) _____ AND Thumb print of participant
Signature of witness _____
Date _____

I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Name of researcher: DR SHEILA GITAU

Signature of researcher: ……. Date:……

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands the purpose and procedure of the study

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.

Name of Researcher: **Dr Sheila Gitau**

Signature of researcher: ……. Date:……

Copy provided to the participant _____(initialed by researcher)

Parent/Guardian has signed an informed consent: Yes_____ No_____

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Sheila Gitau (Primary Researcher)

Mobile Number: +254735-805465

Email: reeesny@gmail.com

Dr Anthony Gatheru

Mobile Number: +254721-654806

Email: gatherua@gmail.com.

Dr George Njogu

Mobile Number: +254722-712207

Email: njogug@gmail.com

Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

College of Health Sciences

P. O. Box 19676 00202 Nairobi

Tel. (254-020) 2726300-9 Ext 44355

E-mail: uonknh_erc@uonbi.ac.ke

Appendix IV (b): Assent Form (Swahili)

Fomu Ya Kutiwa Saini Na Watoto

“Ruwaza Ya Madawa Ya Antibiotiki Nayo Tumika Katatika Kuzuia Ugonjwa Wa Upasuaji Miongoni Ya Wagonjwa Wanaofanyiwa Upasuaji Katika Hospitali Ya K.N.H“

Fomu Ya Idhini

Maelezo:

Fomu fomu hii niya idhini kwa ajili ya watoto wote wagonjwa watakaofanyiwa upasuaji katika hospitali kuu ya Taifa ya Kenyatta katika chumba zote za upasuaji.. Mchunguzi mkuu ni Dr Sheila Gitau chini ya usimamizi kutoka Dr Anthony Gatheru na Dr George Njogu, anaendesha utafiti kuangalia ruwaza ya madawa ya kuzuia ugonjwa wa upasuaji miongoni mwa upasuaji wa wagonjwa katika hospitali ya Taifa ya Kenyatta. Utafiti utafanyika chini ya Idara ya unusukaputi katika Chuo Kikuu cha Nairobi.

Fomu ya kutiwa saini na watoto:

Hi fomu ya kutiwa saini na watoto ina sehemu mbili:

- Sehemu ya Maelezo (kukuelezea zaidi kuhusu utafiti)
- Shahada ya Kutiwa saini na watoto (sahihi ikiwa umekubali kujihusisha na utafiti huu)

Utapewa nakala ya maalezo ya utafiti huu.

Sehemu Ya I: Maelezo

Mimi ni mwanafunzi katika chuo kikuu cha Nairobi nikisomea shahada kuu katika Unusukaputi katika Chuo Kikuu ya Nairobi. Mimi ninafanya utafiti kuangalia ruwadha ya madawa yanayo kinga ugonjwa wa upasuaji miongoni mwa wagonjwa kufanyiwa upasuaji katika hospitali ya taifa ya kenyatta.

Nia

Taarifa uliyopewa ni yako wewe itakusaidia kuamua au unapaswa kushiriki katika utafiti huu. Uko huru kuuliza kuhusu madhumuni ya somo hili na hatari na faida kwa wewe kama wewe kushiriki katika utafiti. Wakati ukisikia kikamilifu nimekajibu maswali yako ameshiba, unaweza kuamua kama unataka kushiriki katika utafiti huu. Kama inaweza kuwa baadhi ya maneno ambayo haukuelewa, tafadhali Niulize ni kueleza kama tunaenda kupitia taarifa. Kama una maswali baadaye, Unaweza kuwauliza Wawasiliani wangu zinapatikana kwenye fomu hii ya kibali.

Hatari

Hakuna hatari yoyote itakayotarajiwa utakaposhiriki utafiti huu. Nimethibitisha kuwa mtoto ameelewa ya kwamba hakuna hatari yoyote ile itayomkabili …….. (saini)

Faida ya utafiti

Utafiti huu utasaidia kuboresha maisha ya watoto wetu na matibabu yao.

Nimethibitisha kuwa mtoto ameelewa faida ya utafiti ……..(saini)

Waanaoalikwa kujihusisha na utafiti

Mtafiti anawakaribisha wagonjwa wote watakaofanyiwa upasuaji wa kutoa findo katika Hospitali ya Taifa Ya Kenyatta .

Kushiriki

Kushiriki utafiti huu utakuwa kwa njia ya kujitolea na kwa hivyo hakuna malipo yoyote atakayolipwa mshiriki wa utafiti huu. Iwapo hungependa kushiriki, uamuzi huu hautaathiri kwa njia yoyote matibabu yako au utakavyiohudumiwa.

Nimethibitisha kuwa mtoto ameelewa ya kwamba kujihusisha na hii utafiti ni kwa njia ya kujitolea …… (saini)

Maelezo kuhusu mchakato

Iwapo utakubali kushiriki utapewa fomu ya kujaza iliyo na seti ya maswali hasa kuhusu hali ya afya ya watoto hawa na idadi ya nyakati za kulazwa hospitalini kwa muda wa mwaka moja.sababu ya kulazwa. Maelezo zaidi pia yatatolewa kwenye file yako kliniki ili kuboresha utafiti.

Nimethibitisha kuwa mtoto ameelewa maelezo kuhusu mchakato ……(saini)

Wakati utakaotumika

Kwa ujumla,utafiti huu utachukua siku sitini(60).Kwa wakati huu,tutahitaji dakika kumi na tan tu kujaza fomu na kuchukua maelezo mengine yatakayohitajika

Usiri

Matokeo ya utafiti huu yatawekwa siri wala hayatapatiwa mtu yeyote asiyehusika na utafiti huu. zaidi ya hayo badala ya jina la mtoto, numbari zitatumiwa kutambuliwa watoto hawa.Matokeo yatazungumziwa na idara ya afya ya watoto pekee wala sio mtu mwingine.

Haki ya kutoshiriki

Kushiriki kwa utafiti huu ni kwa kujitolea na iwapo hungependa kushiriki,uoamuzi wako utaheshimiwa na pia hautathiri kwa njia yoyote matibabu yako. Bali utaendelea kupokea matibabu na huduma ya hospitali hii kama hapo awali.

Pendekezo hili limeangaliwa na kuidhinishwa na Idara ya nusu kaputi ya Chuo kikuu cha Nairobi na kamiti ya maadili ya utafiti katika hospitali ya Kenyatta inayohakikisha kuwa haki za wanaoshiriki utafiti wowote inchini,zinazingatiwa .

Iwapo utakuwa na swali lolote kumbuka una uhuru kuuliza.

SEHEMU YA II: Shahada ya Kutiwa Saini na Watoto

Nambari **Maalum:_____**

Nimesoma maaelezo yote ya utafiti huu au nimesomewa maaelezo haya na nimekuwa na fursa ya kuuliza maswali ambayo yamejibiwa kadri na matarajio yangu kwa njia ya kuridhisha.Kwahio ningependa kupeana saini langu na pia kujitolea kushiriki kwa utafiti huu .

Nakubali kujihusisha na utafiti huu.

Ama

Si kubali kujuhusisha na utafiti huu na sijatia saini lolote…… (alama ya mshiriki)

Moto akikubali:

Jina la mtoto: ……...

Saini la mtoto: …… Tarehe:……

Iwapo mtoto hawezi akasoma:

Nimeona na ninaweza thibitisha ya kwamba mtoto amesomewa yaliyo kwenye hii fomu ya kutiwa saini na mtoto, na mtoto mwenyewe ameweza kuuliza maswali atakayo. Na thibitisha ya kwamba mtoto amekubali kwa hiari yake kushirikiana na hii utafiti.

Jina la shahidi (isiwe mzazi):……..

NA Alama ya Kidole ya Mshiriki

Saini la Shahidi: …… Tarehe:……

Nememsomea ama nimeona na ninaweza thibitisha ya kwamba mtoto amesomewa yaliyo kwenye hii fomu ya kutiwa saini na mtoto, na mtoto mwenyewe ameweza kuuliza maswali atakayo. Na thibitisha ya kwamba mtoto amekubali kwa hiari yake kushirikiana na hii utafiti.

Jina la mpelelezi: DR SHEILA GITAU

Saini la mpelelezi: …… Tarehe:……

Nakala imepewa kwake mshiriki _____(alama ya mpelelezi)

Mzazi/Mgarini amaitia saini Shahada ya Idhini : Ndiyo_____ Hapana_____

Kwa maelezo Zaidi hata baada ya utafiti huu una uhuru wakuwasiliana na watu wafuatao kupitia anwani na numbari za simu silizoandikwa hapa chini.

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Appendix V: Questionnaire

"Patterns of Perioperative Antibiotic Surgical Prophylaxis among Surgical Patients Undergoing Surgery in K.N.H Theatres"

Data Extraction format

The form below should be filled for any patient who has consented to be included in this study. All sections should be filled before submitting the form to the principal investigator. Where appropriate, use ticks or fill in appropriate data.

1. Biodata

Serial No.……

Gender Male ☐ Female ☐

Age in years …….. Months…….

Weight in Kilograms (please weigh patients ;SECA Scale)……

Contacts Telephone No. ……..

2. Cadre of Health care professional prescribing antibiotics

a) Consultant Anesthesiologist ☐

b) Registered clinical officer ☐

c) Registrar ☐

d) Clinical officer in training ☐

3. Medical and surgical history of patients undergoing surgery

a. Type of surgery i) Emergency Yes ☐ No ☐

ii) Elective Yes ☐ No ☐

b. Surgical procedure performed ……..

c. Does the patient have an existing medical condition? Yes ☐ No ☐

If yes, Please specify: i) Diabetes

ii) Hypertension Yes ☐ No ☐

iii) Kidney disease Yes ☐ No ☐

iv) Malignancy Yes ☐ No ☐

v) Previous surgery Yes ☐ No ☐

vi) Obesity Yes ☐ No ☐

d. Duration of hospital stay before current surgery i) Days……

ii) Weeks……..

iii) Months…….

3. Type of wound (See attached Classification)

i) Clean…….

ii) Clean Contaminated……

iii) Contaminated…….

iv) Dirty……

4. Surgical antibiotic usage

a) Were any antibiotics employed for this patient? Yes ☐ No ☐

b) If yes, i) What antibiotic/s (if more than 1 specify all)…….

ii) Dose…….....

iii) Time given…….

c) Were antibiotics prescribed post-operatively ? Yes ☐ No ☐

If yes, i) Antibiotic……

ii) Dose……..

iii) Duration…….

d) Start of surgery (Time)……..

5. Are you aware there are antimicrobial prescription guidelines? Yes ☐ No ☐

If yes, do you follow them in prescribing antibiotics? Yes ☐ No ☐

If No, Please specify why…….

6. Postoperative surgical site infection

Are any of the following signs present around the wound?

i) Day 5.

a. Increased swelling around the wound Yes ☐ No ☐
b. Redness around the wound Yes ☐ No ☐
c. Cloudy wound drainage Yes ☐ No ☐
d. Yellow or greenish-colored pus Yes ☐ No ☐
e. Tenderness, or pain around the wound Yes ☐ No ☐

ii) Day 30.

a. Increased swelling around the wound Yes ☐ No ☐
b. Redness around the wound Yes ☐ No ☐
c. Cloudy wound drainage Yes ☐ No ☐
d. Yellow or greenish-colored pus Yes ☐ No ☐
e. Tenderness, or pain around the wound Yes ☐ No ☐

Appendix VI: KNH/UON-ERC Letter of Approval