INCIDENCE, MICROBIOLOGICAL AGENTS AND PREDICTORS OF SURGICAL SITE INFECTIONS FOLLOWING OPEN SURGERIES AT MUHIMBILI NATIONAL HOSPITAL, OTORHINOLARYNGOLOGY DEPARTMENT.

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By

Kusi Lema

A Dissertation Submitted in Partial Fulfillment of the Requirement for the Degree of the Master of Medicine (Otorhinolaryngology) of Muhimbili University of Health and Allied Sciences

October, 2024

CERTIFICATION

The undersigned certifies that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled "***Incidence, microbiological agents and predictors of surgical site infections following open surgeries at Muhimbili National Hospital, Otorhinolaryngology Department"*** in fulfillment of the requirement for the degree of the Master of Medicine (Otorhinolaryngology) of Muhimbili University of Health and Allied Sciences.

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Date

DECLARATION AND COPYRIGHT

I, Kusi Lema, declare that this dissertation is my original work and that, it has not been presented and will not be presented to any other University for a similar or any other degree award.

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DEDICATION

I dedicate this precious work to my close friends, guardians, young brothers and sisters, and the Hospital management team (HMT) at my workplace for their phenomenal support and encouragement in the whole process of making this work marvelous.

ABSTRACT

Background: Surgical site infection is the most common complication of surgery across all surgical disciplines. It has been associated with increased hospital stay, readmission, increased cost burden to both patients and the health care facilities, re-operation, and death. Adherence to surgical preventative strategies generated from modifiable risk variables significantly reduces the burden of surgical site infections. The magnitude, microbiological agents, and predictors of surgical site infections in the otorhinolaryngology department at Muhimbili National Hospital and Tanzania at large are unknown.

Objective: To determine the incidence, predictors, and microbiological agents of surgical site infections among open surgeries done at Muhimbili National Hospital in the otorhinolaryngology department.

Methodology: This was a hospital-based prospective cohort study, whereby all patients who had undergone open surgeries were assessed for signs and symptoms of surgical site infections 48 hours after an operation during a change of dressing, 7^{th} day from the day of operation which was a day of follow-up and stitch removal and lastly the patients were interviewed at 30^{th} day via phones for the symptoms of surgical site infections, clinically diagnosed SSI cases, swabs were taken for microbiological agents identification through culture, Gram stain and biochemical tests. Twenty four hours following culture; colony morphological characteristics such as margin, color and shape were assessed, followed by Gram staining and finally biochemical tests were carried out, such as using catalase for Gram-positive bacteria; to differentiate streptococci from staphylococcus, coagulase test for differentiating *Staphylococcus aureus* from other Staphylococci and APE20 and oxidase for specific Gram-negative bacterial identification. Data were collected through a structured data collecting tool with mixed questions and a checklist, and the interview started the day before the operation to obtain demographic data and other pre-operative risk factors. Data were entered in STATA version 15.1 for analysis and version 12.0 for graphing, the Chi-square test/Fischer exact test was used to test the statistical significance difference of SSI occurrence among different categorical variables, and the robust Poisson regression test for bivariable analysis based on crude risk ratio (cRR) and multivariable analysis based on adjusted risk ratio (aRR) was used to determine the strength of the relationship between independent and dependent variables.

Results: A total of 89 post-open surgery patients, whose ages ranged from 13 to 78 years, were enrolled in the study. The median age was 44.5 years, and the interquartile range of (36-59). The majority (34.8%) of the study participants were in the age group (36–53), with an overall female preponderance of 1.12:1. The overall incidence of surgical site infections found in this study was 22.5%. About 13 (72.2%) of the bacterial species isolated were Gram-negative. *Pseudomonas aeruginosa* 7 (38.9%) followed by *Staphylococcus aureus* 3 (16.7%) were the most isolated bacterial species in this study.

On bivariable robust regression analysis, factors such as alcohol drinking habits (RR 7.33, 95% CI 3.41-15.72, P<0.0001), human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) comorbidity (RR 5.2, 95% CI 2.84-8.86, P<0.0001), diabetes mellitus (RR 3.19, 95% CI 1.29-7.87, P=0.012), those who didn't receive antibiotic prophylaxis (RR 12.18, 95% CI 4.53-32.77, P=0.0001), high American Society of Anaesthesiologists (ASA) score (III and IV) (RR 6.56, 95% CI 2.16-19.87, P=0.001), and pre-operative waiting time of > 1 day (RR 3.47, 95% CI 1.71-7.04, P=0.001) significantly predicted occurrence of SSI.

Whereas, on multivariable robust regression analysis, factors such as alcohol drinking habits (RR 1.71, 95% CI 1.01-2.94, P=0.048), HIV/AIDS comorbidity (RR 1.87, 95% CI 1.16-3.00, P=0.001) and those who didn't receive antibiotic prophylaxis (RR 9.92, 2.16-45.51, P=0.003), independently (i.e. without effects of confounders) predicted occurrence of SSI in this study.

Conclusion: The findings of this study revealed high incidence (22.5%) of surgical site infections (SSI) in the otorhinolaryngology department caused mainly by *Pseudomonas aureginosa* and *Staphylococcus aureus*. Surgical site infections occurrences were mostly predicted by alcohol use, HIV/AIDS comorbidity, and not using antibiotic prophylaxis in patients who had undergone open surgery. However, the predictors identified in this study can be prevented thus reducing the seemingly high incidence of SSI in the department.

Recommendation: Abstinence from alcohol intake 4 to 8 weeks before surgery for surgical patients should be enforced to reduce the incidence of SSI. Antibiotic prophylaxis is strongly recommended in most otorhinolaryngology procedures since they are class II to IV wounds (83.1%) of all surgeries during the index investigation. In the same vein those patients who lose 1.5litres or more of blood or the procedures which take 1-2 times long half-life from the

first dose of antibiotic prophylaxis, antibiotic redosing must be done. The surgical patients with HIV/AIDS comorbidity should have CD4 levels over 350 cells/μL tested within 12 months for elective surgeries as mandatory preoperative requirement, but for emergence surgeries may be a relative indication.

Many other variables, including wound class, American Society of Anesthesiologists (ASA) scores, pre-op length of hospital stay, smoking, diabetes mellitus, antibiotic redosing, operation time, and body mass index, were found to be ineffective in predicting the incidence of SSI, contrary to previous studies, thus, additional research with big sample size and a long study period is recommended.

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LIST OFABBREVIATIONS.

AIDS	Acquired immunodeficiency syndrome
ASA	American Society of Anaesthesiologist
BMI	Body Mass Index
CDC	Centre for disease control and prevention
CHF	Congestive heart failure
COPD	Chronic obstructive pulmonary disease
DM	Diabetes mellitus
ENT	Ear nose and throat
HAI's	Healthcare-associated infections
HCW's	Health care workers
HIV/AIDS	Human immunodeficiency virus
ICU	Intensive Care Unity
MNH	Muhimbili National Hospital
NHSN	National Healthcare Safety Network
OBGY	Obstetrics and Gynecology
ORL	Otorhinolaryngology
SCIP	Surgical care improvement project
SSI	Surgical site infections
USA	United States of America

DEFINITIONS OF TERMS

Surgical site infection (SSI) is the growth of harmful pathogenic microorganisms on the incision site after the breach of either the skin or mucosa. The infection can occur within the skin and subcutaneous tissue (*superficial*), muscle and fascial layers (*deep*), or in an *organ or cavity* if opened during surgery in a duration of 30 days or 1 year in surgeries involving implant placement.

An implant is a medical device that is designed to replace a missing structure or a malformed or malfunctioning part of the body such as a cochlea.

Open surgeries are those surgeries approached through skin incision into the surgical fields for the direct view of the surgeon e.g., maxillectomy, parotidectomy, and mastoidectomy.

Endogenous microbe includes all micro-organisms such as bacteria, fungi, viruses, or protozoa, which are from the patient's own body such as skin, mucous, or viscus.

Exogenous microbes include organisms, which can be found in surroundings, such as in air, surgical instruments, and other people around such as health care personnel and relatives.

Predictors of surgical site infections include all factors that directly or indirectly predispose patients towards developing surgical site infections of the wound.

Clinical characteristics entail all the independent study variables such as patient comorbidities and lifestyle and perioperative predictors

Body mass index (BMI) according to CDC is the weight in kilograms divided by the person's squared height in meters. Clinically, it indicates if the individual is normal, underweight, overweight, or obese as summarized in the table below.

Table 1: Clinical description of the body mass index

Body mass index (kg/m^2)	Clinical definition
<18.5	Underweight
18.5-24.9	Normal
25-29.9	Overweight
>30	Obese

Wound class is the term that describes the state of the cleanliness of the surgery that is going to be done, it depends on the site of the incision, the prior inflammatory condition where the incision is made, and the degree of contamination before surgery. It is grouped into four classes as seen in the table below.

Table 2: Wound class description custom fit for otorhinolaryngology head and neck surgeries.

WOUND CLASS	*DESCRIPTION*
Clean wound (Class I)	Clean incision, all levels closed, no entry into the aerodigestive tract or middle ear, no salivary tissue or duct encountered, no inflammation, fresh traumatic wound, necrosis, tissue infection, purulence, or unclean wound not encountered.
Clean contaminated (Class II)	Entrance into the aerodigestive tract, middle ear, and oral cavity or salivary tissue (parenchyma or duct), and no inflammation, fresh traumatic wound, necrosis, tissue infection, purulence, or dirty wound.
Contaminated wound (Class III)	Open, fresh traumatic wound, necrosis, or non-infected inflammation (e.g., polyp, cholesteatoma, sinusitis, chronic fungal disease), and no tissue infection, purulence, or dirt.
Dirty/infected wound (Class IV).	Infected tissue, with or without, purulence, dirty wounds, old traumatic wounds, with retained devitalized tissue.

The American Society of Anaestheliogist (ASA) score, is the measure of how fit is patients on the physical dimension towards surgery. It explains the stress of the prior comorbid conditions such as diabetes mellitus of the patient before surgery. It is classified into six classes as summarized by the table below.

Table 3: ASA class and their descriptions

ASA class	*DESCRIPTION*
I	A healthy person, e.g. BMI under 30, a non-smoker patient, no alcohol use, has good exercise tolerance.
II	A patient has a mild systemic disease without functional limits. For example, he or she is a cigarette smoker, social alcohol drinker, and has well-managed conditions including hypertension and obesity with a BMI less than 40.
III	A patient suffers from benign but severe systemic disorders. For example, he or she is functionally constrained by an illness such as uncontrolled hypertension or diabetes, morbid obesity, chronic renal failure, a bronchospastic condition with intermittent exacerbation, stable angina, or an implanted pacemaker.
IV	A patient has a significant systemic illness that is threatening his or her life, such as unstable angina, uncontrolled Chronic Obstructive Pulmonary Disease (COPD), symptomatic Congestive Heart Failure (CHF), or a recent (within three months) myocardial infarction or stroke.
V	A patient who will die within one day unless surgery is performed. Examples include a patient with a ruptured abdominal aortic aneurysm, major trauma, and a massive cerebral hemorrhage.
VI	Moribund, is a patient who is not expected to survive > 24 hours. A brain-dead patient whose organs are being harvested for transplantation into another patient.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

According to the Centre for Disease Prevention and Control (CDC), surgical site infections(SSI) include all infections occurring at or near the surgical incision within 30 days of surgery or after 1 year if an implant was put (1).

Studies show an increased trend of surgical volume compared to previous years in the world with >300 million people being operated on annually (2). Thus, millions of people are at a high risk of getting SSI if preventive measures are not adequately practiced.

In the world, the pattern and surgical volume of otorhinolaryngology (ORL) open surgeries vary widely across countries, and also from facility to facility. This has been linked to the technical know-how among staff working at the otorhinolaryngology (ORL) department and the availability of equipment, and because of that some surgeries like cochlea implants are not performed even by some tertiary hospitals. Surgeries done commonly include neck surgeries such as neck dissection and thyroidectomy, nasal and paranasal surgeries such as septoplasty, polypectomy, and maxillectomy, otological surgeries such as mastoidectomy and tympanoplasty (3).

Because of the anatomical area of surgery, ear, nose, and throat (ENT) surgeons work hand in hand with other disciplines, such as maxillofacial and oncology teams in head and neck cancers and the neurosurgical department in the cases of lateral and anterior skull base pathologies (3).

Despite advances in surgical technique and prevention methods against surgical site infection, the incidence cases are still reported high in different parts of the world, resulting in increased morbidity, prolonged hospital stay, and death. The burden of SSI is 20% of all types of nosocomial infections. It is linked to a 2- to 11-fold increase in mortality risk, as 75% of SSI-related deaths are directly attributable to the SSI (3, 4). With an estimated yearly cost of $3.3 billion, SSI is been said to be the most costly hospital-acquired infection (HAI)

type, prolonging hospital length of stay by 9.7 days and boosting hospitalization costs by more than $20,000 per admission (4,5).

The global burden of surgical site infection is not constantly reported as it has been the case in many other communicable diseases, the reason being that it involves multiple criteria for diagnosis, the absence of reliable data, and the absence of National surveillance systems, especially in developing countries (6). It has been documented that, surgical site infections burden the world immensely with more predilection towards developing countries which is two-fold in magnitude as compared to developed countries (6).

In the United States of America (USA), the annual incidence of SSI varies from 160,000 to 300,000 of the performed cases (5). In a study of surgical site infections in underdeveloped nations, it was discovered that 6% of all operated patients got surgical site infections, and this climbed to 15% after post-discharge surveillance was done. However, in the same study, the magnitude of SSI differed by region, with Africa, Latin America, Asia, and China having 10%, 7%, 4%, and 4%, respectively (7).

In East Africa, for example, surgical site infection has remained higher. The study in Uganda found the incidence of SSI to be 16.4%(8), whereas, in Kenya, one study showed an incidence of 7% (9).

In Tanzania, recent studies on different surgical disciplines such as obstetrics and gynecology, urology, and orthopedics have been done, and the rate of surgical site infection was found to range between 10.9% and 26% (10-12).

Even though the incidence of surgical site infections is proven to be more common in most studies and across surgical disciplines such as general surgery, urology, orthopedics, and obstetrics and gynecology, there is no known data about the incidence, microbiology, and predictors of SSI in ORL open surgeries. No single study has ever been undertaken at MNH, or even in Tanzania at large, to evaluate the incidence, microorganisms, and factors related to SSI.

1.1.1 Predictors of surgical site infection

According to the American College of Surgeons and Surgical Infection Society, surgical site infections are associated with several risk factors which are grouped into; patient-related, such as age, recent radiotherapy, diabetes, obesity, alcohol intake, current smoking, BMI status, and immunosuppression. Preoperative-related, such as emergency versus elective, wound class, proper antibiotic prophylaxis, and glycemic control, and Intraoperative-related factors such as longer duration of the procedure, contamination, and failure in antibiotics redosing to patients with criteria (5).

Studies show that appropriate implementing or practicing the above-mentioned factors, such as abstaining from alcohol 4-8 weeks before surgery, quitting smoking 2 weeks before surgery, taking precautions among patients with comorbidities such as > 350cells/µl of CD4 level in patients with HIV/AIDS, and glucose control among diabetic patients, can reduce surgical site infection by 60%(4,13,14).

A systematic review of 24 previous studies in Ethiopia on the Surgical site infections and the associated risk factors of SSI, duration of more than 1hour of surgery, diabetes mellitus, ASA class of more than I, previous surgery, and clean contaminated wound were found to be associated with surgical site infections development (15).

1.1.2 Microbiology

Puca et al. found that among the most prevalent microorganisms causing surgical site infections, Gram negative bacteria were the most common (57.9%) *Pseudomonas aureginosa* followed by Escherichia *coli* being predominant. Gram positive accounted 36.6% with *Staphylococcus aureus* predominating(79.4%)(16). Moreover, in the study done by Joel Manyahi on the bacteriological spectrum of postoperative wound infections at MNH and MOI, the three most common isolated organisms were Pseudomonas aeruginosa (16.3%), followed by Staphylococcus aureus (12.2%), and Klebsiella pneumoniae (10.8%) (17).

The rise of resistant bacteria, such as Methicillin-resistant Staphylococcus aureus, is currently a serious worry, as it has been linked to increased morbidity and mortality in most cases (18). Like other staphylococcal strains, it lives as normal flora on the skin and other parts of the body without causing harm; nevertheless, it can gain access to or be transferred from one person to another when large breaks occur, such as skin cuts.

Pathogenic microorganisms can be directly inoculated to the surgical incision by surgeons' or nurses' hands, from air, and or the bacteria getting into the incision site after surgery from the patient's own body (19). Infections are caused by the endogenous i.e., from own body or exogenous sources such as those from the soil, surgical instruments, air, or from health care professionals performing the procedure. But, in most cases, surgical site infection develops due to an endogenous source of bacteria (20).

In ORL head and neck surgeries, microbiological isolates differ based on the type of surgery and the site where surgeries were performed, for example, one study on post-ear surgery found *Escherichia coli* to be the most common cause of SSI in patients who underwent mastoid surgeries, followed by *Staph aureus* (21). Whereas a systematic review of 14 articles on cochlea implant surgical site infection prevention, Staphylococcus, and Pseudomonas species were found to be the most consistently reported isolates in those studies (22).

Study of bacterial colonization following tracheostomy among patients in the ICU in one of the hospitals in Oman, *Pseudomonas aeruginosa* and *Acinetobacter baumanii* species were the most common isolates identified during that study (23). In a 5 years prospective study of

oropharyngeal carriage and lower airway colonization of 45 tracheostomized children, Pseudomonas was found to be the commonest isolate (55%) among hospitalized children, and *Staphylococcus aureus* was the common potential pathogen (37%) to those who were not hospitalized i.e. community(24).

In the study on "Antibiotic Sensitivity Patterns of Aerobic Bacterial Agents in Post-Surgical Orofacial Infections", *Staphylococcus Aureus* was the most isolated organism (40%), followed by Klebsiella and Pseudomonas species which are 23 % and 19% respectively(25).

1.1.3 Pathogenesis

Usually, the normal flora and the host's innate immunity are in a state of equilibrium. The equilibrium becomes disrupted when an incision is made on that area because the healing process requires an inflammatory process that mobilizes the local defense mechanism as a result, immunity in that area becomes minimal. When bacterial invasion occurs at this time, the proliferation process will be disinhibited on the wound and hence surgical site infection. This becomes possible because of decreased immunity enough to halt the bacterial invasion, owing to the non-specific inflammatory response which was meant for the healing process of the created incision (26). According to the CDC, surgical site infection is directly proportional to the dose of bacterial contaminating the wound and their virulence, but inversely proportional to the host's resistance (27).

Endogenous microbe

Microbes can invade human tissue by producing toxins or other substances such as inflammatory mediators which mount the inflammatory process. Gram-negative bacteria produce endotoxin which stimulates cytokine production hence the inflammatory response which sometimes may end up in multiple organ failure. Some produce exotoxins such as streptococci, which disrupt cell membrane integrity. Surgical site infections take place mainly from the endogenous source, which can either be the patient's skin, mucus membrane, or viscus. When mucosa or skin is incised, the wound is at risk of contamination by the regional bacteria residing in that area which are mainly aerobic gram-positive cocci such as *S. aureus* and streptococci species (27).

Exogenous microbe

Surgical site infection can also develop from bacteria originating from people surrounding the patient, such as surgeons, nurses, and relatives, or from the air of that environment, and instruments or materials used for surgery. The main microorganisms leading up to this kind of infection are mainly aerobes, such as gram-positive cocci (staphylococci and streptococci) (27).

1.1.4 Time to onset of surgical site infection

Time to diagnosis of surgical site infections has been found to range between 5-7 days(28), However, some studies have revealed that the median time to diagnosis in the majority of surgical site infection cases is nearly two weeks (9-16) days, and the majority of cases were found after a post-discharge surveillance(29,30).

1.2 Problem Statement.

Globally, millions of people are at risk of getting SSI following increased surgical volumes and inadequate practice of control measures (2). In Africa, studies have found surgical site infection to be the most common post-op complication with an estimated 10% incidence, and mortality has been even worse in African countries as compared to the rest of the world (7).

In Tanzania, the burden of surgical site infection still exists(31), for example; the incidence and related predictors of surgical site infections from other surgical disciplines such as General Surgery, Obstetrics and Gynecology, and Urology have been well studied with incidence ranging from 10.9% to 26% (10,12).

The incidence of surgical site infections, microbiological agents, and the related predictors in otorhinolaryngology is barely known worldwide, in fact, no single study has been done in Tanzania for that purpose.

1.3 Conceptual framework

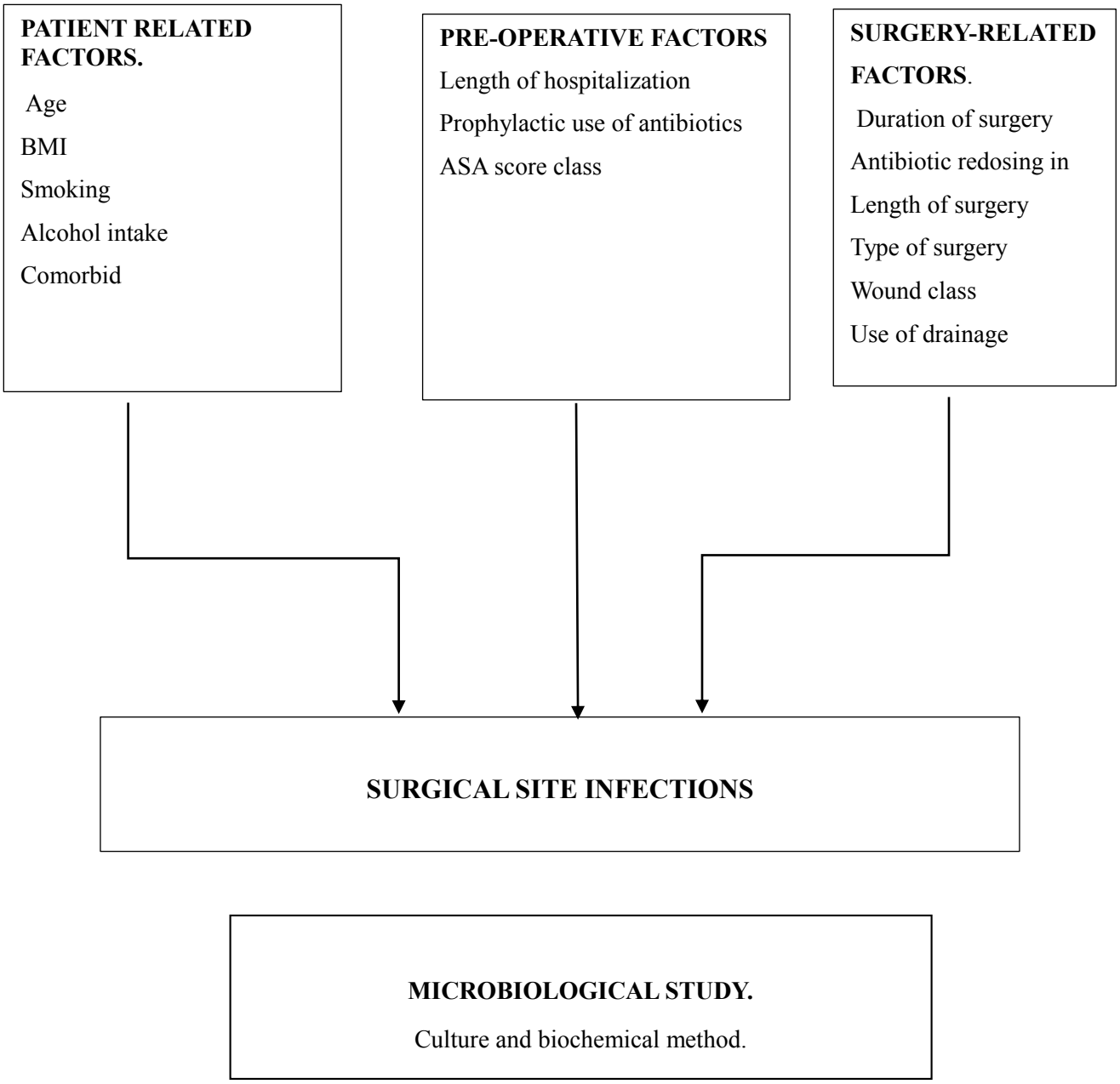


Figure 1: Conceptual framework

1.4 Rationale of the study.

The study was carried out in an attempt to find out the incidence of surgical site infections as an indicator of surgical outcomes in the otorhinolaryngology (ORL) department at Muhimbili National Hospital (MNH). The study generated the possible risk factors related to surgical site infections in the ORL department, so the department will be able to plan pertinent control measures in the future.

This study found the microbiological agents associated with surgical infections in the ORL Department at MNH that would help plan guidelines for antibiotic prophylaxis. The study's findings are going to provide ground information for further studies in the future. The study fulfilled a partial requirement for my Master of Medicine in Otorhinolaryngology.

1.5 Research questions

1. What is the incidence of surgical site infections of the open surgeries in the otorhinolaryngology department at Muhimbili National Hospital?
2. What are the microbiological agents that cause surgical site infection following open surgeries in the otorhinolaryngology department at Muhimbili National Hospital?
3. What are the predictors of developing surgical sites of open surgeries in the otorhinolaryngology department at Muhimbili National Hospital?

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1.6 Broad objective

To determine the incidence, microbiological agents, and predictors of surgical site infections of the open surgeries in the otorhinolaryngology department at Muhimbili National Hospital.

1.7 Specific objectives

1. To determine the incidence of surgical site infections of open surgeries in the otorhinolaryngology department at Muhimbili National Hospital.
2. To determine the microbiological agents causing surgical site infections of the open surgeries in the otorhinolaryngology department at Muhimbili National Hospital.
3. To determine the predictors of surgical site infections following open surgeries in the otorhinolaryngology department at Muhimbili National Hospital.

CHAPTER TWO

2.0 LITERATURE REVIEW.

2.1 Magnitude of surgical site infection

The incidence of surgical site infections following otorhinolaryngology head and neck surgeries varies across studies. A retrospective cohort study by Lebo et al. in the United States and that of Shi et al in China revealed the incidences of surgical site infections owing to head and neck surgeries to be 16.5% and 15.9% respectively (32,33), whereas a prospective study by Ifeacho et al. in Great Ormond Street Hospital, London WC1N 3JH, in the United Kingdom, for pediatric otolaryngology surgeries revealed an incidence of 3.7%(34). In a study by Rasmussen et al. in Denmark, the incidence was 11% and higher incidence was observed among head and neck surgeries compared to rhinological, and ontological surgeries in 13%, 11% and 6 % respectively (35).

Surgical site infections in otorhinolaryngology head and neck surgeries also vary according to the type of surgery performed, as evidenced by studies from different parts of the world, indicating that the incidences of surgical infection vary across different procedures such as septoplasty, laryngotracheal surgery, airway reconstruction in paediatric, head and neck oncological surgery, parotidectomy was 3.3%, 4%, 6.4%, 13.6%, 3.2% respectively (36-37)**.**

The study by Lee D et al. revealed a markedly high surgical site infection incidence among patients who had head and neck oncological surgery at 18.4% (38). Compared to minor surgeries, major surgeries of the head and neck region, in the ear, nose, throat, paranasal sinuses, and salivary glands, contribute highly to developing surgical site infections in the head and neck region(39).

2.2 Risk factors

Patient-related factors

Demographic factors

Several studies have shown high morbidity and mortality rates due to surgical site infections in elderly groups of patients, and the incidence of surgical site infections in this group of patients is relatively high (40,41,42). The possible explanation for that is that, in this age group, there is a decreased ability to handle the stress of trauma such as surgery owing to decreased immunity. Furthermore, studies have revealed that more SSI cases affect males than females, because of the effects of testosterone on cell-mediated immunity (37,43,44).

Patient comorbidities

These are morbid conditions the patient has that in one way or another, contribute to surgical site infections, e.g., obesity, smoking, diabetic mellitus, hypertension, HIV infections, and many others. As revealed in several studies, it has been clearly stated that there is a significant association between comorbidities such as obesity, diabetes mellitus, hypertension, smoking, HIV, alcohol intake, and irradiation with surgical site infection (14,33,34,40,45)**.**

Preoperative factors

Time of awaiting surgery

Studies have revealed that longer than 24 hours of awaiting surgery while in the ward is associated with a high risk of developing surgical site infections, the longer the patient stays, the higher the risk of getting used to hospital-related microbes which oftentimes are resistant to the conventional antibiotics ((40,41,45).

High American Society of Anaestheliogist (ASA) score

This is an important tool in assessing patients' fitness for surgery. It assesses the patient's physical status before anaesthesia, mainly on their comorbidities. This system classifies patients based on the severity of their physical conditions, (class I to VI). It is one of the tools

used to assess the perioperative risk of developing surgical site infections. It has been found that there is a proportional increase in risk of infection with ASA Score (41,45)

Studies have shown that the higher the score of >1, the more likely to develop surgical site infection two-fold (15,45). This is because of the possibly poorly controlled factors that are likely to be the cause of the infection emanating from debilitating systemic comorbidities.

Antibiotic prophylaxis

Antibiotic prophylaxis is the process of giving antibiotics to the patient before the commencement of surgery, or before incision, to prevent infection of the surgical wound (46). When antibiotics are given timely, adequately, and for a reasonable duration, it can potentially halt infections in a risk patient, such as a patient with a clean-contaminated wound, or if the bad consequences of the infection to the surgery are anticipated. Studies revealed that there is an increased incidence of surgical site infection if the antibiotics were to be administered longer than one hour or right after the incision was made or not given at all (31,47).

For the antibiotics to provide clinical benefit, it's recommended that an understanding of which surgery calls for prophylactic antibiotics, the type of antibiotic to be administered, when to administer, and when to discontinue is of paramount importance.

The Surgical Care Improvement Project (SCIP) gave the top three recommendations for antibiotic administration (48). Antibiotics should be administered within the first hour before surgical incision, or two hours before incision if the patient receives vancomycin or fluoroquinolone. Furthermore, redosing is recommended in procedures that last more than four hours, or procedures that take two half-lives from the first dose of prophylaxis, or if blood loss is >1500mls (49).The antibiotic administered should be appropriate to the procedure, i.e., site-specific, microorganism tropism also based on the local antibiogram.

A multivariate study on head and neck squamous cell carcinoma, the study revealed a high incidence of surgical site infections i.e., 45% despite the antibiotic prophylaxis, with the main risk factor being, the presence of longstanding post laryngectomy tracheostomy (49).

Intraoperative related factors.

Wound class

Surgical wound stratification was introduced earlier on by the National Academy of Science back 1964. It was used to assess the preoperative risk of developing an infection after surgery, decide the preoperative management like considering antimicrobial prophylaxis (e.g in a clean-contaminated wound) or treatment (in a dirty or infected wound), and surgical plan (50).

Wound class is important in determining the cleanliness of the surgery. Studies have related that to surgical site infections, and it is been found that the higher the class of surgical wound the more the risk of developing surgical site infections. Surgical site infections can happen in 3.03% and 22.41% of clean and dirty wounds respectively. In otorhinolaryngology, wound class has been not reported consistently notwithstanding its important risk of infection causation (51).

Studies have revealed that, in a surgery that involves the manipulation of mucosal surfaces, e.g., while constructing local regional flaps, such as those in the aerodigestive tract, the surgical site infection rate has been shown to spike up, with the reason being the contamination from the saliva laden with regional flora (52). So many studies have realized the potential risk of developing surgical site infection with an increase in the wound class. This has been found across all surgical disciplines (15,45**,**50).

Duration of surgery

Studies have shown that surgeries that take more than 1 hour of operation have a potential risk of surgical site infection (12,15,45). A systematic review and meta-analysis in Ethiopia showed a two-fold increase in surgical site infection in those operative studies that took > 1 hour of operation(15). A study in Brazil showed that every 1-hour increase in duration had an increased risk of developing surgical site infections by 34% (45). The reasons for that are increased exposure to environmental contaminants, tissue desiccation, and a decrease in the concentration of the prophylactic antibiotics in the body (53). Furthermore, surgeries that

require more than one intervention, such as neck dissection or tracheostomy were highly at risk of developing surgical site infection (38).

Type of surgery (Emergence vs. elective)

A study by Akoko et al showed that emergency surgeries are associated with a high rate of surgical site infection as compared to elective surgeries (54). However, that has been denied by the study of Tan et al., in which elective surgeries were found to have a relatively higher rate of surgical site infections (55) , and the study by Mawala et al, revealed no significance between the two (12).

Use of postoperative drainage

Studies have revealed the use of drainage with the thought of reducing hematoma formation or seroma formation in some countries or facilities' guidelines. But this is not the case all the time as revealed by some studies, whereby hematoma and seroma were still found in 30% despite the presence of drain among patients who developed SSI, i.e., 16.2% of those patients who underwent superficial parotidectomy. The more the drainage has been linked with the more likelihood of SSI development (56).

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1 Study Area

The study was carried out in the otorhinolaryngology (ORL) department of Muhimbili National Hospital (MNH) in Dar es Salaam City, at Upanga in the Ilala district, after being approved by the authority. Muhimbili National Hospital has a total bed capacity of 1500, 25 departments, and 32 specialty clinics, with otolaryngology (ORL) being one of the departments having specialized clinics. Muhimbili National Hospital receives referrals from all regional and zonal hospitals in Tanzania.

The ORL department has a total of 72 beds divided into male, female, and pediatric surgical wards. The ORL department performs major surgeries five days a week (Monday, Tuesday, Wednesday, Thursday, and Friday), with an average of 12 patients operated on per week, and minor surgeries are performed virtually every day of the week at the clinic, excluding Saturday and Sunday.

3.2 Study population

All patients who had undergone open operations during the research period (September 2023 to February 2024).

3.3 Study design

This was a hospital-based prospective cohort study.

3.4 Study Duration

Six months, from September 2023 to February 2024.

3.5 Inclusion and Exclusion Criteria.

3.5.1 Inclusion criteria

All patients who had undergone open surgery at MNH's ORL Department and signed a written consent form.

3.5.2 Exclusion criteria

- Patients who had undergone open surgery with implant insertion.
- A bedridden, comatose patient with limited information such as Body weight and height in the file.
- Mentally handicapped patients

3.6 Case definition of SSI

This was adapted from the Centers for Disease Control and Prevention (CDC) and the National Healthcare Safety Network (NHSN) criteria (57).

The patient has at least one of the following

1. Purulent drainage from the incision site, or from a drain that is placed deep into the organ/space

2. The wound is deliberately opened by the surgeon because of the suspected infection, or spontaneous wound dehiscence.

AND

The patient has at least one of the following

a. Fever

b. Pain/tenderness

c. localized swelling

d. Red

e. Warm

3.7 Sampling technique

It was non-probability convenience sampling.

3.8 Sample size estimation

Yamane's (1967) formula for maintaining a 95% confidence interval(58) was used to estimate sample size: $n = \frac{N}{1+Ne^2}$

Given that,

N is the average number of open surgeries, which was 100 patients from a pilot study done in the ORL department at MNH, and "e", marginal error, approximated to be 5%.

Hence n $= \frac{100}{1+100*0.05^2} = 80$

Hence sample size (n) estimate was 80 patients. Considering the non-responders and loss to follow-up, approximately 10% was added to the sample size to compensate, then the sample size will be equal to 80/0.9 =89.

3.9 Data collection

The study enrolled 89 patients who had undergone open surgeries, and each was followed up for 30 days to identify clinical characteristics of the wound according to CDC standards. Data collection process was divided into three phases, beginning the day before the operation to obtain pre-operative information such as patient's demographics, BMIs (calculated by weight in Kg over height in m^2, after measurement of weight and height) for nutritional status in patients older than 5year and thus classified as normal, underweight, overweight, and obese, comorbidities, patients' lifestyle related predictors such as alcohol and cigarette smoking, ASA score, and time spent in the ward before surgery. On the day of surgery, intra-operative data such as surgery length, wound class, antibiotics redosing, antibiotic prophylaxis, procedure category, and drainage usage data were obtained through direct observation and patients' post-op records. After surgery, patients were evaluated three times, i.e. 48 hours after surgery, on the day of the dressing change, whereby post-operative wound characteristics such as discharge, wound pain, tenderness, and fever were recorded. The same was done during the next appointment, Day 7, the day of stitch removal, and finally, on the 30th day, the patient was interviewed by phone, and the patients with symptoms were asked to come again for further evaluation such as taking a swab for culture.

3.9.1 Specimen collection and laboratory procedures.

Specimens were obtained using sterile cotton after clinical evidence of SSI according to CDC standards, maintained at room temperature in Amies transport media, and taken immediately to the laboratory for identification of microorganisms by culture, Gram stain, and

biochemical methods. The sample was inoculated on the MacConkey number 3 which is for Gram-negative bacteria exclusively and non-selective blood agar, then incubated at 37°C under aerobic conditions, analysis of colony morphology characteristics such as shape, color, edge, elevation, margin and texture were observed after 24 hours, followed by Gram stain procedure. Finally, biochemical tests were subsequently done, whereby Gram-positive bacteria were subjected to a catalase test to differentiate staphylococci from streptococci species, all the catalase-positive organisms, which are the staphylococci then underwent a coagulase test to differentiate staphylococcus aureus from coagulase-negative staphylococcus. Analytical profile indexing was done for Gram-negative organisms such as Enterobacteriaceae using biochemical tests such as API 20E and oxidase tests for identifying individual Gram-negative bacteria responsible for SSI pathogenesis.

3.10 Research tools

A well-structured data collection tool made up of a mixture of questions and a checklist was used to collect data from the patient directly or patients' case notes on the day before surgery, the day of surgery, the day of wound dressing change, the day of stitch removal, and the 30th day following the interview by phone call.

3.11 Study variables

3.11.1 Independent Variables

Social demographic factors such as age, sex, BMI, comorbidities, and lifestyle-related predictors (Diabetes, HIV/AIDS status, hypertension, radiation exposure, smoking, and alcohol consumption), Antibiotics prophylaxis, preoperative hospital stay, duration of surgery, type of operation i.e. emergence/elective, wound class, antibiotic redosing, use of drain, and American Association of Anesthesiologists (ASA score).

3.11.2 Dependent Variables

The dependent variable was surgical site infection.

3.12 Data management and analysis

Data were entered into an Excel spreadsheet and cleaned to ensure quality and consistency. The data was then entered into STATA version 15.1 and descriptive statistics were reported as the median and interquartile range (IQR) for continuous variables and proportions for categorical variables. Chi-square/Fisher's exact test was used to test the statistical significance difference observed in SSI occurrence from among different independent categorical variables. Factors with $p<0.2$ were subsequently analyzed using bivariable and multivariable robust Poisson regression. Bivariable robust Poisson regression analysis was used to identify factors associated with SSI in open surgery patients based on the crude risk ratio (cRR) with a 95% confidence interval (CI), while multivariable Robust Poisson regression analysis was used to investigate the associations between SSI and independent variables after adjusting for other variables. Associations in the multivariable robust Poisson regression analysis models were provided as adjusted risk ratios (aRR) with 95% confidence intervals. A two-sided p-value of <0.05 was judged significant. The graph was created with STATA version 12.0.

3.13 Ethical issues

The MUHAS institutional review board (IRB) provided ethical clearance for my study and the MNH research and publication department provided approval to proceed with data collection. The study only included participants who had signed a written consent form. The study participants who were diagnosed with SSI received immediate therapy. Study participants who felt uncomfortable during the study were offered the freedom to drop out. The participants benefited from the culture results because they were given an antibiotic regimen specific to the isolated bacterial species. No invasive procedure was done for the study participants. Confidentiality was ensured by coding the questionnaire; no names appeared in any of the data collection tools.

3.14 Results dissemination plan

The results of the study were presented and discussed within the ORL department of MUHAS before being submitted to our DPGS. The report was submitted as a dissertation to MUHAS to meet the requirements for the master of medicine in otorhinolaryngology. We will then prepare a manuscript to be published in a peer-reviewed national or international journal.

CHAPTER FOUR

4.0 RESULTS

4.1 Study participants and their demographic characteristics

This study was conducted for a period of 6 months from September 2023 to February 2024. The study enrolled 89 participants who had undergone open Surgeries, representing a 100% response rate. Their ages ranged from 13 to 78 years of age and the median age was 44.5 years (IQR 36-59). Among all the study participants, those who were in the age group (36-53) were the majority 31 (34.8%). Overall, the female respondents 47 (52.8%) were the majority in this study in the female: male 1.12:1 (Table 4).

Table 4: Social-demographic characteristics by age and sex of the study participants who underwent open surgeries in the ORL department at MNH.

Age group in Years ***Median*****= 44.5, IQR [36-59]**	**SEX**		**TOTAL n (%)**
	Female n (%)	**Male n (%)**	
≤17	4 (57.1)	3 (42.9)	**7 (7.86)**
18-35	18 (62.1)	11 (37.9)	**29 (32.6)**
36-53	15 (48.4)	16 (51.6)	**31 (34.8)**
54-71	8 (42.1)	11 (57.9)	**19 (21.3)**
>71	2 (66.7)	1 (33.3)	**3 (3.4)**
TOTAL n (%)	**47 (52.8)**	**42 (47.2)**	**89 (100)**

Note IQR=interquartile range

4.2 Clinical characteristics of the study participants.

The study found that 38 (42.7%) of all study participants had an abnormal BMI, with overweight, obese, and undernourished being 26 (29.2%), 10 (11.2%), and 2 (2.3%), respectively. Smoking and alcohol drinking habits were observed in 12 (13.5%) and 18 (20.2%), respectively. In this study, 15 (16.9%) of the study participants had at least one comorbid with HIV/AIDS, diabetes, and hypertension observed in 7 (7.9%), 3 (3.4%), and 5 (5.6%), respectively. Surgery waiting times > 1 day were observed in 17 (19.1%) of them. The majority of the study participants had ASA scores of I and II of 59 (67.1%) and 17 (19.3%), respectively, and only 3 (3.4%) had ASA scores of IV. Head and neck Surgeries were the most performed at 57 (64%), and the least performed were rhinological open surgeries at 10 (11.3%). Among all the open surgeries, 44 (49%) of them took >1 hour. Of all the open surgeries performed, 75 (84.3%) of them were elective. Clean-contaminated surgeries were the majority of 64 (71.9%), and only 1 (1.1%) of the participants had dirty wounds before surgery. Among the study participants, 67 (75.3%) received antibiotic prophylaxis. Only 1 (20%) Out of 5 patients with criteria, received antibiotic redosing intra-operative. Drainage was used in 30.3% of all the performed open surgeries (Table 5).

Table 5: Clinical characteristics of study participants who underwent open surgeries in the ORL department at MNH.

VARIABLE	FREQUENCE(n)	%
BMI in Kg/m^2		
Underweight	2	2.3
Normal	51	57.3
Overweight	26	29.2
Obese	10	11.2
Active cigarette smoking		
No	77	86.5
Yes	12	13.5
Alcohol drinking		
No	71	79.8
Yes	18	20.2
HIV		
No	82	92.1
Yes	7	7.9

DM		
No	86	96.6
Yes	3	3.4
Hypertension		
No	84	94.4
Yes	5	5.6
Pre op (days)		
≤1	72	80.9
>1	17	19.1
ASA score		
I	59	67.1
II	17	19.3
III	9	10.2
IV	3	3.4
The performed surgeries by site		
Head and neck	57	64.0
Otology	22	24.7
Rhinology	10	11.3
Procedure duration (hours)		
≤1	45	50.6
>1	44	49.4
Procedure category		
Elective	75	84.3
Emergency	14	15.7
Wound class		
Clean	15	16.9
Clean-contaminated	64	71.9
Contaminated	9	10.1
Dirty	1	1.1
Antibiotic prophylaxis		
No	22	24.7
Yes	67	75.3
Antibiotic redosing		
No	4	80
Yes	1	20
Drainage use		
No	62	69.7
Yes	27	30.3
TOTAL	**89**	**100**

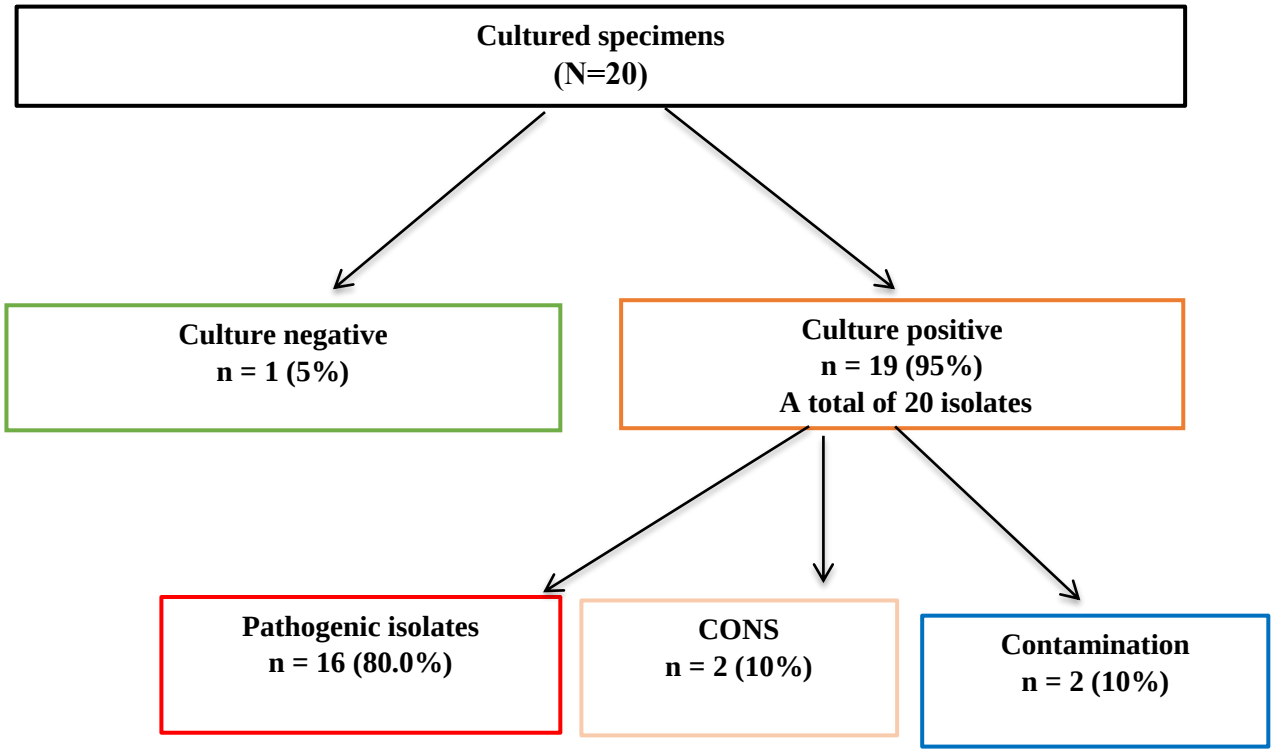
4.3 Incidence of surgical site infections.

From this study, the overall incidence of surgical site infections (SSI) among patients who had undergone open surgeries was found to be 22.5% (Table 6). The incidence of SSI was highest among open surgeries done in rhinology 6 (60%), and the smallest incidence was observed among open surgeries done in otology 1 (4.6%), and that difference was statistically significant (Table 6).

Table 6: Incidence of Surgical site infection by site of operation among patients who had undergone open surgeries in the ORL department at MNH.

Site of operation	Surgical Site Infection		Total n (%)	*P*-value
	Yes n (%)	No n (%)		
Head and neck	13 (22.8)	44 (77.2)	**57 (65.0)**	**0.002**
Otological	1 (4.6)	21 (95.4)	**22 (24.7)**	
Rhinological	6 (60.0)	4 (40.0)	**10 (11.3)**	
Total n (%)	**20 (22.5)**	**69 (77.5)**	**89 (100)**	

4.4 Microbiological Agents



Key: CONS, coagulase-negative staphylococcus aureus

Figure 2: Culture results of specimens collected from patients who had developed surgical site infections in the ORL department at MNH.

A total of 20 specimens from clinically diagnosed SSI were collected for microbiological study. About 19(95%) specimens showed culture-positive results which made a total of 20 isolates, one specimen had two bacterial species in it. Out of the 20 isolates, 16 (80%) were pathogenic organisms, 2 (10%) were coagulase-negative staphylococcus aureus and 2(10%) contaminations.

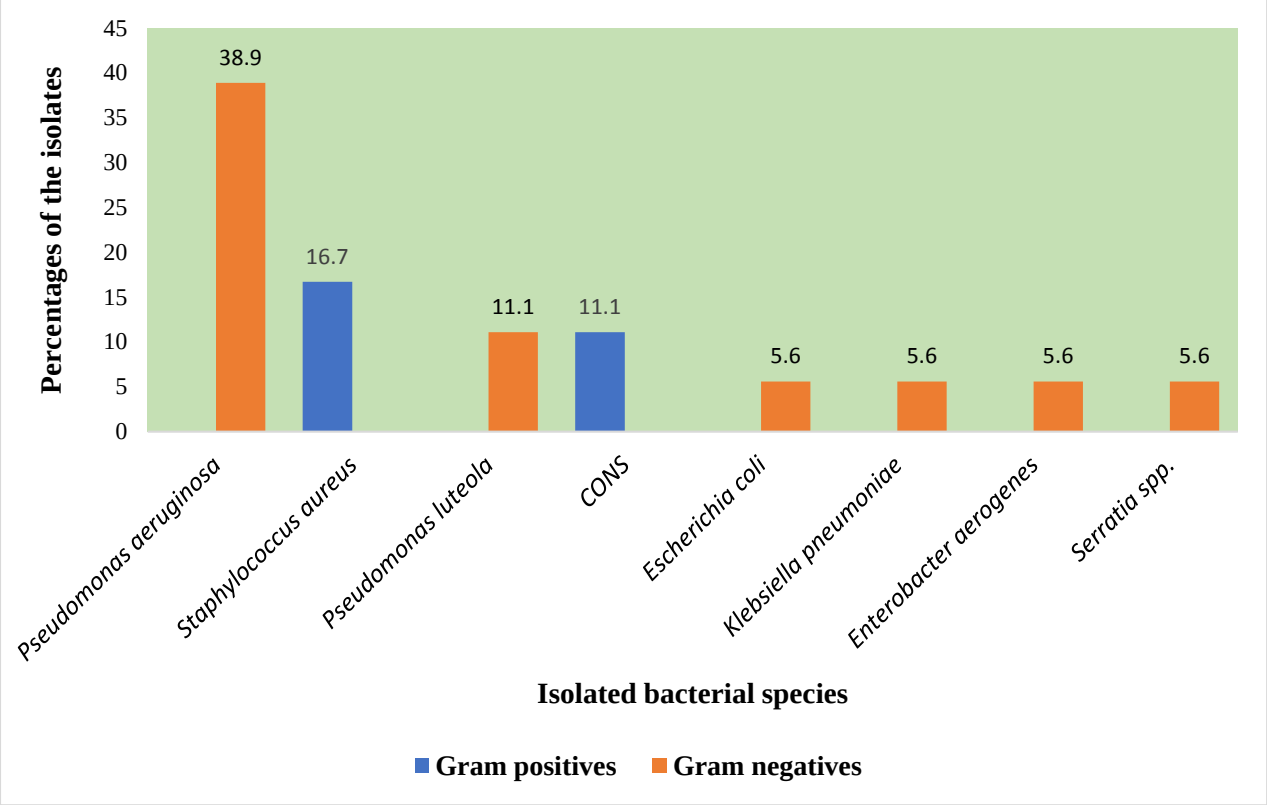


Figure 3: Proportions of isolated bacterial species in all patients who developed surgical site infections in the ORL Department at MNH.

Among all the bacterial species isolated, gram-negative bacteria were the commonest accounting for 72.2%. Of all the bacterial species, *Pseudomonas aeruginosa* was the most isolated bacterial species (38.9%), followed by *Staphylococcus aureus* (16.7%).

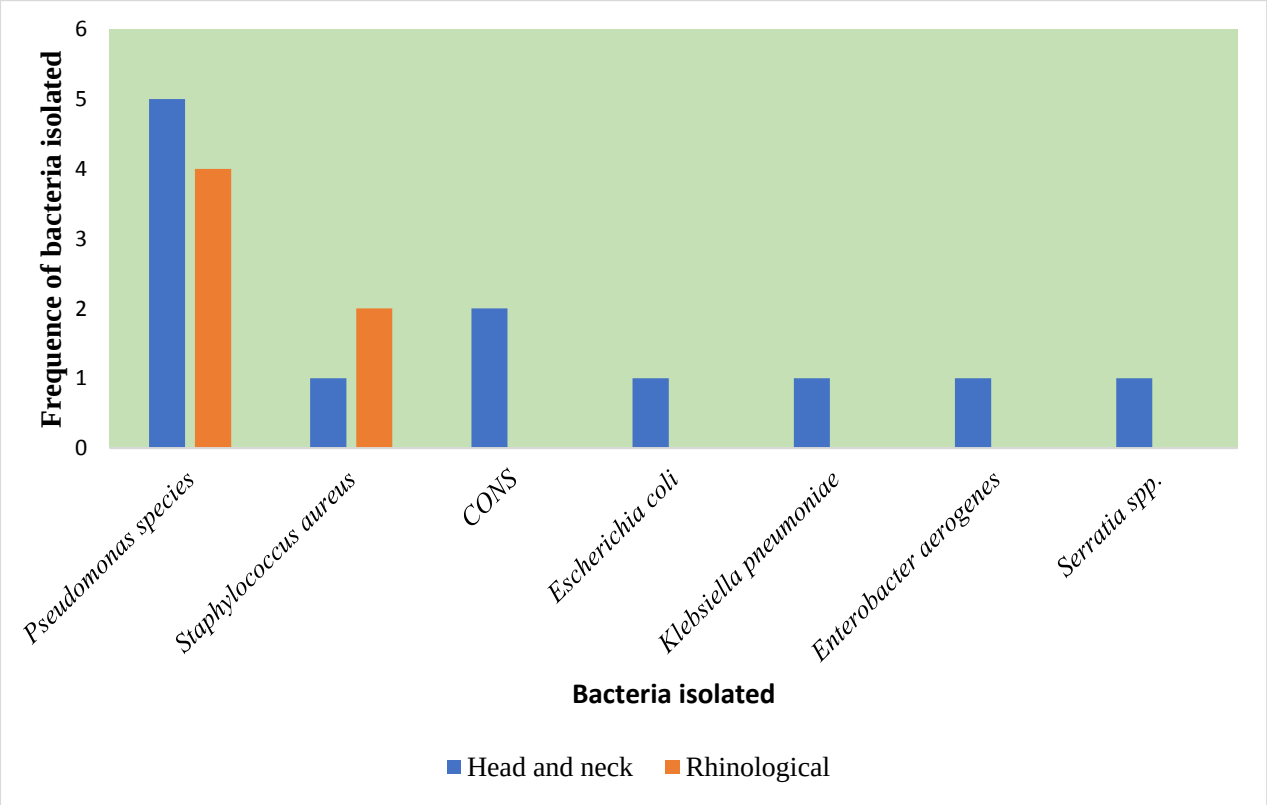


Figure 4: Frequency of bacterial species isolated as per site of surgery.

The figure above shows that *Pseudomonas aeruginosa* species were most frequently isolated among those with SSI who had undergone open head and neck surgeries 5 (55.5%), whereas *Staphylococcus aureus* species were most frequently isolated among those with SSI who had undergone open rhinological surgeries 2 (66.7%). In one case with surgical site infections from otology, culture results revealed no microbiological agent growth.

4.5 Predictors of surgical site infections

4.5.1 Incidence of surgical infections by social-demographic characteristics and clinical characteristics

Among all the study participants who had SSI, those with HIV/AIDS comorbidity had a higher proportion of SSI cases of about 57.1% compared to 19.5% who were HIV/AIDS negative, and that difference was statistically significant ($p = 0.022$). Among all the SSI cases, those who had alcohol drinking habits had higher proportions of 55.6% compared to 14.1% who never drunk, and that difference observed was statistically significant ($p<0.0001$). Of all the SSI cases, a higher proportion was observed in those patients who stayed in the hospital > 1 day before their surgeries at 52.9% compared to 15.3% whose surgeries were done in $\leq$ 1 day and the difference was statistically significant ($p =0.001$). Among all the SSI cases, the highest proportion was observed in those who had ASA III and IV about 66.7% each, compared to 10.2% who had ASA I class, and that difference was statistically significant. Of all the observed SSI cases, a higher proportion was observed in those who didn't receive antibiotic prophylaxis 45.5% compared to 14.9% who received prophylaxis within 30 to 60 minutes before incision, and that difference was statistically significant ($p = 0.003$). Social demographic (such as age, sex), comorbidities such as DM, hypertension, BMI, smoking habit, duration of surgery > 1hr, procedure category, wound class, antibiotic redosing, and drainage usage predictors were not found to be associated with SSI in this study ($p > 0.05$) (Table 8).

Table 7. Incidence of Surgical site infection by social-demographic and clinical characteristics among patients who underwent open surgeries in the ORL department at MNH.

	SURGICAL SITE INFECTION			
Social-demographic predictors	**Yes, n (%)**	**No, n (%)**	**TOTAL, N**	***p*-value**
Age group in Years				
Median= 44.5, IQR [36-59]				0.447
≤17	1 (14.3)	6 (85.7)	7	
18-35	6 (20.7)	23 (79.3)	29	
36-53	7 (22.6)	24 (77.4)	31	
54-71	4 (21.0)	15 (79.0)	19	
>71	2 (66.7)	1 (33.3)	3	
Sex				0.193
Female	8 (17.0)	39 (83.0)	47	
Male	12 (28.6)	30 (71.4)	42	
Comorbid and lifestyle predictors				
BMI				0.778
Underweight	0 (0)	2 (100)	2	
Normal	12 (23.5)	39 (76.5)	51	
Overweight	5 (19.2)	21 (80.8)	26	
Obese	3 (30.0)	7 (70.0)	10	
Cigarette smoking				0.087
No	15 (19.5)	62 (80.5)	77	
Yes	5 (41.7)	7 (58.3)	12	
Alcohol drinking				**<0.0001**
No	10 (14.1)	61 (85.9)	71	
Yes	10 (55.6)	8 (44.4)	18	
HIV				**0.022**
No	16 (19.5)	66 (80.5)	82	
Yes	4 (57.1)	3 (42.9)	7	
DM				0.062
No	18 (20.9)	68 (79.1)	86	
Yes	2 (66.7)	1 (33.3)	3	
Hypertension				0.334
No	18 (21.4)	66 (78.6)	84	
Yes	2 (40.0)	3 (60.0)	5	
Peri-operative predictors				
Pre-OP hospital stay(days)				**0.001**

≤1	11 (15.3)	61 (84.7)	72	
>1	9 (52.9)	8 (47.1)	17	
ASA score				**<0.0001**
I	6 (10.2)	53 (89.8)	59	
II	6 (35.3)	11 (64.7)	17	
III	6 (66.7)	3 (33.3)	9	
IV	2 (66.7)	1 (33.3)	3	
Procedure duration (hours)				0.283
≤1	8 (17.8)	37 (82.2)	45	
>1	12 (27.3)	32 (72.7)	44	
Procedure category				0.551
Elective	16 (21.3)	59 (78.7)	75	
Emergency	4 (28.6)	10 (71.4)	14	
Wound class				0.350
Clean	1 (6.7)	14 (93.3)	15	
Clean-contaminated	16 (25.0)	48 (75.0)	64	
Contaminated	3 (33.3)	6 (66.7)	9	
Dirty	0 (0)	1 (100)	1	
Antibiotic prophylaxis				**0.003**
No	10 (45.5)	12 (54.5)	22	
Yes	10 (14.9)	57 (85.1)	67	
Antibiotic redosing				0.400
No	3 (75.0)	1 (25.0)	4	
Yes	0 (0)	1 (100)	1	
Drainage use				0.970
No	14 (22.6)	48 (77.4)	62	
Yes	6 (22.2)	21 (77.8)	27	
TOTAL	**20 (22.5)**	**69 (77.5)**	**89**	

Note BMI=Body Mass Index, ASA=American Association of Anaesthesiologists.

After bivariable robust Poisson regression analysis, SSI was found to be significantly associated with alcohol drinking habits (cRR 7.33, 95%CI 3.41-15.72, P<0.0001), having HIV/AIDS (cRR 5.02, 95%CI 2.84-8.86, P<0.001), having > 1-day pre-op hospital stay (cRR 3.47, 95%CI 1.71-7.04, P=0.01), higher ASA score such as ASA III and IV (cRR 3.47, 95% CI 1.28-9.44, P=0.015), having diabetes mellitus (cRR 3.19 95%CI 1.29-7.87, P=0.012) and those who didn't receive antibiotics prophylaxis (cRR 12.18, 95%CI 4.53-32.77, P<0.0001).

Multivariable robust Poisson regression analysis revealed factors such as alcohol drinking habits (aRR 1.71, 95%CI 1.01-2.94, P=0.048), having HIV AIDS comorbidity (aRR 1.87, 95%CI 1.16-3.00, P=0.01), and those who didn't receive antibiotic prophylaxis (aRR 9.92, 95%CI 2.16-45.51, P=0.003) were the only independent predictors found to be significantly associated with development of surgical site infections (SSI) in this study (Table 9).

Table 8: Bivariable and multivariable of the socio-demographic and clinical factors associated with surgical site infection among patients who had undergone open surgeries in the ORL department at MNH

		Bivariable analysis		Multivariable analysis	
VARIABLE	**Yes, n (%)**	**cRR (95%CI)**	***p*-value**	**aRR (95%CI)**	***p*-value**
Sex					
Female	8 (17.0)	Ref		Ref	
Male	12 (28.6)	1.68 (0.76)	0.202	0.58 (0.26-1.29)	0.183
Active Cigarette smoker					
No	15 (19.5)	Ref		Ref	
Yes	5 (41.7)	2.14 (0.95-4.82)	0.067	1.24 (0.57-2.71)	0.588
Alcohol drinking					
No	10 (14.1)	Ref		Ref	
Yes	10 (55.6)	7.33 (3.41-15.72)	**<0.0001**	1.71 (1.01-2.94)	**0.048**
HIV					
No	16 (19.5)	Ref		Ref	
Yes	4 (57.1)	5.02 (2.84-8.86)	**<0.0001**	1.87 (1.16-3.00)	**0.010**
DM					
No	18 (20.9)	Ref		Ref	
Yes	2 (66.7)	3.19 (1.29-7.87)	**0.012**	0.86 (0.31-2.39)	0.774
Pre-OP (days)					
≤1	11 (15.3)	Ref		Ref	
>1	9 (52.9)	3.47 (1.71-7.04)	**0.001**	1.36 (0.65-2.88)	0.414
ASA score					
I	6 (10.2)	Ref		Ref	
II	6 (35.3)	3.47 (1.28-9.44)	**0.015**	1.19 (0.56-2.49)	0.623
III	6 (66.7)	6.15 (2.41-15.65)	**<0.0001**	1.63 (0.62-4.24)	0.320
IV	2 (66.7)	6.56 (2.16-19.87)	**0.001**	0.81 (0.35-1.87)	0.627
Antibiotic prophylaxis					
No	10 (45.5)	12.18 (4.53-32.77)	**<0.0001**	9.92 (2.16-45.51)	**0.003**
Yes	10 (14.9)	Ref		Ref	

Note: **cRR** and **aRR** stand for crude risk ratio and adjusted risk ratio respectively, Ref, reference.

CHAPTER FIVE

5.0 DISCUSSION

5.1 Discussion

Among the postoperative complications, SSI is still a major problem in its entirety more so in developing countries, leading to prolonged hospital stays, unnecessary healthcare-associated costs, readmission, reoperation, and death (3-4).

Our study found SSI incidence of up to 22.5%, consistent with the study done by Kibwana et al at MNH in Tanzania, and that of Laloto et al in Ethiopia, whose findings revealed 22% and 19.1% magnitude of SSI respectively (12,59). The comparable findings can be best explained by the shared predictors, such as the same environmental setting, inadequate infection control policy enforcement, and limited resources supply for infection control strategies. The finding revealed a Slightly higher incidence compared to those found in the recent study done in Uganda, which showed incidence of SSI to be 16.4% (8). This can best be explained by sample size differences (110 of the study in Uganda vs 89 study participants of the index study), none use of antibiotics prophylaxis, HIV/AIDS comorbid and alcohol exposure of the index study participants which had no significant influence to the study done in Uganda. The incidence of SSI in this study is strikingly higher than that observed in developed countries such as Latin America, Asia, and China showing incidences of 7%, 4%, and 4% respectively (7). This may be attributed to the well-made preoperative plans, adequate use of antibiotics, adherence to preventive measures, and pertinent infrastructure enough to contain potential pathogens as well as the study setting, the current study was done in the low resource area.

In the study, which was done by Joel Manyahi on the bacteriological spectrum of postoperative wound infections in general surgery, obstetrics and gynecology, and orthopedics at MNH and MOI, the three most common isolated organisms were *Pseudomonas aeruginosa* (16.3%), followed by *Staphylococcus aureus* (12.2%), and *Klebsiella pneumoniae* (10.8%) (17), which is in agreement with the findings of our study, which revealed *Pseudomonas aureginosa* (38.9%), followed by S*taphylococcus aureus*

(16.7%), and coagulase-negative Staphylococcus (11.1%) to be the commonest isolates. This can best be explained by the same environmental setting, which acts as a potential exogenous source of microorganisms in surgical wounds. Similarly, like Staphylococcus, which resides more on the skin, *Pseudomonas aureginosa's* natural habitat is on the skin, throat, and stool for a healthy person. Still, it can also be found in water, soil, and vegetables. The fact that most open surgeries (64%) were of the head and neck, high level of adaptation, high tendency to form biofilms on the wet surface of hospital equipment, and hence resistance to our antibiotic prophylaxis could be the reason why *Pseudomonas aureginosa* was isolated most frequently (60).

Unlike our findings which showed *Pseudomonas aureginosa* the commonest among SSI cases in head and neck surgeries, in the study by Park et al, on risk and etiology of SSI in radical neck dissection surgeries, *Pseudomonas aureginosa* was the least and *staphylococcus aureus* was the most causative agent of SSI in that study (61). This may be attributed to the nature of our study which included all head and neck surgeries, in which some, like tracheostomy, usually enter the throat, where Pseudomonas resides mostly, but, the other study strictly limited to the radical neck dissection with less likelihood of entering the throat. Moreover, our study had one culture-negative result, which was one SSI case from otology unlike previous study on microbiological patterns after mastoid surgeries that revealed *Escherichia coli* followed by *Staphylococcus aureus* as the common isolated bacterial species (21), that culture-negative results can be due to the difficulty of culturing anaerobes in our setting.

In this study, though the p-value was >0.05, most surgical site infections were observed in the age group of > 71 years. This finding is supported by many other previous studies (40,41), and it is theoretically true that elderly patients are at stake of infections due to decreased immunity levels, comorbidities, smoking, and alcohol intake being prevalent in this age group(62).

In the same vein, although the P-value was >0.05, male patients were found to have more incidence of surgical site infection compared to females, which also displays the likeness of the findings of 10 years of surveillance in Germany(44,61). Theoretically, this is true,

because of the impaired cell-mediated immunity in males due to the effects of testosterone (43).

Furthermore, as previous research shows (12,15,45), in those patients who had taken a duration of > 1hr of the procedure, SSI cases were proportionally higher compared to those without. The recommendation from the Surgical Care Improvement Project (19) (SCIP) is that antibiotic redosing must be given in addition to the first prophylaxis provided within 30 to 60 minutes before skin incision, for surgeries that take 1-2 times the half-lives of the first antibiotic prophylaxis given, or 1.5 liters of blood loss or the procedure which lasts > 4 hours. In the index study, five patients met the criteria to receive antibiotic redosing, ironically; only one received the antibiotic intra-op, and among the four who didn't receive it, 3 (75%) developed SSI. This may be because, the longer the surgery lasts, the greater the danger of contamination and blood loss in those patients, resulting in an increased risk of SSI.

After bivariate analysis in the index study, patients with diabetes mellitus had a 3.19-fold increased risk of having SSI, which is consistent with earlier research (15,40). This is in keeping with previous hypotheses that, patients who are diabetic suffer from blood vessel diseases such as microangiopathy, poor immune response, and delayed wound healing, which creates an environment for SSI development (63).

Previous research has shown that a higher risk of SSI increases with ASA score(15,41,45), which is supported by our bivariable analysis, which demonstrated that individuals with ASA IV had a 6.56-fold increased risk of getting SSI compared to those with ASA I. The ASA score is a broad indicator of the body's status; the higher the class, the more likely debilitating systemic illnesses that eventually compromise immunity and hence higher the chance of having SSI.

Following bivariable analysis, individuals who had a pre-operative hospital stay of more than one day had a 3.47 higher risk of having SSI, similar to prior studies (41,45). This is consistent with the assumption that, the longer you stay in the hospital, the more likely you are to harbor potential hospital-acquired pathogens.

Multivariate analysis of this study showed that Patients who had alcohol drinking habits had a 1.71-fold increased risk of developing surgical site infections compared to those who didn't. This finding is consistent with many other previous studies (40,64), this is because, alcohol tends to impair cell migration to fight offending micro-organisms, and also, in the initial stages of wound healing wound, debris is not cleared up owing to the absence of macrophages on the incision site hence harboring the nidus for infections.

Like previous studies (12,56), patients who had HIV/AIDS as an independent predictor were significantly associated with the risk of developing SSI 1.87 times those who had not. This is because patients with HIV/AIDS, usually have impaired cell-mediated immunity to tackle the offending pathogens, impaired immunological process toward wound healing, and malnutrition (14).

Those who didn't receive antibiotic prophylaxis had a 9.92 increased risk of developing SSI compared to those who received prophylaxis 30 to 60 minutes before surgery. This fact is also evidenced by previous study by Cheng et al (65-68). The absence of bacteriostatic or bactericidal activity offered by appropriate prophylactic antibiotics might lead to the proliferation of potential micro-organisms from either endogenous or exogenous sources in the cut surgical wound skin and thus infections of the surgical wound (24,46).

5.2 Study limitations

In comparison to previous research of other surgical disciplines, the sample size in my study was rather small. Missing data in a few critical patients posed a significant barrier to my investigation. Follow-up with a few study participants from upcountry proved ineffective. Our setting cannot culture anaerobic organisms. My study was limited to the already known comorbidities only.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion.

The findings of this study revealed a high incidence (22.5%) of surgical site infections (SSI) in the ORL department primarily caused by *Pseudomonas aureginosa* and *Staphylococcus aureus*. It was mostly predicted by alcohol use, HIV/AIDS comorbidity, and not using antibiotic prophylaxis in patients requiring open surgery. However, all of the factors discovered in this study are within our control and hence the seemingly high incidence of SSI discovered can be reduced by upholding the preventive strategies.

6.2 Recommendations.

Abstinence from alcohol intake 4 to 8 weeks before surgery for surgical patients should be enforced to reduce the incidence of SSI. Antibiotic prophylaxis is strongly recommended in most ORL procedures since they are class II to IV wounds (83.1%) of all surgeries during my investigation. Surgical patients with HIV/AIDS should have CD4 levels of over 350 cells/μL, especially for elective surgeries, tested within 12 months in clinically asymptomatic patients and should be tested routinely in patients with clinical symptoms of AIDS, but for emergency surgeries, this can be a relative indication. Antibiotic redosing among procedures that take > 4 hours or > 2 half-lives of the given first dose of antibiotics, or with blood loss of 1.5L, is strongly recommended.

Many other predictors, such as wound class, ASA scores, pre-op length of hospital stay, smoking, diabetes mellitus, antibiotic redosing, procedure duration, and BMI, failed to independently predict the occurrence of SSI, in contrast to previous literature. Thus, further research with a large sample size and a long study period is strongly recommended.

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8.0 APPENDICES

8.1 APPENDIX 1. DATA COLLECTING TOOL

Serial No……

Date…….

Name of the procedure…….

A. PATIENTS' GENERAL INFORMATION

Social demographic

File No……Phone No ……

Address……Occupation …….

Age……. Gender Male ☐ Female ☐

Height(m)…… Weight (kg)…… BMI (kg/m^2)……(5 years and above) MUAC…… (under five)

B. PREDICTORS (RISK FACTORS)

Comorbidities

1. Current cigarette Smoker: Yes ☐ No ☐
2. Alcohol intake: Yes ☐ No ☐
3. Diabetes: Known. Yes ☐ No ☐
4. HIV status: Known. Yes ☐ No ☐
5. Radiation exposure, Yes ☐ No ☐
6. Hypertension: known. Yes ☐ No ☐
7. Malnourished Yes ☐ No ☐
8. Others ……

Perioperative-related risk factors

1. Patient's days spent in the ward prior surgery ……
2. ASA Score ……
3. SDuration of the procedure …….
4. Category of the procedure: Emergence ☐ Elective☐

5. Wound class: Clean ☐ Clean-contaminated ☐ Contaminated ☐ Dirty ☐

6. Antibiotic prophylaxis was given within 1h: ☐ No ☐
7. Use of drainage: Yes ☐ No ☐

8. Antibiotic redosing is done (if the procedure has taken 4hrs and above or blood loss was more than 1500mls). ☐, ☐ N☐

C. GUIDE FOR SURGICAL SITE INFECTIONS DETECTION, (*TICK WHERE CRITERION IS MET*)

Surgical Site Infection (SSI). Yes ☐ No ☐

(*Tick where it applies based on the criteria below)*

The patient has at least one of the following

1 Purulent drainage from the incision site, or from a drain that is placed deep into the organ/space

2 Wound is deliberately opened by the surgeon because of the suspected infection, or spontaneous wound dehiscence.

AND

The patient has at least one of the following

a Fever

b Pain/tenderness

c localized swelling

d Red

e Warm

NB *The following will not be included as criteria for surgical site infections: 1. Stitch sinus alone 2. Signs of cellulitis such as erythema, warmth, and swelling alone do not meet criteria 3. The fever of 24-48 hours after surgery doesn't necessarily mean an infectious process.*

D. MICROBIOLOGY STUDIES.

Organism identified	Site of surgical wound

NB. *If the surgical wound is characterized by foul-smelling discharge, crepitus on the soft tissue around, infections on the peri-oral such as dental abscess regions, and tissue damage around (gangrene).*

8.2 APPENDIX 2: ENGLISH VERSION CONSENT FORM

CONSENT FORM TO PARTICIPATE IN THE STUDY ON INCIDENCE OF SURGICAL SITE INFECTIONS, MICROBIOLOGICAL AGENTS AND THE PREDICTORS OF INFECTION.

I**NTRODUCTION**

My name is KUSI LEMA, a post graduate master student in the department of ORL at Muhimbili University of health and allied sciences, I am doing research on the surgical site infections, microbiological agents and the predictors of infections among patients who have undergone open surgeries at MNH ORL department. This study is important to knowing the burden and improve the surgical services offered in the department.

PARTICIPATION IS VOLUNTARY

Your participation in the study is very important contribution in achieving the very purpose of the study. Nevertheless, to participate in the study is entirely your choice, and also, you can choose to withdrawal from the study at any time if at all deem inconvenient to you.

STUDY PROCEURE AND CONFIDENTIALITY

You will be asked some questions to answer by the interviewer, only your file Number will be recorded and the information you give will be kept confidential.

SIDE EFFECTS

No harm is expected in this study

BENEFITS OF THE STUDY

Your information is very important in improving surgical services in the department in the future.

COMMUNICATION

If you have any concerns, you may contact me at 0718138409, or if any intolerable mistreatment, contact the supervisor's Phone number Dr Daudi Ntunaguzi, 0686365208, or you may come and complain directly to Muhimbili University of Health and Allied Sciences.

DECLARATION

I……. have read and understood the content of this form, I willfully agree to participate in the study herein.

Signature----------

Investigator/assistant investigator signature……

8.3 APPENDIX 3. SWAHILI VERSION CONSENT FORM.

FORMU YA RIDHAA YA KUSHIRIKI KATIKA UTAFITI UNAOHUSU MAAMBUKIZI YANAYOTOKEA BAADA YA UPASUAJI KATIKA HOSPITALI YA TAIFA YA MUHIMBILI IDARA YA KOO, SIKIO NA PUA.

UTANGULIZI.

Jina langu naitwa KUSI LEMA, Mwanfunzi wa udaktari bingwa wa sikio, pua na koo, katika chou kikuu cha Muhimbili cha afya na sayansi shirikishi, ninafanya utafiti unaohusu maambukizi yanayotokea baad ya mgonjwa kuwa amepasuliwa hasa kidonda kilichotengenezwa kwenye ngozi. Dhumuni kuu, ni kutambua ukubwa wa tatizo na visababishi, ili kuboresha huduma ya upasuaji katika idara.

KUSHIRIKI NI HIARI.

Ushiriki wako ni wa muhimu sana ili kufikia dhumuni kuu la utafiti huu. Hata hivyo, ushiriki ni wa hiari kabisa. Pia, unaweza kuamua kujitoa katika utafiti pale utakapoona umekwama kuendelea au utafiti unakuletea madhara.

JINSI YA KUFANYA UTAFITI

Katika kupata taarifa, utaiulizwa maswali ya kujibu na Mtafiti. Hatutachukua jina lako, ila, namba ya faili, na taarifa utakazotoa zitatunzwa kwa usiri mkubwa.

ATHARI

Hakutakuwa na athari yeyote kushiriki kwenye utafiti huu.

FAIDA

Taarifa utakazotoa ni za muhimu katika kutambua ukubwa wa tatizo, na katika kutengeneza mikakati ya kuboresha huduma ya upasuaji.

MAWASILIANO

Unaweza kuwasiliana na mimi kupitia namba hii, 0718138409, au namba ya msimamizi mkuu wa utafiti huu, kupitia 0686365208.

TAMKO

Nimesoma na kuelewa maelezo yaliyo katika fomu hii, nami nimekubali pasipo shuruti kushiriki katika utafiti huu.

Sahihi ya mshiriki…….

Sahihi ta mtafiti/msaidizi…….

8.4 APPENDIX 4.ETHICAL LETTER

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA.282/298/01.C/1906 Date: 11/09/2023

MUHAS-REC-09-2023-1906
KUSI LEMA
SCHOOL OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: INCIDENCE, MICROBIOLOGICAL AGENTS AND PREDICTORS OF SURGICAL SITE INFECTIONS FOLLOWING OPEN SURGERIES AT MUHIMBILI NATIONAL HOSPITAL, OTORHINOLARYNGOLOGY DEPARTMENT.

Reference is made to the above heading,
I am pleased to inform you that the Chairperson has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 11/09/2023
EXPIRATION DATE OF APPROVAL: 11/09/2024

STUDY DESCRIPTION:
Purpose:
The purpose of this hospital follow-up study is to determine the incidence, predictors, and microbiological agents of surgical site infections among open surgeries done at MNH in the otorhinolaryngology department.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided.
https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014844.pdf and in the MUHAS archives.

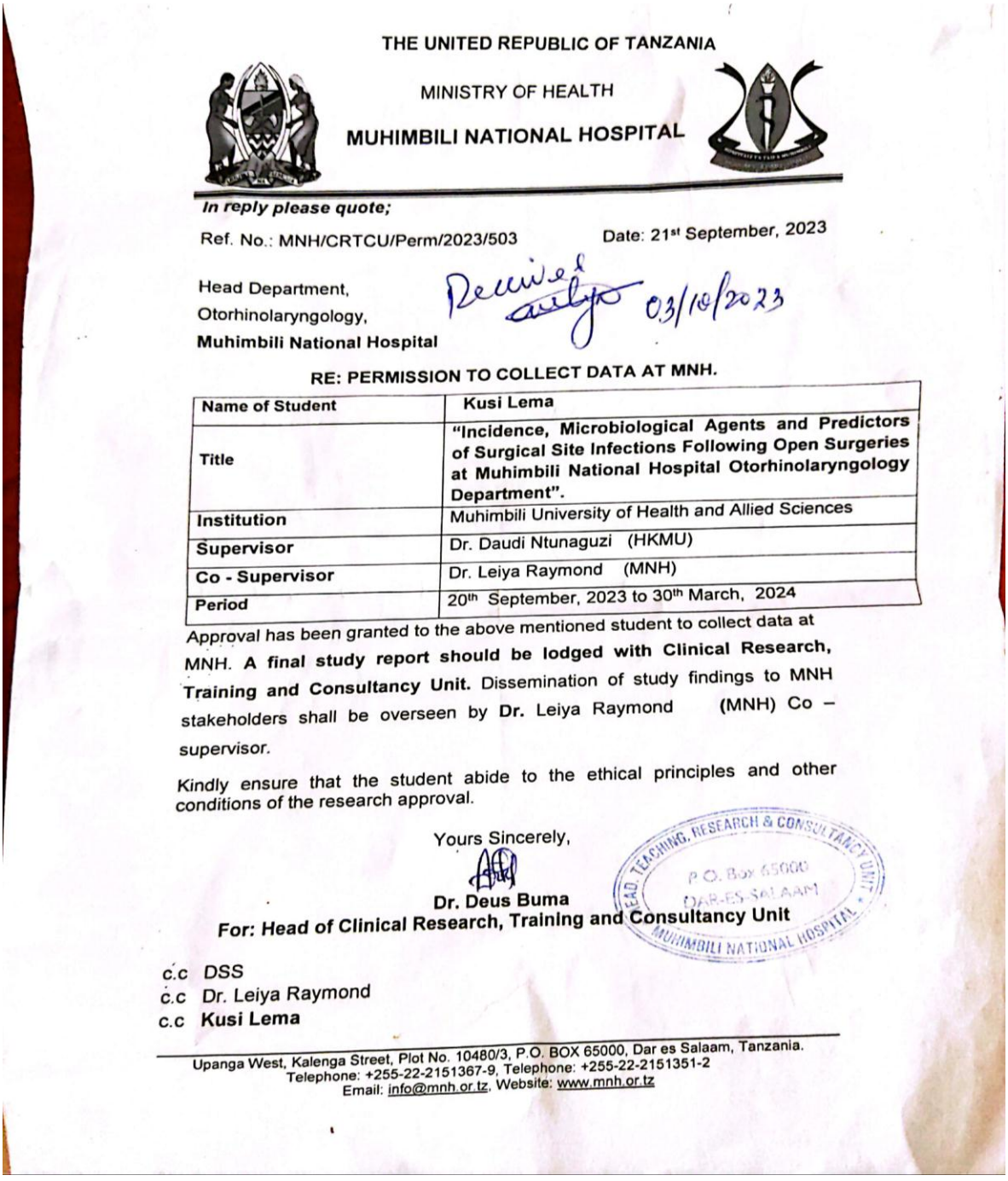
The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country.
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Nahya Salim Masoud,
Chairperson, MUHAS Research and Ethics Committee

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research, Publications & Innovations
Box 65001

8.5 APPENDIX 5. PERMISSION LETTER



THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL

In reply please quote;

Ref. No.: MNH/CRTCU/Perm/2023/503 Date: 21st September, 2023

Head Department,
Otorhinolaryngology,
Muhimbili National Hospital

Received 03/10/2023

RE: PERMISSION TO COLLECT DATA AT MNH.

Name of Student	**Kusi Lema**
Title	**"Incidence, Microbiological Agents and Predictors of Surgical Site Infections Following Open Surgeries at Muhimbili National Hospital Otorhinolaryngology Department".**
Institution	Muhimbili University of Health and Allied Sciences
Supervisor	Dr. Daudi Ntunaguzi (HKMU)
Co - Supervisor	Dr. Leiya Raymond (MNH)
Period	20th September, 2023 to 30th March, 2024

Approval has been granted to the above mentioned student to collect data at MNH. **A final study report should be lodged with Clinical Research, Training and Consultancy Unit.** Dissemination of study findings to MNH stakeholders shall be overseen by **Dr.** Leiya Raymond (MNH) Co – supervisor.

Kindly ensure that the student abide to the ethical principles and other conditions of the research approval.

Yours Sincerely,

Dr. Deus Buma

For: Head of Clinical Research, Training and Consultancy Unit

HEAD TEACHING, RESEARCH & CONSULTANCY UNIT P.O. Box 65000 DAR-ES-SALAAM MUHIMBILI NATIONAL HOSPITAL

c.c DSS
c.c Dr. Leiya Raymond
c.c **Kusi Lema**

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