MICROBIAL COLONIZATION OF SURGICAL INSTRUMENTS AND SURGICAL SITES INTRA-OPERATIVELY IN MAIN THEATRES OF KENYATTA NATIONAL HOSPITAL, KENYA

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Microbial Colonization of Surgical Instruments and Surgical Sites Intra-Operatively in Main Theatres of Kenyatta National Hospital, Kenya

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DECLARATION

This thesis is my original work and has not been presented for a degree in any other University.

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This thesis has been submitted for examination with our approval as the University Supervisors:

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DEDICATION

I dedicate this work to my adorable Twins Amani and Pendo. You inspired me to be up and about for a good course.

I dedicate this work to all the perioperative teams; who’s great work is unseen to many but the results are immense.

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ACRONYMS AND ABBREVIATIONS

ACH	Air Changes per Hour
AFT	Air Filter Treatments
AGN	Acute Glomerulonephritis
AMR	Anti-microbial Resistance
ASA	American Society of Anesthesiologists
APA	American Psychological Association
BMI	Body Mass Index
BPS	Board of Postgraduate Studies
BSc.	Bachelor of Science
CDC	Centre for Disease Control
CLSI	Clinical and Laboratory Standards Institute
CONS	Coagulase-Negative Staphylococci
C/S	Caesarian section
HAI	Hospital Associated Infections
HCAI	Health Care Associated Infections
HR	Hazard ratio
IPC	Infection prevention and control
JKUAT	Jomo Kenyatta University of Agriculture and Technology
KII	Key Informant Interview
KNH	Kenyatta National Hospital
KNH/UON ERC	Kenyatta National Hospital/ University of Nairobi Ethics Research Committee

KRPoN	Kenya Registered Perioperative Nurse
MRSA	Methicillin Resistant Staphylococcus Aurius
MSSA	Methicillin Susceptible Staphylococcus Aurius
MSc.	Master of Science
NACOSTI	National Commission for Science, Technology & Innovation
NPT	Negative Pressure Therapy
OMRU	Ottawa Model of Research Use
OR	Operating room
PACU	Post Anaesthesia Care Unit
P-UDAF	Partial Undirectional Air Flow
PPEs	Personal Protective Equipment
SOPs	Standard Operating Procedures
SPSS	Statistical Package for Social Sciences
SSIs	Surgical site Infections
WHO	World Health Organization

DEFINITION OF OPERATIONAL TERMS

Cardiothoracic Surgery	A surgical specialization involving surgical treatment of organs inside the chest cavity and general management and treatment of conditions affecting the heart and lungs.
Colonization	The presence of bacteria on an object or body surface without causing disease in the person
Delphi Method	Is a process used to arrive at group opinion or decision by surveying a panel of experts. Experts respond to several rounds of questionnaires and the responses are aggregated and shared with the group after each round.
Fastidious	Very attentive to and concern about accuracy and details of the identification of microorganisms.
General Surgery	A surgical specialization involving surgical treatment and management of organs in the abdominal cavity. The organs include; esophagus, stomach, small intestine, large intestine, liver, pancreas, gallbladder, bile ducts and appendix. The thyroid gland and mammary glands are also under this specialty.
Guidelines	A general rule, principle, or piece of advice.
Hemostat	This is a surgical instrument or tool used in most surgical procedures to control and arrest bleeding. The hemostat has handles that can be held in place by their locking mechanism while in use.
Intraoperative Phase	The period of time that begins with the patient admitted to the operating room, anesthesia administration, and performance of the surgical procedure, reversal of anesthesia and ends with the patient transported to the post anesthesia care unit (PACU) or the recovery room.

Kaplan- Meier	Is a statistical method approach that gives researchers a way to present survival data.
Microorganism	Organisms that can only be seen through a microscope. Microorganisms include bacteria, protozoa, algae and fungi.
Microbial	Relating to or characteristic of a microorganism especially bacterium causing disease.
Microbial Colony	A visible cluster of microorganisms growing on the surface of or within a solid medium presumably cultured from a single cell.
Morbidity	Refers to having a disease or a symptom of disease. It also refers to medical problems caused by a treatment administered to a patient.
Mortality	Death or the number of deaths in a certain group of people in a certain period of time.
Neurosurgery	A surgical specialization concerned with diagnosis, management and surgical treatment, and rehabilitation of disorders of the nervous system. This includes the brain, spinal cord, peripheral nerves, and cerebrovascular system.
Operating Theatres	Is a facility within the hospital where surgical operations are carried out in an aseptic environment.
Orthopedics Surgery	The branch of surgery concerned with conditions involving the musculoskeletal system
Perioperative	The period time of contemplation of surgery through the operative period to full recovery. It includes surgical unit admission, anesthesia, surgery, and recovery. Perioperative refers to the three phases of surgery; Pre-operative, Intra operative and post-operative.
Perioperative Team	A unit of personnel to include surgeons, Anesthesiologists, perioperative nurses and

	technicians providing the continuum of care beginning with preoperative care and extending through intra operative procedures, and postoperative recovery.
Preoperative Phase	The period of time between the decision to have surgery and the beginning of the surgical procedure.
Primary closure	Closure of the skin level during the original surgery regardless of the presence of drains or other devices.
Postoperative Phase	The time after surgery the patient is transferred to the recovery room or post anesthesia care unit (PACU) to the moment patient is transported back to the surgical unit, discharged from the hospital until the follow-up care.
Resident flora	Refers to microorganisms residing under the superficial surface of the stratum corneum and also found on the surface of the skin.
Social wash	This entails the initial cleaning of the surgical site using soap and water. It is done by non-scrubbed personnel member of the surgical team. It is classified as a clean procedure.
Specialized Surgeries	A group of surgeries requiring or involving detailed and specific knowledge or training.
SSI Attributable Mortality	Deaths that are directly attributable to surgical site infections. The numerators refer to surgical patients whose cause of death was directly attributable to SSI and the denominator usually refers to all surgical patients in a patient population.
Sterilization	The process that eliminates, removes, kills, or deactivates all forms of life and other biological agents like prions present in a specific surface,

	object or fluid, for example food or biological culture media.
Surgery	The branch of medical practice that treats injuries, diseases and deformities by the physical removal, repair or readjustment of organs and tissues often involving cutting and stitching the body.
Surgicals	Relating to or used in surgery. This includes gloves, gauzes, drapes, sutures, gowns, face masks among others.
Surgical Antibiotic prophylaxis	Refers to the prevention of infectious complications by administering an effective antimicrobial prior to exposure to contamination during surgery.
Surgical hand preparation	An antiseptic hand wash or hand scrub performed preoperatively by the surgical team to eliminate transient flora and reduce resident skin flora.
Surgical Instrument	A specially designed tool or device for performing specific actions or carrying out desired effects during a surgery or operation, such as modifying biological tissue, or to provide access for viewing it. Over time, many different kinds of surgical instruments and tools have been invented. Most surgical instruments are made from stainless steel.
Surgical Instrument Trays	A collection of surgical instruments and items which are used during surgery. They are usually designed and set up for a specific procedure.
Surgical prepping	Surgical site preparation, or prepping, is a crucial step in reducing the risk of surgical site infections. It involves cleaning and disinfecting the skin around the incision site to minimize microbial contamination. This process typically includes three steps: shaving (if necessary),

	scrubbing with an antiseptic solution, and applying an antiseptic solution to the surgical area.
Surgical procedure	An operation where at least one incision including a laparoscopic approach is made through the skin or mucus membrane, or reoperation via an incision that was left open during a prior operative procedure and takes place in an operating room.
Surgical Site Infections	An infection that occurs after surgery in the part of the body where surgery took place. Surgical sites can be superficial infections involving the skin only. Other surgical site infections are more complicated and can involve tissues under the skin, organs or implanted materials.
Surgical Teams	A team of people who perform surgery and related tasks. Roles in the team include surgeon, assistant surgeon, scrub nurse, circulating nurse and anesthesiologist.
Surgical Wound	A wound created when an incision is made with a scalpel or other sharp cutting device and then closed in the operating room by sutures, staple adhesive tape or glue and resulting to the close approximation to the skin edges.
Survival Time	Survival time analysis considers a variable that has a start time and when a particular event occurs. When the event occurs it’s the end time.
Team of Experts	Is made up of individuals with high level skills or knowledge in a certain domain acquired over many years of experience.
Time Zero	The starting point of an event.
Transient flora	Microorganisms that colonize the superficial layers of the skin and are more amenable to

	remove by routine hand washing and hand scrubbing.
Urology Surgery	Also known as genito urinary surgery is a branch of medicine that focuses on the treatment of surgical and medical diseases of the urinary system and the reproductive organs.

ABSTRACT

Surgical site infections (SSIs) have the highest frequency of postsurgical complications with a global range of 2.5-41.9% and have a significant impact upon the health or illness process of the patient and satisfaction levels. In addition to potential economic consequences, SSIs can have a negative impact on patient outcomes and may potentially be life-threatening. There are no practice guidelines to inform the perioperative teams on when to change the surgicals and instruments when presumed to be contaminated. This study determined surgical instruments exposure time and microbial colonization in relation to SSIs in the Main Theatres of Kenyatta National Hospital, Kenya and came up with strategies and recommendations that will lead to development of practice guidelines for the perioperative teams. A mixed method quantitative and sequential qualitative was used. In the quantitative arm; analytical cross-sectional design and purposive sampling method was adopted. Check lists and standard laboratory request forms for data collection were used. A sample of 92 patients was used. The qualitative arm Seven experts in the subject area were purposively sampled for the Key Informants Interviews. Data was analyzed using Statistical Package for Social Sciences (SPSS) software. Descriptive and Inferential statistics such as Chi-square and t-test were used to describe the data and show the relationship between variables respectively. Bivariate analysis was used to determine the strength of association between dependent and independent variables. *P* values less than or equal to 0.05 was considered statistically significant. Qualitative data was transcribed verbatim by using the Colaizzi thematic analysis transcription techniques. Field notes were compared with the audio recordings for validity. Data was analyzed and described verbatim. Results showed that more than half of the instruments were colonized by micro-organisms intraoperatively (51.6%; n=48). About twelve percent (11.8%; n=11) patients had microbial colonization on the surgical site pre-surgery. A few instruments were found to be contaminated at time 0. A third of the population got post-surgery microbial colonization on the surgical site (31.2%; n=29). *Staphylococcus aureus* was the most common microorganism in surgical sites and the surgical instruments. There was 50% of microbial colonization of instruments after 4 hours intraoperatively. The longer the surgery the more the exposure of instruments and the higher was the microbial colonization rate. There is need to enhance the processing and sterilization of surgical instruments. By the fourth hour of surgery surgical instruments should be changed and social wash should be done to all surgical sites before the actual surgical prepping. It is recommended that these strategies should be adopted by Kenyatta National Hospital management and Ministry of Health to guide the perioperative teams intraoperatively.

CHAPTER ONE

INTRODUCTION

1.1 Background Information

Surgical site infections (SSIs) are the most frequent postsurgical complication and one with the highest impact upon the health or illness process of the patient and satisfaction levels. In addition to potential economic consequences, SSIs can have a negative impact on patient outcomes and may potentially be life-threatening. The burden and suffering posed by surgical site infections (SSIs) on patients' safety globally in terms of pain, delayed surgical site healing, increased use of antibiotics, revision surgery, increased length of hospital stay, morbidity and mortality rates, which are also reflected in excess health care costs (Rezaei et al., 2025).

Globally, in a systematic review, surgical site infection rates have been reported to range from 2.5% to 41.9%. In the United States, approximately 2% to 5% of the 16 million patients undergoing surgical procedures each year have postoperative surgical site infections. (Brown et al., 2017). Butterworth and Zgonis (2015) found out that an infection rate of between 0.5 % and 6.5 % is accepted as normal in elective surgery among surgeons. In another study they found a much higher total surgical site infection rate (15.3 %) which was much higher than that accepted as normal by these authors.

Surveillance programs focused on healthcare-associated infections (HAI) including SSI are essential tools to prevent their incidence and reduce their adverse effects, thereby allowing for the reduction of patients' risk of infection. As widely shown in the literature from high income countries, including the U.S., the incidence of HAI can be reduced by as much as 30%, and by 55% in the case of SSIs (Umscheid et al., 2021).

According to World Bank's categorization based on 2012 gross national income per capita, 68% of the world countries are low-income and lower middle-income economies also referred to as lower income countries, or developing countries World bank classifications of 2014. Lower income countries comprise more than 75% of the world population. However, far too little attention has been paid to the incidence of

SSIs in limited-resource countries, where standard methodological approaches are urgently needed (Wanyoro et al., 2023).

1.2 Statement of the Problem

Great care is often taken in addressing factors that are perceived as readily modifiable, other factors may be overlooked, be thought to be uncontrollable or be taken for granted as already being ideal. Specifically, the absolute sterility of surgical trays and instruments is often assumed. There are no clear guidelines for how long an operating room tray can be exposed to the open environment before the contamination risk becomes unacceptable (Dalstrome et al., 2020).

Studies have shown that 80 to 90 % of bacterial contaminants found in the wounds after surgery emanate from air contaminated with microbes present in operating theatres. This indicates that as other surgicals are changed and the surgical instruments are not changed there is high chances of surgical wounds contamination since they are all exposed in the same measure (Bali et al., 2020).

A survey conducted in 14 countries by World Health Organization attributed 8.7% prevalence of nosocomial infections mainly acquired from poorly controlled operating theatres environment. This originated from the use of medical devices and procedures. Modern surgical procedures and therapeutic invasive techniques are a source of surgical site infections. The equipment and instruments in most hospitals are limited and this leads to prolonged use and overuse of the equipment posing contamination risks to the surgical patients. (Gniadek et al., 2019).

In a study done in Michigan, United States of America at a high-volume teaching and referral hospital operating rooms, the aspect of foot traffic in and out of the OR intraoperatively was found to be significantly higher than anticipated. Frequent opening of the OR door disrupts air flow systems and thus may limit the effectiveness of measures for prevention of contamination of surgicals and open instrument tray intraoperatively (Lynch et al., 2019).

In a study done in Mwanza, Tanzania it was recommended that overall standard for cleaning the operating theatre environment, decontamination and sterilization of surgical instruments and trays must be raised to effect reduction risk of the surgical site contamination and iatrogenic transmission (Mpogoro et al., 2014).

Various types of surgeries are carried out in the operating rooms of Kenyatta National Hospital ranging from simple surgeries to complex and specialized surgeries. Time taken varies from as short as 15 minutes to hours and the longest time on record is 23 hours 20 minutes of the successful separation of the Siamese twins in November 2016. (KNH annals,2019). The current practice during surgeries is that, the surgical team may change the gowns, linen and gloves as a measure of infection control but the instruments are not changed. Further in the operating theatres there are no guidelines to inform the surgical teams after how long they should change the surgicals and instruments when presumed to be contaminated. Following this observation the researcher developed interest as to why the instruments are not changed despite them having been exposed in the same measure as the other surgicals.

1.3 Justification

Surgical site infection (SSI) is a commonly occurring healthcare associated infection ranging from wound discharge associated with superficial skin infection to life threatening conditions such as severe sepsis (Anderson et al., 2025). Surgical Site Infections have a significant impact on both the patients and the health care system as they can lead to increased morbidity and mortality related to revision surgery, delayed wound healing, increased use of antibiotics and increased length of hospital stay (Harrop et al., 2022).

The World Health Organization indicates that reduction or no Surgical Site Infections is one of the excellent markers for measuring and monitoring the health system performance, the surgical team has an obligation to ensure SSIs are prevented intraoperatively. (WHO, 2019)

In relation to the four agendas of the government of Kenya, health care is one of the main pillars. There is great expansion of the health care facilities across the country especially in the perioperative environment. The perioperative teams need to be informed on the current practices which are evidence based in order to give quality health care to the patients and the entire population. Kenyatta National Hospital was chosen as a study site since it is the largest hospital in the East and Central Africa. It is the pillar hospital in training medical personnel of all professions and levels. It has been used as a benchmarking institution for all the other level six and lower hospitals in establishing centers of operations and services.

The knowledge of the surgical teams on how to prevent contamination of surgical instruments and when to change them once contaminated makes a strong foundation on the prevention of surgical sites infection. This should therefore be well defined and clearly outlined in order to ensure prevention of SSIs.

There are gaps in the perioperative practice in terms of managing microbial colonization of surgical instruments and surgical sites intraoperatively. The results and findings of this study will be used as a platform to give recommendations on developing perioperative guidelines and provide new knowledge which is evidence based. This will improve on infection control measures regarding surgical instruments, prevention of SSIs intra operatively and patient service delivery.

1.4 Research Questions

a) How long does it take for microbial colonization to occur on exposed surgical instruments and surgical sites intraoperatively in main theatres of Kenyatta National Hospital?

b) Which type of microbials colonize the exposed surgical instruments and the surgical site intraoperatively in main theatres of Kenyatta National Hospital?

c) What is the relationship between type of surgery specialization and microbial colonization time in main theatres of Kenyatta National Hospital?

d) What strategies will counter microbial colonization on surgical instruments and surgical sites intraoperatively in main theatres of Kenyatta National Hospital?

1.5 Objectives

1.5.1 Broad Objective

To determine Microbial Colonization of Surgical Instruments and Surgical Sites Intraoperatively in Main Theatres, Kenyatta National Hospital.

1.5.2 Specific Objectives

- **a)** To determine duration of time taken to microbial colonization on surgical instruments and surgical sites intraoperatively in main theatres of Kenyatta National Hospital.
- **b)** To determine and compare the types of microbial colonies isolated on the exposed surgical instruments and the surgical site intraoperatively in main theatres of Kenyatta national Hospital.
- **c)** To determine the relationship between type of surgery specialization and microbial colonization time in main theatres of Kenyatta National Hospital.
- **d)** To explore strategies to counter Microbial Colonization on surgical instruments and surgical sites intraoperatively in main theatres of Kenyatta National Hospital

1.6 Hypothesis

H0: There is no relationship between time of exposure and microbial colonization of exposed surgical instruments intraoperatively.

H1: There is a relationship between time of exposure and microbial colonization of exposed surgical instruments intraoperatively.

H0: The microbial colonies isolated on the exposed surgical instruments and the surgical site are similar.

H1: The microbial colonies isolated on the exposed surgical instruments and the surgical site are not similar.

H0: The median time of microbial colonization for the five surgical specialties is not equal.H1- The median time of microbial colonization for the five surgical specialties is equal.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter covers literature on Surgical Site Infections, the operating room environment do’s and don’ts and timings of exposure and contamination of opened sterile operating room trays. It also covers the laboratory conventional methods isolate and identity of microorganisms. To achieve this, the researcher searched several databases including different university library digital repositories, PubMed, Google Scholar, Hinari, Medscape, Scopus and CrossRef.

This review discusses the prevalence of SSIs, organisms causing SSIs, risk factors, prevention of SSIs and the impact of SSIs. The literature used was obtained from original work on SSIs in different areas of surgeries in different settings around the world.

2.2 Surgical Site Infections

Surgical Site Infection (SSI) is a healthcare-associated infection occurring within 30 days of an operative procedure (or up to 90 days to 1 year for implants) affecting the skin, subcutaneous tissue, deep soft tissues, or organs/spaces manipulated during surgery. SSIs often present with fever, pus, redness, and pain. The classifications of SSIs are as follows;

Superficial Incisional SSI: Involves only skin and subcutaneous tissue of the incision.

Deep Incisional SSI: Involves deep soft tissues, such as fascial and muscle layers.

Organ/Space SSI: Involves any part of the anatomy (organs or spaces) other than the incision that was opened or manipulated.

2.3 Historical Perspectives of Surgical Site Infection Prevention

The modern-day practice of surgical site infection (SSI) prevention is based on key observations from several 19th and early 20th century physicians and scientists. In 1846, Ignaz Semmelweis noted that Austrian women delivering in teaching wards before the adoption of hand hygiene had a significantly higher mortality rate than women undergoing childbirth by midwives. While working in the Vienna General Hospital, Semmelweis first introduced the idea of hand washing with chlorinated water as a means of decreasing puerperal fever. It was not until Louis Pasteur's “germ theory” and the identification of *Staphylococcus species* and *Streptococcus pneumoniae* did Semmelweis' observation and empiric response regarding infection prevention resonate with practitioners.

Joseph Lister, the father of aseptic surgery, experimented with carbolic acid dressings for post-operative amputation patients while William Keen was one of the first surgeons to practice Lister's infection control in the operating room. Keen demanded that the patient's room be scrubbed with carbolic solution the day before the operation, and all those participating in the surgery wash their hands. Sterile gowns, caps, and mask implementation began in 1883. In 1889, when severe contact dermatitis to the carbolic acid solution developed in Caroline Hampton, the scrub nurse for William Stewart Halsted, Dr. Halsted commissioned the Goodyear Rubber Company to make a pair of rubber gloves for her to use during surgery. Shortly thereafter, he mandated that the entire surgical team wear rubber gloves during the operation. In 1891, Ernst von Bergmann proved that heat sterilization of surgical instruments was superior to chemical methods.

In 1928, Alexander Fleming discovered the antimicrobial nature of penicillin, and modern-day antimicrobial prophylaxis was begun. As scientists developed new and ever more powerful antimicrobial agents, the concept of a host microbiota associated with the skin, mucosal surfaces, urogenital, and gastrointestinal tract emerged, and researchers began to appreciate the vast range of in vivo environments in which these organisms flourished. Later in the century, Frank Meleney and William Altemier demonstrated mixed aerobic-anaerobic infections in cases of progressive gangrene of the abdominal wall leading to the acceptance that most surgical infections are polymicrobial. Armed with basic knowledge on pathogenesis, treatment, and prevention, widespread use of antiseptic techniques was adopted by all caretakers of surgical patients.

2.4 Prevalence of SSIs

In the most recent point prevalence survey of inpatients in England, SSI was reported as the third most frequently occurring healthcare-associated infection (HCAI), causing 15.7% of all reported infections. This means almost 2 out of every 10 infections are SSI. In the United States, 2-5% of surgeries are likely to end up with SSI (Anderson et al., 2024). These statistics show that SSIs are a common problem not only in low-income regions where infection prevention and control is a constant problem but also in high income regions.

In terms of types of surgeries done, SSI prevalence rates range as low as 2.9% and as high as 17.9% (Jido & Garba 2022). In an English hospital post discharge surveillance to determine the rate of SSI among patients, Jenks et al (2014) reported that the overall SSI rate was 5.1%. They also noted that multiple intra-abdominal, cardiac, large bowel and cholecystectomy surgeries had the highest rates of 9.9%, 10.8%, 12.8% and 13.0% respectively. Hip replacement, cranial and spinal surgeries recorded the lowest rates of at least 1%. Other SSI rates included caesarean section at 7.6%, bile duct, liver and pancreas at 9.5% and small bowel at 9.3%.

These prevalence rates differ in different settings mostly because of methods used to collect the surveillance data. In most developed countries, surveillance was done at least 28 days post discharge while in developing countries only inpatient surveillance was recorded. In their study on SSI following C/S in Kano, Nigeria, Jido and Garba (2022) reported, the prevalence of SSI following CS as 8.9%, which compared favorably with infection rate in Jenks et al (2014) report based in England. This rate was however higher than the 3.2% as reported in Paris France by Barbot et al (2014). In a study done in Nairobi, Kenya it was recommended that making 3 antenatal visits made before coming for caesarian section was significantly associated with minimal chance of sepsis OR 0.2 [95% CI 0.1-0.8], P value 0.021 (Chelimo et al., 2018). Despite these rates, few hospitals have the resources to perform comprehensive surveillance of surgical procedures regularly and recent studies done in different settings around the world have confirmed that SSIs are significantly underestimated. (Leaper et al., 2015).

Surgical site infections (SSIs) are probably the most preventable of the health care-associated infections. The care bundle approach is an accepted method of packaging best, evidence-based measures into routine care for all patients and, common to many guidelines for the prevention of SSI, includes methods for preoperative removal of hair (where appropriate), rational antibiotic prophylaxis, avoidance of perioperative hypothermia, management of perioperative blood glucose and effective skin preparation. Reasons for poor compliance with care bundles are not clear and have not matched the wide uptake and perceived benefit of the WHO 'Safe Surgery Saves Lives' checklist. (Leaper et al., 2015).

Despite these interventions, SSI rates remain high, indicating a need for further research to optimize intervention bundles and improve compliance across surgical stages. The implementation of SSI prevention bundles, tailored to colorectal surgery, has shown a reduction in SSI rates and costs. Grouping interventions according to the peri-operative phase may increase compliance (Cunha et al., 2025).

In a systematic review study it revealed that there is a need to implement safety measures, particularly in low-and middle-income countries such as the African Region to maintain the health and safety of patients. Furthermore, strengthening the healthcare systems of low-income countries and of the countries in the WHO African region is of paramount importance and can be achieved by educating and providing training to healthcare providers to enhance their skills (Aiken et al., 2012).

The World Health Organization’s general guideline or recommendations on preventing surgical site infection, which address the major issues, including surgical site infection prevention and reducing potential risk factors, SSI surveillance, the importance of a clean environment in the operating room, and the decontamination of medical devices and surgical instruments should be disseminated and implemented (Desacha et al., 2023).

2.5 Organisms Causing SSIs

In a two-year surveillance of 14,300 surgical episodes, Jenks et al 2014 identified 282 SSIs during admission and readmission, 98 (34.8%) were deep or organ space and 184 (65.2%) were superficial infections. On post-discharge follow-up of more than half of the patients included in the study, a further 451 (3.2%) infected wounds were found, of which 48 (10.6%) were deep or organ space and 403 (89.4%) superficial infections. These findings suggest the organism causing SSIs is found on the skin. Coagulase negative staphylococcus, which is found on the human skin, is an important opportunistic pathogen causing HCAIs (Wilderstrom et al., 2022).

In a retrospective cohort study to investigate the epidemiology and microbiological etiology of prosthetic joint infections across 10 hospitals in Australia over a 3-year period, 163 cases of prosthetic joint infection were identified. From a review of the microbiological culture results, it was reported that methicillin-resistant Staphylococcus aureus (MRSA) and coagulase-negative staphylococci were isolated in 45% of infections. In addition, polymicrobial infections, particularly those involving Gram-negative bacilli and enterococcal species, were also common (Peela et al.,2022).

In a systematic review done it was concluded that Staphylococcus Aureus is a commonly isolated organism in SSIs accounting for 15 – 20% of SSIs occurring in hospital. MRSA presents challenges with treatment due to multiple antibiotic resistances (Korol et al., 2023).

2.5.1 Types of Microorganisms

2.5.1.1 Staphylococcus Aureus

Staphylococcus aureus is a Gram-positive spherically shaped bacterium, a member of the Bacillota, and is a usual member of the microbiota of the body (normal flora), frequently found in the upper respiratory tract and on the skin. Staphylococcus aureus, is primarily transmitted through direct skin-to-skin contact. It can also spread through contact with contaminated objects or inhalations of droplets from coughs and sneezes. Staphylococcus infections are generally spread through direct contact with infected individuals or contaminated surfaces.

Inflammatory staphylococcal diseases include the following conditions: Staphylococcal skin infections include impetigo, folliculitis, furuncles, carbuncles, paronychia, surgical wound infection, blepharitis, and postpartum breast infection. S. aureus is the most common cause of boils. The infection is acquired either by self-inoculation from a carrier site, such as the nose or through contact with another person harboring the bacteria. Bacteremia and septicemia may occur from any localized lesion, especially wound infection or as a result of intravenous drug abuse. S. aureus is an important cause of acute bacterial endocarditis, of normal or prosthetic heart valves, which is associated with high mortality. S. aureus is the most common cause of osteomyelitis in children. The bacteria reach bone through blood stream or by direct implantation following trauma. S. aureus causes pneumonia in postoperative patients following viral respiratory infection, leading to empyema; it also leads to chronic sinusitis. S. aureus causes deep-seated abscesses in any organ after bacteremia. Reservoir, source, and transmission of infection. Human cases and carriers are the important reservoir of infection. Human cases of cutaneous and respiratory infections shed large numbers of staphylococci into the environment for a prolonged period of time. Staphylococci colonize the skin very early in life (in neonates on the umbilical stump). Staphylococci shed by the patients and carriers contaminate handkerchiefs, bed linens, blankets, and other inanimate fomites and persist in them for weeks. Staphylococcus aureus found in the nose and sometimes on the skin, especially in hospital staff and patients is the main source of infection in hospitals. Domestic animals, such as cows, can also be reservoirs of staphylococcal infection. Methicillin-resistant staphylococci Methicillin-resistant S. aureus (MRSA) denotes resistance of S. aureus to penicillin, as well as to all other beta-lactam antibiotics including the third-generation cephalosporins and carbapenems. Resistance to methicillin is due to the production of a novel PBP, designated as PBP 2a. PBPs are the targets of beta-lactam antibiotics. Infections caused by MRSA are being increasingly reported worldwide since 1980. The infection is also being increasingly reported now, from different hospitals. MRSA usually colonizes the broken skin and can cause a wide range of local and systemic staphylococcal infections. Hospital staffs harboring MRSA are the chief source of infection for the patients. These strains can cause a wide range of infections including bacteremia, endocarditis, and pneumonia. These strains are increasingly recognized as important agents of hospital-acquired infection in hospitalized patients undergoing prosthetic heart valve surgery.

2.5.1.2 Coagulase-Negative Staphylococci (CONS)

Coagulase-Negative Staphylococci (CONS) are the normal flora of the skin. CONS are opportunistic bacteria. They cause infections in debilitated or immunocompromised patients and in patients fitted with urinary catheters, cardiac valves, pacemakers, and artificial joints. They form white nonpigmented colonies, morphologically similar to those of Staphylococcus aureus. They are differentiated from Staphylococcus aureus by their failure to coagulate the plasma due to the absence of the enzyme coagulase. CONS of medical importance include S. epidermidis, S. saprophyticus, S. haemolyticus, S. saccharolyticus, S. hominis, S. schleiferi, S. lugdunensis, and Staphylococcus simulans.

2.5.1.3 Streptococcus

Streptococcus, from Ancient Greek meaning "twisted" is a genus of gram-positive spherical bacteria that belongs to the family Streptococcaceae, within the order Lactobacillales, in the phylum Bacillota. Streptococci are part of the normal flora in humans and animals. They are nonmotile, nonsporing, spherical or ovoid cocci, and have hyaluronic acid capsules. They are catalase negative by which they are distinguished from staphylococci. They are relatively fastidious bacteria requiring enriched medium, such as blood agar for their growth. S. pyogenes is the species classified under group A streptococci. It is the most important human pathogen causing: Pyogenic infections, such as bacterial pharyngitis and cellulitis. Toxin-mediated diseases, such as scarlet fever and toxic shock syndrome. Immunologic diseases, such as acute glomerulonephritis (AGN) and rheumatic fever.

2.51.4 Bacillus

The family Bacillaceae consists of rod-shaped Gram-positive bacteria that form endospores. The family includes two main groups of spore-forming bacteria: The anaerobic spore-forming bacteria of the genus Clostridium and the aerobic or facultatively anaerobic spore-forming bacteria of the genus Bacillus. The genus Bacillus is frequently known as aerobic spore bearers. They are ubiquitous and are present in soil, dust, air, and water. These bacteria are also frequently isolated as contaminants in bacteriological culture media. The genus Bacillus consists of more than 50 species. Bacillus anthracis and Bacillus cereus are the two most important species that cause infections in humans and animals. B. anthracis causes anthrax, while B. cereus causes food poisoning.

2.5.1.5 Clostridia

Clostridia is a common cause of infection, particularly in healthcare settings, and is often associated with antibiotic use and are more commonly associated with skin and soft tissue infections, antibiotic-associated diarrhea, and food poisoning. It produces toxins that damage the intestinal lining, leading to inflammation and symptoms. Clostridia infections are frequently linked to antibiotic use, as antibiotics can disrupt the normal gut flora, allowing clostidia to multiply and produce toxins.

Tetanus, gas gangrene, and botulism are three major clinical syndromes caused by Clostridium species. Pathogenicity of clostridia is attributed to the following features: They produce a number of neurotoxins, enterotoxins, and histolytic toxins. They survive as spores in adverse environmental conditions. They grow well in enriched media in anaerobic conditions.

2.5.1.6 Pseudomonas

Pseudomonas and related bacteria are obligatory aerobic non fermentative and mostly oxidase-positive bacteria. Most of them are motile by presence of one or two flagella. They are ubiquitous bacteria, primarily saprophytic, and are found in soil, water, and in moist environment. All these bacteria belong to family Pseudomonadaceae, which contains over 200 species. Most of them are pathogenic to plants, insects, and reptiles. A few species cause disease in humans. These are Pseudomonas aeruginosa, Pseudomonas fluorescence, Pseudomonas putida, Pseudomonas stutzeri, Burkholderia cepacia, Burkholderia mallei, Burkholderia pseudomallei, Stenotrophomonas maltophilia and Acinetobacter baumannii.

2.6 Laboratory Conventional Methods; Isolate and Identity of Microorganisms

In order for a laboratory to successfully undertake isolation, identification, and antimicrobial susceptibility testing responsibilities, it must participate in on-going investments in materials, supplies, media, reagents, and quality control, along with periodic training of personnel and quality assessment or proficiency testing. Antimicrobial susceptibility test methods must be performed as described according to internationally recognized clinical guidelines such as those provided by the Clinical and Laboratory Standards Institute (CLSI).

Conventional methods used to isolate and identity of the microorganisms include the following;

- Culture; this includes growing of the microorganisms
- Colonial morphological characteristics of the microorganisms
- Gram stain microscopy
- Biochemical test; automated identification and antimicrobial sensitivity testing

The above tests are reliably used to test for microorganisms and give authentic results. Any deviations from antimicrobial susceptibility testing methods may invalidate the test results, especially for fastidious organisms. (CDC, 2019).

2.7 Risk Factors for Surgical Site Infections

The factors associated with and leading to SSIs have been studied widely. Many studies have grouped them as those related to the patient, the type of surgery and how it was done, healthcare delivery system and specific surgeon factors. Some of these risk factors can be anticipated and their ability to cause SSI reduced or eliminated if they are identified and treated early. Other risk factors such as increased age and gender cannot be modified at all.

In a systematic review and meta-analysis to determine the risk factors for SSI after breast surgery, Xue et al (2012) proved 14 out of a possible 20 patient factors to be significant for SSI. Among the factors included were increased age and higher body mass index (BMI).

A retrospective review of a prospectively followed cohort of primary total knee arthroplasties also found patient factors associated with deep SSI to be a BMI of +35 (hazard ratio [HR] = 1.47), diabetes mellitus (HR = 1.28), male sex (HR = 1.89) (Namba et al., 2023).

Patients with preexisting medical conditions and previous surgeries and therapies have also been shown to be at risk of SSI. Hypertension, diabetes mellitus, osteonecrosis, and posttraumatic have been named as prevalent conditions predisposing patients to SSI (Namba et al., 2013; Xue et al., 2012). In breast surgery, an American society of anesthesiologists (ASA) score of 3 or 4, previous breast biopsy or operation, preoperative chemoradiation, hematoma, seroma, more intraoperative bleeding, postoperative drain, longer drainage time and second drainage tube placed have also been significantly associated with SSI. In the same review by Xue et al (2012), where eight studies which included 681 cases and 2064 controls, factors like smoking habit, immediate reconstruction, axillary lymph node dissection, preoperative chemotherapy, corticosteroid usage and prophylactic antibiotic didn't show statistical significance.

Hospital and surgeon volumes also influence the occurrence of SSIs. Namba et al (2023) found that when the hospital cases for primary total knee arthroplasty were below 100 cases per year the incidence of deep SSI was 1.5% and when the cases were above 200 cases per year this incidence was 74.5%. This was also reported for surgeon volumes as well where when their cases were below 20 per year the incidence of deep SSI was 8.2% and 52% when they had more than 50 cases per year. An evaluation of total knee arthroplasty infection rates across the United States of America using inpatient data found a greater incidence of SSI in urban, high-volume hospital as compared to hospitals in rural areas (Kurtz et al 2020). Operative time has also been listed as a risk factor for SSI by several authors with Namba et al 2013 recording a 9% increased risk per fifteen-minute increment. Increase in operative time can be considered proxy for the complexity of the surgical procedure. In a study to determine prosthetic joint infection risk in a medicare population found that knee arthroplasty operative time of more than 210 minutes was associated with an increased risk of infection compared to a lower time of less than 120 minutes (Kurtz et al 2020).

2.8 Preventing Surgical Site Infections

Since pathogens are responsible for the occurrence of SSI, antibiotics have been used to reduce their incidence. Many studies have shown that the timely administration of preoperative antibiotics reduces the risk of SSI significantly (Forbes & McLean. 2013). In a retrospective comparative study to compare the rate of infection with and without the use of Vancomycin powder application during posterior cervical instrumentation reported a significant decrease in infection rate in the intervention group (0%) compared to the control group (15%) (Caroom et al., 2018).

They also found that the risk was reduced even further when the Vancomycin powder was used intra-wound during the surgery than after the surgery. Similarly, a study aiming to determine the risk factors for SSI after breast surgery found that the use of prophylactic antibiotics did not significantly influence the incidence of SSIs (Xue et al 2012). Other therapies like perioperative normothermia and hyperoxia in the prevention of SSIs remains controversial but may improve outcomes in specific subsets of the surgical population (Forbes & McLean, 2023).

In surgical oncology patients, the efficacy of negative pressure therapy (NPT) in preventing SSIs has been tested with Blackham et al (2018) actually proving that it decreases SSIs in oncology patients. The goal of preoperative patient skin antisepsis is to reduce the risk of the patient developing a surgical site infection (SSI) by removing soil and transient microorganisms at the surgical site. All patients undergoing surgical procedures requiring a skin prep, shall have the appropriate anatomical area prepared prior to the time of the incision.

Skin preparation agents will be used in accordance with manufacturer's recommendations, in cooperation with surgeon's preference. Preoperative skin antiseptic agents used should be cleared and approved by Regional Medical Center's Infection Control Committee.

As part of the skin preparation process, hair removal is achieved through clipping using disposable accessories. Clipping, and removal, of clipped hair from the bed or stretcher should be completed prior to moving the patient to the operating room suite.

2.9 Surgical Site Prepping

2.9.1 General Skin Preparation Consideration

The use of skin preparation agents can be specific to intact skin, mucous membranes and open wounds. Selection of proper agent for each specific preparation areas and circumstance. Reference to manufacturer's recommendations. Use extreme care to prevent prepping solution from pooling in skin folds as this may cause skin irritations and burns.

Apply skin prepping solution using sterile gloves and observing sterile technique. Dabbing of prepped area is allowed to remove excess following the prepping, but do not wipe off. Use sterile towels to help absorb solution that may inadvertently drip or run into skin folds and under the patient. Employ sterile technique during use. Remove any previously placed, non-sterile, soiled absorbent material immediately after prepping is completed. Be careful to avoid contamination of prepped site. Adhere to drying time recommendations.

Considerations need to be put in place when using Alcohol based prepping because alcohol fumes may be trapped, particularly if drapes are placed while still drying. This situation will increase the potential for fire and patient burns, when cautery is activated. A separate prepping tray or kit shall be used for each patient, each site.

2.9.2 Prepping Procedure

Expose the area to be prepped while maintaining the privacy of the patient, as much as possible, particularly if patient is awake. Place absorbent pads to keep patient, and operating room table, as dry as possible Ensure kit, package, or prepping tray are open and ready for use. Perform hand hygiene and don sterile gloves. Begin prepping site using appropriate technique and approved prepping solutions for surgical cases and follow manufacturer's recommendation in each type. Surgical Preparation of the Skin, if using iodoform/chlorhexidine scrub, begin at incision site and, using concentric circles, scrub/apply agent outward. Do not re-prep using the same brush or sponge, but work to periphery. Discard sponge. Repeat with new or additional sponges/brush until supply is exhausted. Use sterile towels to dab off scrubbing agent's bubbles or pooled solution. If using applicator apply following manufacturer's recommendation, method and drying time. Commonly, dry time is three minutes. This reduces fire potential by allowing alcohol fumes to evaporate and not be trapped under drapes. While prepping, caution should be taken not to reach over, or across, the prepped area or touching the prepping sponge to bed cover, blankets, patient gown. Discard the applicator after reaching the periphery or a contaminated area. Use another sterile applicator for additional applications. When the incision site is more highly contaminated than surrounding area like the anus, perineum, stoma, open wound, catheter, drain and axilla then prep the areas with the lower bacterial count first, followed by the area of higher contamination. Once prepping is complete, remove absorbent pads being mindful to maintain and not contaminate.

2.10 Impact of Surgical Site Infections

Patients with SSI have a significantly higher overall comorbidity burden, higher perioperative mortality rates, longer length of stay, and higher complication rates. In their evaluation Poultsides et al. (2019) found that the average cost of in-hospital care was double for SSI versus non-SSI patients. Jenks et al. (2018) reported that the length of stay in hospital for SSI patients was more than 3 times longer than that of non-SSI patients.

In terms the impact of SSIs on cost, Jenks et al (2018) in a study in an English hospital over a two-year period reported the median additional cost attributable to SSI was £5,239 and the aggregate extra cost over the study period was £2,491,424. They went further and calculated the opportunity cost of eliminating all SSIs in the hospital during that period and they found the overall financial benefit for the hospital would have been only £694,007. This is interesting to note because in seven surgical categories, the hospital would have actually been worse off if it had successfully eliminated all SSIs.

In another review of cost burden analysis in the united states of America, Zimlichman et al. (2022) found that the total annual costs for the 5 major infections were $9.8 billion, with surgical site infections contributing the most to overall costs (33.7% of the total), followed by ventilator-associated pneumonia (31.6%), central line–associated bloodstream infections (18.9%), C diffusible infections (15.4%), and catheter-associated urinary tract infections (<1%).

In a study done at Mbarara hospital Uganda; Despite good practices incorporation and improvements in operating room practices, instrument decontamination and sterilization methods, improved surgical technique, and best practices of infection prevention and control strategies, surgical site infections remain a major cause of hospital-acquired infections. The rates are increasing globally even in hospitals with most modern facilities and standard protocols of preoperative preparation and antibiotic prophylaxis. In the developing countries where resources are limited, even basic life-saving operations, such as cesarean sections and laparatomies, are associated with high infection rates morbidity and mortality (Lubega, Bazira et al., 2019). In the developed countries, SSI has been reported to affect from 5% to 15% of hospitalized patients in regular wards and as many as 50% or more of patients in intensive care units (ICUs), while in developing countries the magnitude of the problem remains largely underestimated. In Uganda, data about SSI is still scarce and the true incidence and cost per patient are unknown. A research study done to determine the incidence of SSI among elective surgeries on the surgical ward in 2007 found the postoperative incidence density to be 15.9% and no risk factors were associated with SSIs (Lubega, Bazira et al., 2019). It is evident SSIs remain an area of concern for the health workers, hospitals and patients. Efforts to reduce the incidence and impact SSI should be enforced to ensure better outcomes and better use of available resources.

2.11 Surgical Instruments and Trays

A surgical instrument is a specially designed tool or device for performing specific actions or carrying out desired effects during a surgery or operation, such as modifying biological tissue or to provide access for viewing it. Over time, many different kinds of surgical instruments and tools have been invented. Some surgical instruments are designed for general use in surgery, while others are designed for a specific procedure or surgery. Accordingly, the nomenclature of surgical instruments follows certain patterns, such as a description of the action it performs for example, scalpel, the name of its inventors, for example, the Kocher forceps or a compound scientific name related to the kind of surgery for example, a tracheotome which is a tool used to perform a tracheotomy.

A surgical tray is an instrument found in an operating room. The surgical tray holds all of the tools and equipment that are expected to be required to complete a scheduled surgical procedure. The surgical instruments are taken out of an autoclave or sterilizing machine and placed onto the surgical tray. They come in different designs usually dependent on the type of instruments they hold and the different specialties of surgery.

Surgical instruments can vary widely by the field of surgery that they are used in. In general instruments can be divided into five classes by function:

a) Cutting and dissecting instruments: Scalpels, scissors, and saws, osteotomes, chisels

b) Grasping or holding instruments:

  - This included forceps and clamps predominantly divided in traumatic tissue crushing and atraumatic tissue preserving. Examples of traumatic tissue forceps include;
  - Dissecting forceps, sponge holding forceps, towel clips, tissue forceps.

- Atraumatic tissue preserving forceps include, Debakey's, babcocks, green amitage among others. Numerous examples are available for different purposes by field

c) Hemostatic instruments: This includes instruments utilized for the cessation of bleeding

- Artery forceps are a classic example in which bleeding is halted by direct clamping of a vessel
- Sutures are often used, aided by a needle holder
- Cautery and related instruments are used.

d) Retractors: Surgery is often considered to be largely about exposure

- A multitude of retractors exist to aid in exposing the bodies cavities accessed during surgery. Examples include the Morris, Divas, kellys, cannyralles, Langenbergs, phinochieto, Doro-j-arm among others.

e) Tissue unifying instruments and materials:

- This would include instruments that aid in tissue unification such as needle holders or staple applicators.

Surgical instruments are an integral part of the perioperative environment. They are used directly and invasively on the patient. This is a major factor in transmission of surgical site infections if proper handling and strict follow up of guidelines is not observed.

A study done at University of Tokyo Hospital Japan, the researchers demonstrated that intraoperative contamination of surgical instruments was not infrequent in spite of various means of preventing Surgical Site Infections, such as preoperative administration of antibiotics, preoperative skin preparation, and intraoperative aseptic technique. In general, the surgical field is considered to remain aseptic during operation. However, microbes gradually recover in the surgical field and could cause microbial contamination of sterilized surgical instruments. The relatively high incidence of contamination of surgical instruments sheds light on the mechanisms of SSI development. The study also suggests that surgical gloves play a role as fomites in the surgical field by transportation of microbes. (Saito et al, 2019.)

There is a possibility that skin drapes and meticulous surgical skills may be far more important for decreasing the risk of SSI than we previously considered. Change of surgical instruments after prolonged exposure should be recommended even more strongly as basic practice. (Saito et al, 2019).

2.12 The Operating Room Environment

Breaks in sterile technique and microbial contamination in the operating room are categorized into four types based on how quickly the event is recognized. Type 1 break is caught immediately. Types 2 and 3 are recognized progressively later. A type 4 break is not recognized at all by the operating room team. The most common breaks in sterile technique are with pre-operative instrument sterilization, placement of sterile instruments onto a designated sterile field, hand washing and drying, gloving, gowning, draping, cleansing of the incision area, and general surgical technique. Meticulous attention during each phase of the operative setup by all personnel helps to limit inadvertent microbial contamination. During the procedure, operating room doors should remain closed unless necessary team members need to enter or exit. The operating room should also have high efficiency particulate air filters, positive air pressure, and directional airflow to reduce airborne microbial contamination (Gaines et al., 2019).

Despite standard aseptic practice, meaningful breaks in sterile technique do occur, which can result in significant morbidity and hospital costs. In the autumn of 1999, SSIs developed with the same strain of *Pseudomonas aeruginosa* in 16 patients who underwent median sternotomies at a hospital in Ann Arbor, MI. This strain of bacteria was linked back to the onycholysis of one nurse's thumbnail. The reason behind the significant break in technique was thought to be a new brand of latex surgical gloves that were introduced into the operating room during this period; however, the evidence for such a theory was weak, because the use of the gloves in other surgical settings did not result in similar results. Future research is thus needed to determine host and environmental reservoirs of nosocomial pathogens.

Even with best practices to maintain sterility, it is impossible to eradicate all bacteria from the operating room. The patient and all of the operating room employees introduce host-associated microbes near the sterile field through skin, hair, and nasal shedding as well as via breath aerosol transmission despite wearing standard operating room attire (Edminstone et al., 2020). Many attempts have been made to address this seemingly unavoidable bioburden. One example is the use of protective suits with hoods and self-contained exhaust system, which has been adopted by many orthopedic practices, especially for joint replacements. While studies do show that its use can improve measures of sterility inside the operative field (e.g., bacterial colonization), there is insufficient evidence to suggest their use decreases surgical infections. Another tried solution is the use of ultraviolet (UV) radiation to further sterilize the operating room. The use of UV lights began as early as the 1940s. Similar to the initial enthusiasm for space suits, early studies showed that it does decrease the bioburden within the operating room. There is little evidence to suggest, however, that its use decreases the rate of hospital-associated infections.

The proper operating room environment requires sterile equipment, adequate disinfection of the patient’s skin, and maintenance of clean air in the OR. For this reason, all staff put on masks, hats, and garments designed to minimize seeding the air with bacteria-laden fomites and aerosols. In addition, ORs themselves are isolated, positive-pressure environments designed to recirculate air through filtered ventilation ducts. There are several factors that interfere with sterility of the environment as follows;

2.12.1 Humidity and Temperature

Temperature and humidity are some factors which influence the growth of theatre microorganisms which need continuous monitoring and there are set standards. In the

United States of America for example they specify air temperature of 70 to 75F (21-24 degrees C) with humidity of 50-60% which provides a balance between the patient's safety and operator comfort (Ellis, 2013). In Kenya, temperatures of 19-21 degrees C and humidity of 50-60% is ideal for the theatre environment as it inhibits microbial growth. Other recent studies recommend varying humidity of 20-60% and temperature of 68-750F or 18-21 degrees C (Arthur, 2019).

In operating theatres, air circulation is crucial for maintaining a sterile environment and preventing infections. This is achieved through specialized ventilation systems that ensure high air changes per hour, precise air movement control, and effective contaminant removal.

Key aspects of air circulation in operating theatres:

- **High Air Change Rates:**

Operating theatres typically have 20-25 air changes per hour (ACH), with some using up to 40 ACH. This ensures rapid removal of contaminated air and replacement with fresh, filtered air.

- **Filtered Air Supply:**

Supply air is filtered in multiple stages, including a HEPA filter, to remove dust, bacteria, and other particles.

- **Laminar Flow:**

The airflow is designed to be low turbulence, almost laminar, above the operating table to minimize the risk of aerosolized contamination.

- **Partial Unidirectional Airflow (P-UDAF):**

Some theatres use P-UDAF systems, where air is supplied from above and flows downward, sweeping away contaminants and directing them towards exhaust grills.

- **Overpressure:**

The operating theatre is maintained at a slight overpressure compared to surrounding areas, preventing air from flowing in from the outside.

- **Air Pressure Stabilizers:**

These devices ensure that the desired differential air pressure is maintained, further controlling airborne contamination.

- **Contamination Control:**

Effective ventilation systems, coupled with appropriate cleaning and sterilization practices, help minimize the risk of surgical site infections.

By implementing these measures, operating theatres can create an environment that significantly reduces the risk of infection for both patients and healthcare professionals.

2.12.2 Frequent opening of the OR door

Frequent opening of the operating room door disrupts the airflow system and thus may limit the effectiveness of measures for surgical sites infections. This occurs due to movement of staff in and out of the OR preoperatively, intraoperatively and postoperatively

2.12.3 Foot Traffic in and Out of the OR

In a study done at University of Michigan hospital by Lynch et al 2019, which is defined as a high-volume academic Centre. The researchers did the study in response to unexplained increase in SSI rates at the institution. One prominent aspect of the review was foot traffic in and out of the OR which was found to be significantly higher than anticipated. This is a vehicle of the operating theatres environment contamination. This was attributed to staff either collecting surgicals, equipments and others were just passing by to greet friends and colleagues.

2.12.4 Increased Crowding in the OR

Studies have shown that increased crowding on the operating room is associated with a high postoperative surgical site infection rate. The more the human traffic is in an operating theatre the higher the chances of surgical site infection rates. Sterile technique is defined as a set of standard practices with the goal of minimizing microbial contamination to reduce the rate of SSI. While the standard practices may vary slightly depending on the institution and clinical situation, maintaining an aseptic operating room environment generally focuses on environmental cleaning, hand hygiene, pre-operative skin preparation for the patient, surgical attire, and general technique while working in a sterile field. Recommendations for operating room personnel regarding the maintenance of sterile technique. Surgical gowns, gloves, and drapes should be used in the operating room, and sterile technique should be applied once gowned and draped. Instruments brought onto the sterile field should be placed and handled in such a way as to maximize the maintenance of sterility. The sterile field should be monitored constantly by all operating room personnel.

2.13 Theoretical Framework

2.13.1 The Ottawa Model of Research Use

The Ottawa Model of Research Use (OMRU) is an interactive model developed by Logan and Graham (1998). The OMRU views research use as a dynamic process of interconnected decisions and actions by different individuals, professionals in clinical practice relating to each of the model elements (Logan & Graham, 1998).

The OMRU models describes aspects in which research is a useful way of coming up with evidence in clinical practice. This includes six key elements as follows;

- Evidence-based innovation
- Potential adopters
- The practice environment
- Implementation of interventions
- Adoption of the innovation

- Outcomes resulting from implementation of the innovation (Graham & Logan, 2004).

The Ottawa Model of Research Use (OMRU) offers a “comprehensive, interdisciplinary framework of elements that affect the process of health-care knowledge transfer, and is derived from theories of change, from the literature, and from a process of reflection” (Graham & Logan, 2004).

It promotes research use, and could be used by policymakers and researchers (Logan & Graham, 1998). The OMRU is an example of a planned change theory, which helps “administrators control factors that will influence the likelihood of changes occurring at the organizational level and how these changes occur” (Graham & Logan, 2004, p. 2). The Ottawa Model of Research Use has been used in nursing to explore the barriers and supports for adoption of new innovations, describe the process of adoption of new innovation or guidelines, implement a new research based guidelines, and to increase evidence-based practice across health-care settings. The feasibility and effectiveness of using the OMRU in actual practice contexts was supported by findings from a number of studies. The authors found out that the Ottawa Model of Research Use, or OMRU (Logan & Graham, 1998), to be a particularly useful conceptual framework for guiding the implementation of continuity-of-care innovations that are being evaluated in the context of research and that require major practice or organizational changes. They also found it helpful in planning and guiding knowledge transfer activities (including the implementation of continuity-of-care innovations) in practice settings (Graham & Logan, 2004).

The authors expressed positive results after using the OMRU and gave recommendations as one of the preferred models of use in clinical practice and evidence based innovations. It is a prescriptive type of research model and the six key elements can be described in three types of activities as elaborated below:

In this study OMRU will be used to determine the Microbial Colonization Time of Surgical Instruments Intra operatively in the operating theatre. Microbial colonization time of surgical instruments and the surgical specialty interact with each other in terms of:

(a) Attributes of the innovation e.g., to come up with clear time range of microbial colonization commencement, clear timelines as to when to change surgical instruments and other surgicals involved.

(b) Attributes of the practice environment e.g., the surgical teams in the different surgical specialties and

(c) Attributes will be determined by the outcome of a and b above. However this will have presence of a research champion, and autonomy.

The Ottawa Model of Research Use provides a framework for implementing clinical innovation. When developing and implementing a clinical innovation, input from end users and consumers is pivotal. Incorporating the innovation into a practice guideline provides a structure to imbed research evidence into practice. Innovations are more quickly adopted if they are compatible with current values, beliefs, and practices and are seen as more advantageous than the current practice (relative advantage); are easy to use (low complexity); are observed by others to be in use (observability); and can be easily tested before being formally adopted (trialability) (Graham & Logan, 2004).

2.13.2 The Ottawa Model of Research Use

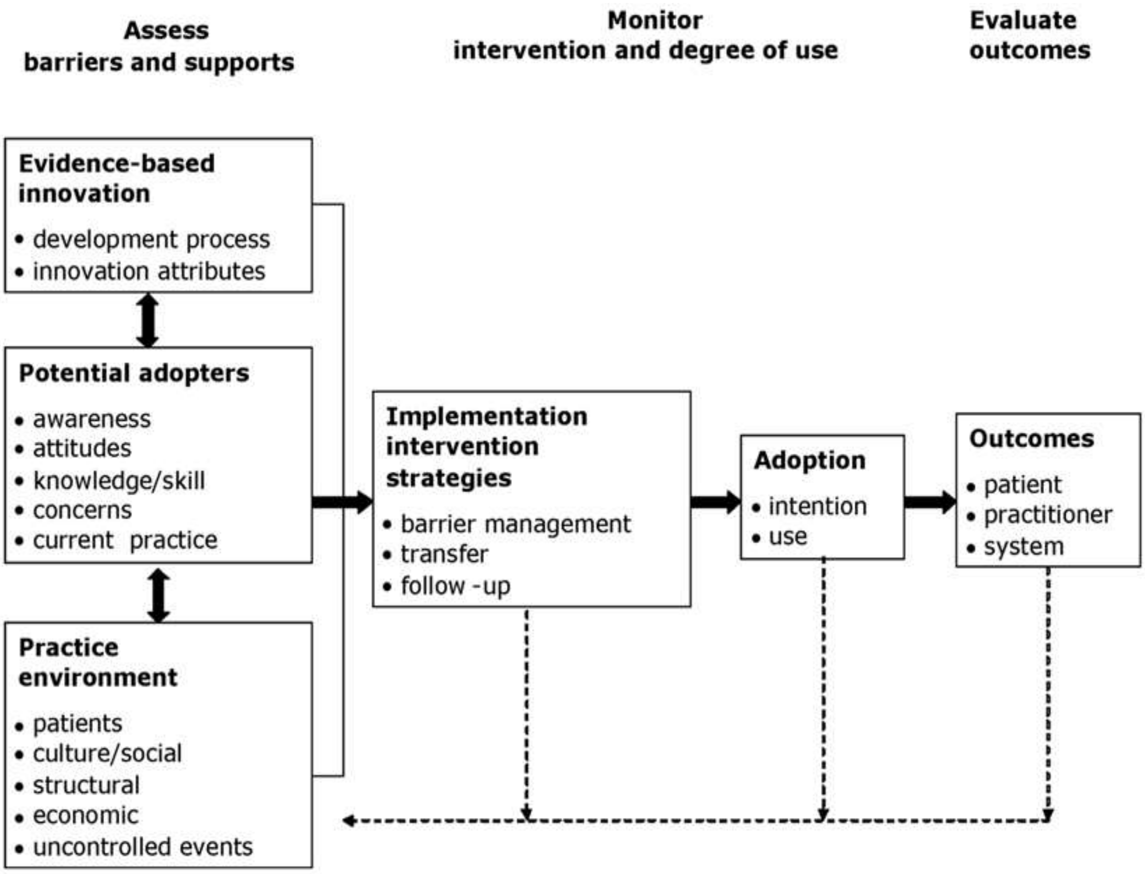

Figure 2.1: The Ottawa Model of Research Use

2.14 Conceptual Framework

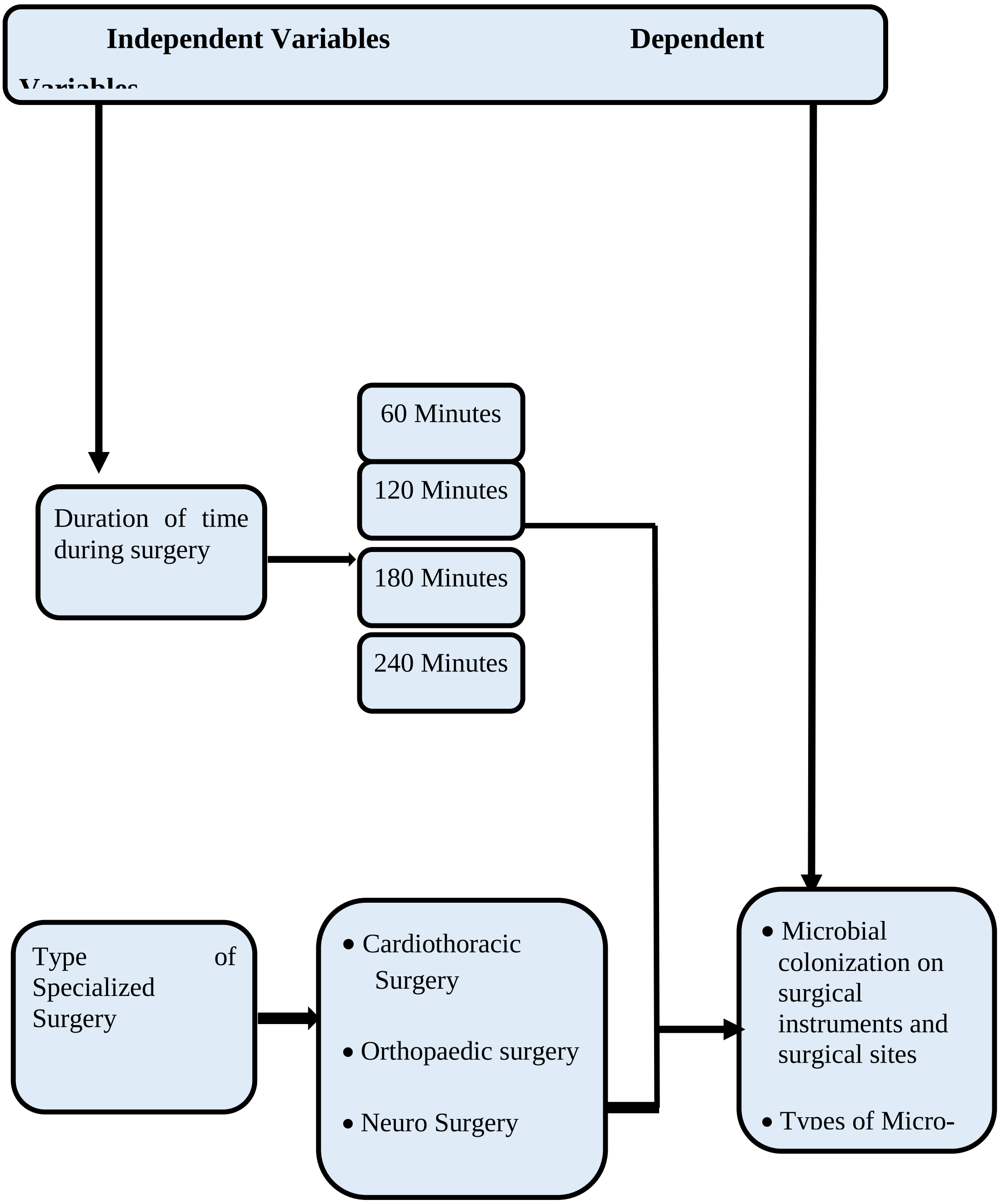

Figure 2.2: Conceptual Framework

CHAPTER THREE

MATERIALS AND METHODS

3.1. Research Design

The design was a mixed method which comprised of both quantitative and qualitative designs. The quantitative arm was an analytical cross-sectional study. Quantitative experimental approach to data collection, analysis and presentation was adopted. Qualitative arm Explanatory sequential design was used. The explanatory sequential design emphasizes the quantitative phase, followed by the qualitative phase (Creswell, 2011). The purpose and reason of the second qualitative phase is often to explain and elaborate the results found or discovered in the first quantitative phase, and other times to explain outliers that are not entirely consistent with the collected data. The aspect of analysis of qualitative data is used to explain the quantitative phase's results, or elaborate more on the results thus the term ‘explanatory’ is used.

The explanatory sequential design has several phases as follows; Phases of explanatory sequential design. The explanatory sequential design entails several phases, including setting up ontological (which is the philosophical of being and existence exploring what kind of things and how they relate to each other) and epistemological position. This basically means the study of knowledge and how things get to be known. This leads to establishing an approach to inquiry, data collection or collecting data, analyzing the collected quantitative data, in the event that the data collected is insufficient or does not answer the questions then recollecting data is done, followed by analyzing the qualitative data, and finally integrating and reporting the results. Setting ontological and epistemological position Researchers often work within the realm of paradigms which is a fundamental set of assumptions, values and beliefs provides a broad framework of approach and understanding the researcher’s worldview. Their general methodology for doing research is predicated on distinct theoretical considerations. This is the lens through which a researcher views reality and conducts the study (Saunders et al., 2019). The initial theoretical concept is Ontology, and it is concerned with 'reality'. The second is concerned with the nature of 'knowledge' about what exists or is thought to exist and is referred to as epistemology. In essence the ontological position concerns reality, whereas epistemological position concerns knowledge about the reality. In general, there are two opposing ontological positions in epistemology of social science research such as objectivism and constructivism and this is explained below.

Objectivism is reality. It proposes that researchers see the world experimentally or through experiment, which states or implies that reality has an objective existence. On the other hand, constructivism believes that human beings are meaning-making entities and that the integration of such meanings in social life occurs within the cycle of social existence. Indeed, constructivism's ontological premise highlights the social construction of reality.

In this way, the knowledge created by objectivists differs from that produced by constructivists and this is how it occurs. It is important to note that positivism and interpretivism are two distinct theoretical perspectives. When the researcher has Knowledge of the research object this lets researchers determine what to research, how to carry out the research and what design is to work to create and recreate the ultimate results hence the knowledge. On the other hand a positivist perspective, the only way to get the reality is to do laboratory evaluations or the ‘lab-test-science’ what researchers called systematic scientific steps. Positivism's perspective is to undertake systematic, step-by-step attempts to adapt natural science's perspective to social sciences. In essence, positivist scholars believe that there is only objective reality and that the analytical techniques used to find it are concerned with hypothesis, replication, reliability, and generalization. This is the same thinking in the quantitative aspects of research. In this sense, positivists align themselves with objectivists, who assert that the purpose of research is to experiment on phenomena that can only be observed and quantified, with the exception of knowledge that cannot be directly observed or quantified, such as emotions, feelings, and so on.

Interpretivism offers a whole new perspective on this. The interpretivists challenge the positivist premise that there is no one objective reality since the world is fundamentally social and created socially. The world is about people's perceptions of reality and their perceptions of the world as a consequence of their interactions with others and the environment in which those interactions occur. In this view, constructivism and interpretivism are synonymous. Other theoretical paradigm, for example, critical realism states that there is an observable structure or reality that exists independently of human thought. This school of thought focuses on power structures and social inequities aiming to promote social change.

According to critical realists, this structure is what generates the phenomena that surround us, and therefore the social reality can only be understood if people understand the structure. This indicates that although there is no direct connection between our experience of reality and our knowledge of it, there is an indirect connection between meaning and representation. Thus, there is something external to us, and our perception of it is filtered via our limited ability. If at a personal level there are limitations of interpretation then it ends at that but this does not imply that it's the correct reality. In this way, the realistic ontology establishes its boundaries by suggesting that everything is socially created and beyond our comprehension, but it seems realistic only when empirical.

Pragmatism, as a research philosophy, provides a degree of adaptability in the production of knowledge because it recognizes the existence of many different realities, pragmatism's epistemology does not include a single line of inquiry, but multiple ways of inquiry. Pragmatism emphasizes practical solutions and uses a combination of methods to address complex real-world problems. Pragmatism often rejects the dichotomy between realism and anti-realism that is fundamental to positivist rhetoric and social scientific interpretations. Indeed, pragmatists acknowledge the existence of several realities, but recognize that they are always changing and dependent on our actions and experiences. This describes the real world that is dynamic in nature.

The many realities are then comprehended by integrating various perspectives. By integrating empirical analyses with scientific evidences, the pragmatic researcher aims to develop a more complete knowledge of the research issue. Thus, the empirical inquiry would contribute to a more holistic perspective of research, ultimately leading to a balanced conclusion. In this sense, pragmatists acknowledge the existence of some established social structure, but also acknowledge the involvement of individuals in their formation and development a highly interpretivist perspective. Pragmatists embrace both interpretivist and positivist views, and by integrating these two viewpoints, pragmatism allows a more complete understanding of research objectives. Each of the paradigms mentioned before has its own set of advantages and disadvantages. The researcher and the research objective shall decide how much adherence to a rigorous philosophical position is necessary to complete the research work. Due to the fact that being limited and too focused on a particular philosophical perspective may obstruct the study of those areas that may expand their understanding of the field of science, it is recommended that social science research be conducted without regard for rigid philosophical constraints, however some researchers may consider it otherwise.

In terms of philosophical worldviews explanatory sequential design incorporates two distinct research traditions, researchers may consider adopting two distinct worldviews or a single philosophical position that is appropriate for completing the research task. Setting approach of inquiry Divergent views on social reality create divergent opinions on the logic that underpins the creation of an inquiry. Scientific methodology is the interplay of abduction, which involves the acceptance of explanatory plausibility, induction, which includes the empirical testing of putative inferences, and deduction, which entails deriving implications from accepted inferences. The quantitative approach typically follows a deductive logic of inquiry, which entails shifting away from specific facts and toward a generalized theory or abstract scientific ideas; in other words, theory drives the hypothesis of the inquiry. As a thinking process, deduction is a movement from particular provisions to a more general perspective (Saunders et al., 2019).

A researcher uses a deductive method to research when he or she formulates hypotheses and implications based on pre-existing theories about the topic of the study. The methodology for data collection is dictated by theoretical assumptions. Following that, the assumptions are verified or refuted in light of real evidence, thus validating or refuting the theory. On the other hand, inductive reasoning is a method of reasoning from the general to the particular, in which broad conclusions are derived from evidence. Inductive inquiry progresses from evidence to generalizing ideas and finally to theory building. It should be emphasized, however, that no study can be performed entirely on the basis of deductive or inductive reasoning. Inductive reasoning is a component of any deductive inquiry. When testing hypotheses based on collected data, for example, the process of moving from observations to general statements is used, i.e., inductive reasoning is applied. On the other hand, inductive logic-based research often utilizes theory as a springboard, a broad framework for generating research topics. When developing an explanatory research design, researchers must choose which method of inquiry is appropriate for the investigation's framework. Data collection phase the process begins with the development of instruments for obtaining raw data or the selection of pre-existing databases that are relevant to the study's objectives. The process of instrument creation is influenced by the technique of inquiry chosen. For example, if the data collecting technique is a survey, the development of a questionnaire is a crucial step. Similarly, interviewing is a method for eliciting information from a respondent via the use of a prepared sequence of questions (Saunders et al., 2019).

The sequence, content, and structure of questions, as well as the techniques used to answer them, should all be structurally consistent. In this regard, the questionnaire is comparable to a standardized interview. The questionnaire's quality has a significant effect on the research's reliability. A questionnaire may include structured questions as well as open-ended inquiries. In social science research, surveys are often used to collect quantitative data. Survey method may be classified based on how the interviewer and responder interact or communicate. The responder answers to the questionnaire's questions through mail/e-mail (correspondence survey) or in person (in-person survey/face-to-face survey). Direct contact with respondents through organized interviews is possible, as is indirect connection with respondents via telephone interviews including those using internet assisted technology and systematic questioning via online polls. Additionally, survey techniques may be classified as individual and group, mass and specialized. However, survey techniques are not without their drawbacks. For instance, coverage error, sampling error, non-response error, and measurement error are only a few of the difficulties to consider prior to using the survey method.

Analysis of quantitative data, data analysis is divided into two stages: quantitative and qualitative. Quantitative data analysis techniques are intended for the examination of measurable features in order to provide quantitative findings. Such analysis entails the processing of data using organized methods that are quantitative in nature. For instance, descriptive analysis entails determining, characterizing and describing the target population. Descriptive analysis and descriptive data are two distinct concepts. Descriptive analysis provides response to the query "what happened?" by summarizing descriptive information and historical data in preparation for future investigation. It analyzes data using statistical techniques such as principal component analysis, cluster analysis and factor analysis to cluster, categorize, and determine the variables affecting the outcomes. It often involves correlation studies, which serve as a breeding ground for hypotheses that may be investigated experimentally in more depth. Predictive analysis is a technique that forecasts unknown variables by answering the question "what might happen?" based on the study of collected data. Several techniques, such as mathematical statistics and modeling, may be utilized in this case. Prescriptive analysis addresses the question "what to do?" through the use of what-if scenarios. In prescriptive analysis, researchers use techniques to evaluate all gathered and processed data in order to determine the best answers for a given question. Workflow of Explanatory Sequential Design of MMR (developed by author based on literature) Recollecting data. This phase of data gathering is driven by the quantitative result. The data collected during this phase are qualitative (for example, text, video, audio, and image), which determines what techniques should be utilized to acquire data that provides additional insight into the research. In-depth interview, focus group discussion and observation are just a few of the methods utilized to gather qualitative data during this phase. The in-depth interview is a method for extracting essential information via open-ended or organized dialogue between the interviewer and the interviewee. It's worth noting that the word 'in-depth' refers to the connection between the interviewer and responder during the deliberate conversation. In-depth interview technique has a number of benefits and drawbacks. In-depth interview approach requires extensive planning and the creation of a certain relationship with the interviewees. Due to the established trust relationship, this technique enables the respondent to provide requested details. As a result of the developed trust connection, the responder is able to give required information.

By and large, the information collected is unique and comprehensive, usually very bulky in nature allowing researchers to combine and analyze large amounts of data. This method's peculiarity is manifested in the meticulous preparing and review of all questions for the respondent. The interviewer's preparation, knowledge, and even presentation all contribute to the effectiveness of the in-depth interview. Here, preparation and a sense of proportion are required; it is also necessary to be a very attentive listener and recording of data and taking of field notes is also required to capture all the details. The increased urgency with which in-depth interviews are conducted puts extra resource limitations on both the investigator and the interviewee. The focus group discussion technique is similar to that of an interview, except that it is conducted in groups rather than individually.

A focus group may refer to the research technique itself or, more precisely, to a group of respondents who will take part in the inquiry. The researcher seeks the respondents' subjective or objective views on the topics during the group discussion. The effectiveness of focus group discussions is determined by a variety of factors, including a well-designed preparation, participant composition, skilled group moderator, and comfortable location.

3.2 Study Site

The study was carried out in the Main operating theatres of Kenyatta National Hospital. This Hospital was founded as the native civil hospital, in 1901 with a bed capacity of 40. In 1952 it was renamed the King George VI Hospital, after King George VI of the United Kingdom. At that time the settler community was served by the nearby European Hospital now Nairobi Hospital. The facility was renamed Kenyatta National Hospital, after Jomo Kenyatta, following independence from the British. It is currently the largest referral and teaching hospital in the country. Kenyatta National

Hospital employs over 6,000 staff and has a bed capacity of 1,800. However, due to congestion, the patient numbers can rise as high as 3,000.

The hospital offers curative, preventive, diagnostic and rehabilitation services. Kenyatta National Hospital is the largest teaching and referral hospital in East, Central and sub-Saharan Africa. It was founded in 1901. It is located in Nairobi at Upper hill area along Hospital Road off Ngong Road and about four kilometers from Nairobi City Centre. To the west is Mbagathi Road and south is Nairobi Railway line. The hospital sits on 45.7 hectares of land. It has 50 wards with a 2000 bed capacity. It receives referrals from all the 47 counties and their associated county hospitals. (KNH Strategic Plan 2009 -2013).

Main theatres department has 12 theatres in number and are located on the first floor of the tower block. The theatres operate on different specialties to include ENT, Orthopedics, Maxillofacial, General surgery, Plastic, Ophthalmology, Neurosurgery, Obstetrics, Gynecology, Urology, Paediatric Surgery and cardiovascular surgeries. Main operating theatres receive patients from the respective surgical wards, Accident and Emergency department and outpatient clinics. (KNH Strategic Plan 2009 -2013).

3.3 Study Population

The study populations comprised of four categories.

These included the patients, the surgical instruments, the surgical specialties and the perioperative experts.

3.3.1 The Patients

The study population comprised of surgical patients. These are patients seen in the surgical outpatient clinics, the Accident and Emergency department and the wards. Clerking and diagnostic investigations are done and diagnosis is made. When the decision for surgery is made, they are admitted and theatre lists are prepared. Copies of the theatre lists are sent to the admitting wards and the operating theatres. The patients in the study population were selected from the theatre lists which were sent a day prior to the main theatres before surgery. The researcher and research assistants would then visit them and recruit them into the study if they fitted the inclusion criteria. They were given the consent forms of the study to sign. The total target population was 92 patients.

3.3.2 The surgical Instruments

Sterile surgical instruments were picked from the instrument trays but were not used during surgery. They were picked from the sterile instruments trays which were used from the above selected patients. These included different types of instruments to include retractors, artery forceps, tissue forceps, dissecting forceps, scissors and dilators. They were picked randomly upon opening of the set during setting time. The instruments were picked by the principal investigator or the research assistant after having surgically scrubbed according to the laid down procedure, gowned and gloved. Only one instrument would be picked from the set for the purposes of data collection and this would not affect the process of surgery.

3.3.3 The Surgical Specialties

The surgeries were selected from the following specialties; Orthopaedics, Neuro surgery, Cardiothoracic surgery, General surgery and Urology. These surgery specialties were selected due to the length of surgeries per case as the surgeries were to last at least 4 hours. The patients above were randomly selected from either of these specialties.

3.3.4 The Perioperative Experts

Perioperative experts who were the Key Informant Interviewers comprised of the three professions that make up the surgical teams. They were a total of 15. They comprised of 5 surgeons, 5 Perioperative nurses and 5 Anesthesiologists. The sample that led to saturation included 2 surgeons, 3 Perioperative Nurses and 2 Anesthesiologists.

3.4 Sample Determination

Sample size was determined by using single population proportion formula by considering the following assumptions: 95% confidence interval (CI), 50% proportion since there is no previous study in the study areas, and 5% marginal error. All surgical instruments used during surgeries in the operating theatres at KNH that fulfilled the laid-out criteria of the study were recruited. Stratified random sampling were used to capture the five specialties.

In the qualitative arm an explanatory sequential study the determination of the sample size was guided by the concept of data saturation. (Saunders et al., 2019) defined data saturation as the stage where no additional information can be gathered. The author recommended that a sample size of five to twenty participants is sufficient in qualitative research to reach data saturation. In a systematic review, (Saunders et al., 2019), noted that most descriptive phenomenological studies included between four and sixty-two participants. The researcher conducted interviews until saturation was achieved with 7 participants who were the KIIs.

The study sample size was determined using the Cochrane formula. The target population was 120 (total number of the 5 specialized surgeries done per month) samples. Out of the many specialties of surgery 5 were conveniently selected based on the length of time taken in the particular surgeries. This was a minimum of four hours. Averages of 3 surgeries are done in every working day excluding weekends. Every surgery done had a control and four samples each. The data was collected for an average of eight weeks. (3x5x8=120) thus less than 10,000.

$$n=z^2\ q/d^2$$

Where,

n=the desired sample size (if the target population is greater than 10,000)

z=the standard normal distribution at 95% confidence level (=1.96)

P=the expected population correlation coefficient (population effect size)

50% (large effect size) will be used to determine the sample size (state why 50% was used)

q=1-p

d=level of precision (set at +or -5% or 0.05)

Substituting these figures in the above formula:

N= $\underline{(1.96)^2(0.5)\ (0.5)}$

$(0.05)^2$

Since the target population is less than 10,000, the sample size is adjusted using the following formula:

nf=n/1+ (n/N)

Where nf = the desired sample size when population is less than 10,000

n=the desired sample size when population is more than 10,000

N=the estimate of population size which is 120.

Hence nf=384/1+384/120

1+3.2

=4.2

=384/4.2

=92

3.4.1 Sample Size According to Stratas

The stratas included the 5 surgical specialties Cardiothoracic surgeries, Neuro surgeries, Orthopaedic surgeries, Urology surgeries and General surgeries. P represents the number of surgeries in a speciality per month.Cn = P x n/N

Cn = Cardiac surgeries

10 x 92/120

= 8

Nn = P x n/N

Nn = Neuro

12 x 92/120

= 9

On = P x n/N

On = Orthopaedic surgeries

36 x 92/120

= 28

Un = P x n/N

Un = Urology Surgeries

22 x 92/120

= 17

Gn = P x n/N

Gn = General Surgery

40 x 91/120

=30

Total population sample

8+9+28+18+30

= 92

3.5 Inclusion Criteria

- Surgical patients who were received in the Receiving area of main theatres. They were due for surgery and were categorized among the five selected surgical specialties.
- They were free from any infections and gave consent for the study prior. This was verified from the full haemogram test where normal levels of the white blood cell count were verified. The normal range is between 4300-10800/cubic mm. Patients who recorded above the normal range were considered infected and therefore were excluded from the study. This is a mandatory test done for all patients due for surgery.
- The specialized surgery lasted a minimum of four hours. The specialties included Orthopaedics, Neuro surgery, Cardiothoracic surgery, General surgery and Urology.
- Sterile surgical instruments randomly selected from sterile surgical trays intraoperatively. The trays were opened in the presence of the researcher/ research assistant to verify no previous contamination.

3.6 Exclusion Criteria

- All surgical patients who had active infection.
- Patients who did not consent for the study.

- All surgical instruments of questionable sterility status. This included those which were opened in the absence of the researcher or research assistant, and the sterility band missing or tampered with.
- All surgical instruments of surgeries done under 4 hours.
- First positive instrument sample at 0 minute was excluded. This included all the other subsequent swabs of the surgical instruments and the surgical sites.

3.7 Sampling Technique - Qualitative

This study used purposive sampling, also referred to as selective sampling, a non-probability technique commonly applied in explanatory sequential research. This approach involved intentionally selecting participants based on their characteristics and the study’s objectives, focusing on specific traits, conditions, or phenomena that are key to the research questions. Purposive sampling was used to select key informants also called ‘information-rich cases’ who are assumed to be having a different perspective or information, willingness to talk, and better experience on the subject matter. This approach is crucial since it aimed to explore specific themes, patterns, or phenomena within a subset of a population, which requires detailed and nuanced insights.

Sampling concluded at 7 KIIs when data saturation had been achieved, ensuring that the data was comprehensive, rich, relevant, and thorough. By focusing on particular characteristics or experiences, this sampling allowed the researcher to delve into the depth and complexity of the subject matter, providing rich, detailed insights. The key objective of purposive sampling was to gain a deep understanding of the phenomena from a specific perspective or within a specific context. In essence, purposive sampling was used to extract meaningful and in-depth information from the selected group of participants, hence providing qualitative insights that are often unattainable through more generalized sampling methods.

The sample included Experts in the Perioperative professions. They are in the consultant level in their areas of specialization with vast experience in practice.

3.8. Variables

3.8.1 Independent Variables

- Surgery specialization; Orthopaedic surgery, Neuro surgery, Cardiothoracic surgery, General surgery and Urology surgeries.
- Duration of time during surgery; Time 0, 60 minutes, 120 minutes, 180 minutes and 240 minutes

3.8.2 Dependent Variables

- Microbial colonization (+/-) of the surgical instruments and the surgical sites.
- Types of microbial colonies

3.9 Study Tools

- A data collection check list was used to verify obtained samples collected from the surgical instruments and surgical sites.
- Standard lab request forms for culture and sensitivity were used in the microbiology laboratory.
- Key Informant Interview guide.

3.10 Data Collection

Data was collected by the following procedure;

3.10.1 The Surgical Site

- The surgical site was swabbed at 0 minute on commencement of surgery.
- Sterile swabs were obtained from the laboratory and were used to collect samples.
- The surgical site was again swabbed at the end of surgery
- All the samples were well labeled and transported to the department of Medical Microbiology of University of Nairobi for processing within two hours of

collection. If not within 2 hours it was refrigerated at 2-8^0c then taken for processing.

- The refrigerator was located at the reception area of the main theaters and is easily accessible by personnel from all the 12 operating rooms.

3.10.2 The Instruments

- On opening a sterile instrument tray one instrument was picked and placed on a sterile surface in the operating room separate from the instruments in use.
- The selected instrument was randomly selected to include either a haemostat, a retractor, a tissue forcep a dissecting instrument or a cutting instrument.
- Sterile swabs were obtained from the laboratory and were used to collect samples from the above instrument.
- Swabbing was done on the full length of the selected instrument.
- Swabs were collected on the instrument and this was done at intervals of 0 minutes. This was the control sample.
- Subsequently 60minutes, 120 minutes, 180 minutes and 240 minutes respectively.
- All the samples were well labeled and transported to the department of Medical Microbiology of the University of Nairobi for processing within two hours of collection. If not within 2 hours it was refrigerated at 2-8^0c then taken for processing.

3.10.3 In the Laboratory

Once in the Laboratory each swab was inoculated onto Blood Agar, MacConkey Agar and Sabo Raunds Dextrose Agar. The BA was incubated under 5- 10 percent Co2 to grow fastidious bacteria, MAC aerobically at 37°C for 18 – 24hrs while SDA was incubated at 25 °C for up to 5 days to grow fungi.

MacConkey Agar and Blood agar plates were checked for growth or No Growth. The plates with growth the bacteria identification were carried out by - Colonial morphological characteristics observed and noted. Initial identification was based on gram staining of pure isolates. Consequently, the colonies were subjected to biochemical tests depending with the gram staining reaction and microscopic morphology. These tests include Catalase test, Coagulase test, Urease test, Methyl Red test, Indole, Voges Proskauer test, motility test, lysine decarboxylase, Citrate utilization test, Tripple Sugar Iron agar and Oxidase test.

From Sabo Raunds Dextrose Agar after overnight incubation and up to 5 days (if no growth on the first day incubation) check for growth or no growth. If growth, check whether the colonial morphology is for yeasts or for molds. If growth was for yeasts grams stains were performed followed by biochemical tests for identification of yeasts. If growth of the fungi was molds will perform Lactophenol cotton blue microscopy for identification of the fungi.

Quality assurance measures in the laboratory included:

- The staff downed in Personal Protective Equipment (PPEs) to include face shields, face masks, gloves, lab coats and plastic aprons.
- Standard Operating Procedures (SOPs) were strictly adhered to during processing of the samples
- Aseptic technique and conditions were observed while collecting the samples. The principal investigator and research assistants were changing from street clothes into scrubs, caps and masks, then perform the surgical scrub, gown and glove before collecting the samples since this was during sterile surgical procedures.
- All the instruments, swabs and sample containers were sterilized. Verification was checked from the autoclaving machine calibrations and the instruments were tagged with autoclaving tape which turned black to indicate sterility of instruments and swabs.
- All the culture media was prepared aseptically and incubation was done to ensure no growth of microorganisms.
- Standard microorganisms available in the laboratory was used to quality control the work. It is a standard practice to have standard microorganisms in every laboratory to compare them with the cultured microbes from the samples received in the laboratory.

3.10.4 Research Assistants

The research assistants were two Medical Microbiologists. One of the two is a Perioperative Nurse trained as a theatre nurse. Their academic credentials are BSc. Medical Microbiology/ MSc. Medical Microbiology and BSc. Nursing/ KRPoN/ MSc. Medical Microbiology respectively. Their roles included random sampling of surgeries that last a minimum of four hours and omit those below four hours. Select patients and surgical instruments that fall in the inclusion criteria, collecting swabs at intervals as stated above, proper labeling of the samples and transporting them to the laboratory. Filling up the data collection check lists and lab request forms and filling the check list of the confounding factors as trained by the principal investigator. The principal investigator trained the research assistants and was part of the team in performing the above roles.

3.11 Pretesting of Study Tool

Pretesting of the data collection tools was done in the Trauma theatres of KNH which are situated in the Accident and Emergency department on the ground floor. This assisted the researcher to review the checklist. This included the checklists, data collection techniques and research ethics.

3.12 Data Cleaning and Entry

Data was scrutinized at the point of collection for accuracy and after the experimental process for completion and entered into a data base (Epi Info version 3.5.3).

3.13 Data Analysis

The data was coded, entered into Epi Info version 3.5.3 statistical package, and exported to SPSS version 25.0 software for analysis. At the beginning of the analysis, summation of the practice scale was made. Then, the variables were recoded and dichotomized. Descriptive statistics were used to illustrate the medians and interquartile ranges, and frequencies of the study variables. Time-to-event outcomes are common in medical research as they offer more information than simply whether or not an event occurred. To handle these outcomes, as well as censored observations where the event was not observed during follow-up, survival analysis methods were used. Kaplan-Meier estimation was used to create graphs of the observed survival curves, while the log-rank test was used to compare curves from different groups. If it was desired to test continuous predictors or to test multiple covariates at once, survival regression models such as the Cox model or the accelerated failure time model (AFT) was used. Odds ratios with 95% confidence interval was used to determine the strength of association between dependent and independent variables. *P* values less than or equal to 0.05 were considered as statistically significant. The differences in time to microbial colonization per surgical specialty was determined by Kruskal Wallis test (to compare the median times to infection per surgical specialty). Any sample that had no microbial growth by the end of the study time will be right censored. Any sample that had microbial growth at 0 minute will be left censored.

3.14 Data Presentation

The analyzed data was presented in the form of tables, box plots and survival curves.

3.15 Validity and Reliability of the Tool - Qualitative

In qualitative research, reliability and validity are assessed differently than in quantitative research due to the nature of qualitative data, which is often subjective and context-dependent. The study considered reliability and validity in the context of to explore strategies that will be used to minimize microbial colonization of surgical instruments and surgical sites intraoperatively.

3.15.1 Credibility (Internal Validity)

To enhance credibility, techniques such as member checking, sharing of the findings with participants to ensure their accuracy and interpretation of the data was used.

3.15.2 Transferability (External Validity)

To enhance transferability, a detailed description of the research context, participants, and data collection procedures was provided so that readers can assess the relevance of the findings to other situations.

3.15.3 Dependability (Reliability)

A clear audit trail was maintained, which documented all decisions made during the research process, this contributed to dependability.

3.15.4 Confirm Ability (Objectivity)

To enhance confirmability, there was engagement in reflexivity by acknowledging and documenting own biases and how they may have influenced the research.

3.16 Data collection Procedure - Qualitative

An introductory letter from the institution was provided to introduce the research study. The researcher was then scheduled to conduct interviews with the respondents. In-depth interviews (IDI), key informant interviews (KIIs) were conducted in a face-to-face manner.

In-Depth Interviews (IDI): In-depth interviews were conducted individually with the respondents. These interviews were provided a platform for a detailed exploration of the participants' experiences, perceptions, and insights related to the research topic. Each IDI was expected to last approximately 20 minutes to 30 minutes. The researcher conducted and recorded these interviews with the assistance of a trained research team to ensure a comprehensive and confidential exchange of information.

Key Informant Interviews (KII): Key informant interviews were individually conducted with relevant experts and this included surgeons, perioperative nurses and anaesthesiologists. These interviews were delved into their experiences and strategies to explore on minimizing and elimination of microbial colonization of surgical instruments and surgical sites intraoperatively and any recommendations for improvement. The duration of KII varied depending on the depth of insights provided but was expected to range from 20 minutes to 30 minutes. Audio recording and detailed note-taking was used to ensure the accurate capture of information.

3.17 Data Management - Qualitative

3.17.1 Data Analysis and Presentation

Data from interviews was transcribed, coded, and analyzed thematically. Themes related to proper surgical instruments sterilization, change of instruments and other surgicals intraoperatively and suggestions for improvement were identified, each theme had an independent code. These themes helped in understanding how to minimize microbial colonization intraoperatively in the operating theatres. Themes were generated through Colaizzi’s seven step framework. Colaizzi thematic analysis is a qualitative research method used to analyze data, particularly from interviews, to understand the meaning of lived experiences. It involves a structured seven-step process, starting with reading transcripts and identifying significant statements, and culminating in a detailed description of the phenomenon being studied validated by the participants.

Initial Steps include Reading and Identifying Key Statements data analysis begins with reading the interview transcripts and carefully identifying significant statements that capture the essence of the lived experience. The second step involves Developing Meanings and Themes. Researchers then interpret these significant statements, extracting the underlying meanings and ideas. These meanings are then grouped and categorized into themes, representing overarching concepts that emerge from the data. The third step is Describing and Validating. A descriptive account of the phenomenon is developed based on the identified themes. Finally, the findings are validated by ensuring the participants' perspectives are reflected in the analysis and that the description is an accurate representation of their lived experience.

Benefits of Colaizzi Analysis are:

Rigorous and Structured: The seven-step process ensures a systematic and thorough analysis.

Participant-Centered: The method emphasizes the participants' perspectives and experiences, ensuring the analysis reflects their understanding of the phenomenon.

Rich and Detailed Descriptions: The method allows for a detailed and nuanced description of the phenomenon under study.

In essence, Colaizzi thematic analysis is a method for exploring the meaning of lived experiences through a structured and rigorous process, ultimately providing a rich and detailed description of the phenomenon being studied. Finally, validating the findings was accomplished by comparing the researcher’s descriptive results with experts’ experiences.

Explanatory sequential was employed to cross-verify findings from the quantitative data and the qualitative data from the key informants. This will enhance the validity and reliability of the study's conclusions. The data will be presented as themes in tables and illustrative quotes for the raw data.

3.18 Ethical Consideration

Before conducting the study, the research proposal ethical review and permissions were sought at;

- Kenyatta National Hospital, University of Nairobi Research Ethics Committee for approval. (KNH/UoN/ERC) (*P65/02/2021)*
- Permission to carry out the study in KNH was sought from the Kenyatta National Hospital Theatres department administration.
- Permission was sought from Jomo Kenyatta University of Agriculture and Technology Board of Postgraduate Studies. (JKUAT BPS)

- Permission was sought from National Commission for Science, Technology and Innovation. (NACOSTI). (*NACOSTI 166233*.)

The patients' population who fulfilled the inclusion criteria was voluntarily given consent forms to participate in the study. The raw data was kept in a safe under key and lock and can be accessible to the authorized persons only. The documents remain under safe custody for ten years before destruction according to research documents ethics. The study results were presented to KNH management and recommendations given. The work has been published in two scientific journals and presented in three scientific conferences.

The study participants were informed about the study's objectives and potential benefits prior to providing their signed informed consent. They were as well be informed that the information they will have shared will be treated as unanimous and confidential. Likewise, respondents were informed that their involvement in the study is voluntary, and they have the freedom to withdraw from the study at any point before its completion. During the interview, the study participants will be known and identified by codes. They were also be informed that the study will carry no monetary as well as other direct benefits, but it will be utilized by the management for improvement.

Confidentiality and originality were maintained through proper citation, cross-referencing, and listing all scientific sources at the end of the report. The study will adhere to the APA referencing style throughout.

Autonomy: Participants were assured that their safety is a top priority and that the risks involved will be minimal. In the event of any discomfort during the study, the researcher will take prompt action to offer required support. However, such issues are not expected to occur.

Confidentiality and Privacy: At the start of the interview, the researcher will reassure respondents of their confidentiality and anonymity. For example, participants will be assigned codes in place of their names. Their information will remain confidential, and the findings will be presented without revealing their identities. To safeguard privacy, the interview will be conducted in the manager's office within the operating theatres.

Beneficence: Participants were informed that the study will not offer any financial rewards or direct benefits. However, the findings will be used by management to improve their well-being through the development and implementation of policies.

Justice: The researcher ensured fairness and justice throughout the data collection process. For example, the inclusion and exclusion criteria will be applied equitably to ensure that participants with the relevant information are able to share their experiences with the investigator.

Risks: The participants were not predisposed to any physical nor economic risks when taking part in the study. However, the study required them to take some time off their busy schedule for an interview. They were encouraged to express their thoughts, feelings, and experiences at their own pace and comfort level. The researcher actively listened, provided reassurance, and validated their emotions throughout the interview process.

Key Informant Interviews guides: Individual interviews were conducted with key informants, including perioperative nurses in management level, Surgeons of consultancy level, and anaesthesiologists of consultancy level. These interviews were in-depth and detailed discussions, and their duration varied depending on the complexity of the information provided. On average, these interviews lasted between 17 minutes to 20 minutes, allowing ample time for key informants to share their perspectives and insights regarding strategies to employ to minimize microbial colonization on surgical instruments and surgical sites intraoperatively. Saturation was reached when in the course of interviewing the same themes kept coming up repeatedly and more than ¾ of the participants had been interviewed.

Recording: All interviews were audio-recorded using a Samsung Galaxy A32 mobile phone to ensure the accuracy of data capture. The use of audio recording was to facilitate the comprehensive documentation of the discussions and aid in subsequent analysis. Informed consent was sought from key informants regarding the recording of the interviews to ensure compliance with ethical and privacy considerations. Additionally, detailed field notes were taken during the interviews to complement the audio recordings and provide immediate insights for subsequent analysis.

The code of conduct that guides our behavior and how we interact with other people is called morality. The moral principles are:

3.18.1 Informed Consent

Ensuring the ethical treatment of participants is paramount in this research. Prior informed consent will be obtained from all participants, guaranteeing their voluntary and informed engagement in the study. Participants will be provided with comprehensive information about the research's purpose, procedures, potential risks, and benefits. They will also be informed of their right to withdraw from the study at any point without facing any consequences. Informed consent forms will be utilized to document participants' voluntary agreement, promoting transparency and respect for their autonomy.

3.18.2 Confidentiality

Safeguarding the privacy and confidentiality of participants is a core ethical principle in this research. To protect their identities and personal information, a coding system or pseudonyms was assigned to each participant. All data collected, including audio recordings, transcripts, and written notes, was stored securely and anonymously. Researchers took every precaution to ensure that sensitive information shared during interviews remained confidential, reinforcing trust between the researchers and key informants' interviewers. Identities of the respondents were kept private and confidential.

3.18.3 Institutional Review

Ethical approval was sought from the Kenyatta national Hospital and University of Nairobi Ethics and Research Committee. The ethical review process is vital to assess the research's adherence to ethical guidelines, participant protections, and the study's overall ethical soundness. Recommendations and modifications suggested by the ERC were promptly addressed and implemented to ensure that the research was conducted ethically and with due diligence, promoting the welfare and rights of all participants involved in the conversation with the interviewer.

3.18.4 Dissemination

The results of this study have been presented in 4 Perioperative scientific conferences, three local and one international conference. The work has been published in 3 journals. The results were also presented to the management and the perioperative teams of the Kenyatta National Hospital.

CHAPTER FOUR

RESULTS

This chapter presents the results to answer the research questions of the four objectives sequentially. The results are presented in form of tables, graphs and verbatims. They include the following:

4.1 Response Rate

A sample size of 92 patients was targeted. The number of patients recruited were 92, making a response rate of 100%. According to Mugenda and Mugenda (2003), a response rate of 50% is adequate for data analysis and reporting; a rate of 60% is good and a response rate 70% and over is excellent.

4.2 Time taken for Microbial Colonization on Surgical Instruments and Surgical Sites

4.2.1 Surgical Instrument Microbial Colonization

More than half of the instruments were colonized by micro-organisms intra-operatively (51.6%; n=48). Table 4.1 displays the results.

Table 4.1: Surgical Instrument Colonization

	Frequency	Percent	Cumulative Percent
Not Colonized	45	48.4	48.4
Colonized	48	51.6	51.6
Total	93	100	

4.2.2 Surgical Site Microbial Colonization

The surgical site pre-surgery, 11.8%; (n=11) patients had microbial colonization. A third of the population got post-surgery microbial colonization on the surgical site

(31.2%; n=29). The cumulative incidence of microbial colonization was 269 per 1000 patients (N=25).

The prevalence was 34.4% (344 per 1000 patients). Some patients got a secondary microbial colonization intra-operatively.

Table 4.2: Occurrence of Surgical Site Microbial Colonization

		Frequency	**Percent**
Pre-surgery patient status	No growth	82	88.2
	Colonized	11	11.8
Post-surgery patient status	No growth	64	68.8
	Colonized	29	31.2
Incidence	NO	68	73.1
	YES	25	26.9
Prevalence	NO	61	65.6
	YES	32	34.4

4.2.3 Time to Microbial Colonization on the Surgical Instrument

Seventy five percent (75%) of the surgical instruments survived microbial colonization at zero minutes (a quarter of the instruments were colonized at zero minute). Sixty two percent of the surgical instruments survived microbial colonization at 60 minutes. Fifty five percent of the surgical instruments survived microbial colonization at 120 minutes. Fifty one percent (half) of the surgical instruments survived the microbial colonization at 180 minutes. Forty seven percent of the surgical instruments survived microbial colonization at 240 minutes. The median time to colonization was 230 minutes while the mean was 240 minutes. Tables, 4.3, 4.4 and figure 4.1 & 4.2 displays the results.

Table 4.3: Survival Table for Surgical Instruments

ID	Time	Status	Cumulative Proportion Surviving at the Time		N of Cumulative Events	N of Remaining Cases
			Estimate	Std. Error		
1	0	Colonized	.	.	1	92
2	0	Colonized	.	.	2	91
3	0	Colonized	.	.	3	90
4	0	Colonized	.	.	4	89
5	0	Colonized	.	.	5	88
6	0	Colonized	.	.	6	87
7	0	Colonized	.	.	7	86
8	0	Colonized	.	.	8	85
9	0	Colonized	.	.	9	84
10	0	Colonized	.	.	10	83
11	0	Colonized	.	.	11	82
12	0	Colonized	.	.	12	81
13	0	Colonized	.	.	13	80
14	0	Colonized	.	.	14	79
15	0	Colonized	.	.	15	78
16	0	Colonized	.	.	16	77
17	0	Colonized	.	.	17	76
18	0	Colonized	.	.	18	75
19	0	Colonized	.	.	19	74
20	0	Colonized	.	.	20	73
21	0	Colonized	.	.	21	72
22	0	Colonized	.	.	22	71
23	0	Colonized	0.753	0.045	23	70
24	0	Not Colonized	.	.	23	69
25	0	Not Colonized	.	.	23	68
26	60	Colonized	.	.	24	67
27	60	Colonized	.	.	25	66
28	60	Colonized	.	.	26	65
29	60	Colonized	.	.	27	64
30	60	Colonized	.	.	28	63
31	60	Colonized	.	.	29	62
32	60	Colonized	.	.	30	61

33	60	Colonized	.	.	31	60
34	60	Colonized	.	.	32	59
35	60	Colonized	.	.	33	58
36	60	Colonized	.	.	34	57
37	60	Colonized	0.62	0.051	35	56
38	120	Colonized	.	.	36	55
39	120	Colonized	.	.	37	54
40	120	Colonized	.	.	38	53
41	120	Colonized	.	.	39	52
42	120	Colonized	.	.	40	51
43	120	Colonized	0.553	0.052	41	50
44	180	Colonized	.	.	42	49
45	180	Colonized	.	.	43	48
46	180	Colonized	.	.	44	47
47	180	Colonized	0.509	0.052	45	46
48	195	Not Colonized	.	.	45	45
49	200	Not Colonized	.	.	45	44
50	205	Not Colonized	.	.	45	43
51	215	Not Colonized	.	.	45	42
52	220	Not Colonized	.	.	45	41
53	225	Not Colonized	.	.	45	40
54	225	Not Colonized	.	.	45	39
55	230	Not Colonized	.	.	45	38
56	230	Not Colonized	.	.	45	37
57	240	Colonized	.	.	46	36
58	240	Colonized	.	.	47	35
59	240	Colonized	0.468	0.053	48	34
60	240	Not Colonized	.	.	48	33
61	240	Not Colonized	.	.	48	32
62	240	Not Colonized	.	.	48	31
63	240	Not Colonized	.	.	48	30
64	240	Not Colonized	.	.	48	29
65	240	Not Colonized	.	.	48	28
66	240	Not Colonized	.	.	48	27
67	242	Not Colonized	.	.	48	26
68	243	Not Colonized	.	.	48	25
69	245	Not Colonized	.	.	48	24
70	255	Not Colonized	.	.	48	23

71	255	Not Colonized	.	.	48	22
72	259	Not Colonized	.	.	48	21
73	265	Not Colonized	.	.	48	20
74	270	Not Colonized	.	.	48	19
75	280	Not Colonized	.	.	48	18
76	284	Not Colonized	.	.	48	17
77	288	Not Colonized	.	.	48	16
78	288	Not Colonized	.	.	48	15
79	290	Not Colonized	.	.	48	14
80	295	Not Colonized	.	.	48	13
81	299	Not Colonized	.	.	48	12
82	300	Not Colonized	.	.	48	11
83	303	Not Colonized	.	.	48	10
84	310	Not Colonized	.	.	48	9
85	315	Not Colonized	.	.	48	8
86	315	Not Colonized	.	.	48	7
87	335	Not Colonized	.	.	48	6
88	345	Not Colonized	.	.	48	5
89	351	Not Colonized	.	.	48	4
90	358	Not Colonized	.	.	48	3
91	380	Not Colonized	.	.	48	2
92	420	Not Colonized	.	.	48	1
93	420	Not Colonized	.	.	48	0

4.2.4 Survival Function for the Surgical Instruments

The mean survival time for the microbial colonization of the instruments was 230 Minutes (95%CI: 192 to 269). The median time was 240 minutes (Four hours). Meaning 50% of the surgical instruments were colonized at 4 hours. The longer the surgery the higher the risk of microbial colonization.

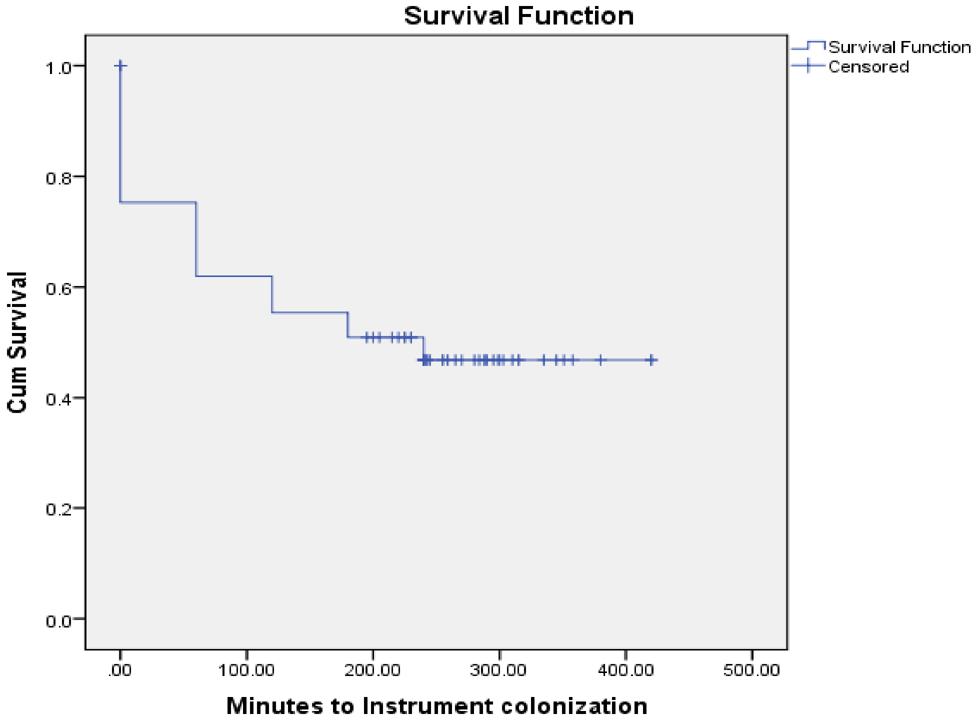

Figure 4.1: Censored Indicate the Surgery Ended before the Event Occurred (Microbial Colonization)

Table 4. 4: Mean and Median Survival Time

Means and Medians for Survival Time

Mean				Median			
Estimate	Std. Error	95% Confidence Interval		Estimate	Std. Error	95% Confidence Interval	
		Lower Bound	Upper Bound			Lower Bound	Upper Bound
230.33	19.551	192.011	268.649	240	.	.	.

a Estimation is limited to the largest survival time if it is censored.

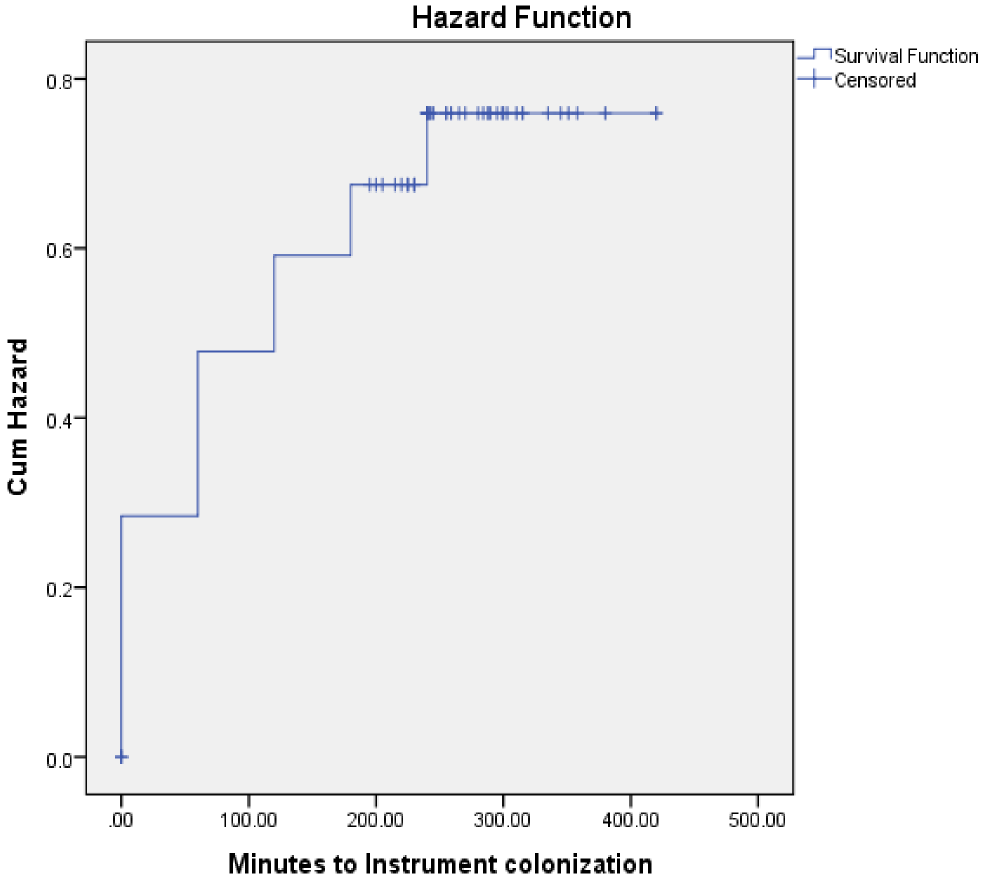

Figure 4.2: Hazard Function for the Surgical Instruments

4.2.5 Time to Microbial Colonization on the Surgical Site (Patient)

Ninety nine percent (99%) of the of the surgical sites (patients) survived microbial colonization at 195 minutes (only 1% was colonized at 195 minutes). A proportion of 96.5% and 95% of the of the surgical sites (patients) survived microbial colonization at 230 and 234 minutes respectively (only 3.5% and 5% of the surgical sites were colonized at 230 & 234 minutes respectively).

Approximately 92% and 90% of the of the surgical sites (patients) survived microbial colonization at 240 and 250 minutes respectively. 88% and 86 % of the surgical sites (patients) survived microbial colonization at 265 and 272 minutes respectively. 83% and 81% of the surgical sites (patients) survived microbial colonization at 280 and 285 minutes respectively. Seventy-nine (79%) and approximately 77% of the surgical sites (patients) survived microbial colonization at 288 and 290 minutes respectively. Seventy-three (73%) and 71% of the surgical sites (patients) survived microbial colonization at 295 and 297 minutes respectively. 68% and 64% of the surgical sites (patients) survived microbial colonization at 300 and 302 minutes respectively. 61% and 57% of the surgical sites (patients) survived microbial colonization at 303 and 315 minutes respectively.

Fifty two (52%) and 47% of the surgical sites (patients) survived microbial colonization at 345 and 351 minutes respectively. 42% and 21% of the surgical sites (patients) survived microbial colonization at 358 and 420 minutes respectively.

Table 4. 5: Time to Microbial Colonization for the Surgical Sites Intra-operatively

Survival Table						
	Time	**Status**	**Cumulative Proportion Surviving at the Time**		**N of Cumulative Events**	**N of Remaining Cases**
			Estimate	**Std. Error**		
1	195	YES	0.989	0.011	1	92
2	200	NO	.	.	1	91
3	205	NO	.	.	1	90
4	210	NO	.	.	1	89
5	215	NO	.	.	1	88
6	220	NO	.	.	1	87
7	220	NO	.	.	1	86
8	220	NO	.	.	1	85
9	225	NO	.	.	1	84
10	225	NO	.	.	1	83
11	230	YES	.	.	2	82
12	230	YES	0.965	0.02	3	81
13	230	NO	.	.	3	80
14	234	YES	0.953	0.023	4	79
15	240	YES	.	.	5	78
16	240	YES	.	.	6	77
17	240	YES	0.917	0.03	7	76

18	240	NO	.	.	7	75
19	240	NO	.	.	7	74
20	240	NO	.	.	7	73
21	240	NO	.	.	7	72
22	240	NO	.	.	7	71
23	240	NO	.	.	7	70
24	240	NO	.	.	7	69
25	240	NO	.	.	7	68
26	240	NO	.	.	7	67
27	240	NO	.	.	7	66
28	242	NO	.	.	7	65
29	243	NO	.	.	7	64
30	244	NO	.	.	7	63
31	245	NO	.	.	7	62
32	245	NO	.	.	7	61
33	245	NO	.	.	7	60
34	248	NO	.	.	7	59
35	248	NO	.	.	7	58
36	250	YES	0.901	0.033	8	57
37	250	NO	.	.	8	56
38	250	NO	.	.	8	55
39	251	NO	.	.	8	54
40	255	NO	.	.	8	53
41	255	NO	.	.	8	52
42	255	NO	.	.	8	51
43	255	NO	.	.	8	50
44	257	NO	.	.	8	49
45	259	NO	.	.	8	48
46	260	NO	.	.	8	47
47	260	NO	.	.	8	46
48	265	YES	0.882	0.038	9	45
49	270	NO	.	.	9	44
50	270	NO	.	.	9	43
51	270	NO	.	.	9	42
52	270	NO	.	.	9	41
53	272	YES	0.86	0.043	10	40
54	280	YES	0.839	0.047	11	39
55	280	NO	.	.	11	38

56	280	NO	.	.	11	37
57	280	NO	.	.	11	36
58	284	NO	.	.	11	35
59	285	YES	0.815	0.051	12	34
60	288	YES	0.791	0.055	13	33
61	288	NO	.	.	13	32
62	290	YES	0.766	0.059	14	31
63	291	NO	.	.	14	30
64	292	NO	.	.	14	29
65	292	NO	.	.	14	28
66	295	YES	0.739	0.063	15	27
67	297	YES	0.711	0.066	16	26
68	299	NO	.	.	16	25
69	299	NO	.	.	16	24
70	300	YES	0.682	0.07	17	23
71	300	NO	.	.	17	22
72	300	NO	.	.	17	21
73	300	NO	.	.	17	20
74	302	YES	0.648	0.074	18	19
75	303	YES	0.614	0.078	19	18
76	310	NO	.	.	19	17
77	315	YES	0.577	0.081	20	16
78	315	NO	.	.	20	15
79	315	NO	.	.	20	14
80	321	NO	.	.	20	13
81	333	NO	.	.	20	12
82	335	NO	.	.	20	11
83	345	YES	0.525	0.089	21	10
84	351	YES	0.472	0.094	22	9
85	358	YES	0.42	0.097	23	8
86	360	NO	.	.	23	7
87	366	NO	.	.	23	6
88	370	NO	.	.	23	5
89	380	NO	.	.	23	4
90	420	YES	.	.	24	3
91	420	YES	0.21	0.116	25	2
92	440	NO	.	.	25	1
93	460	NO	.	.	25	0

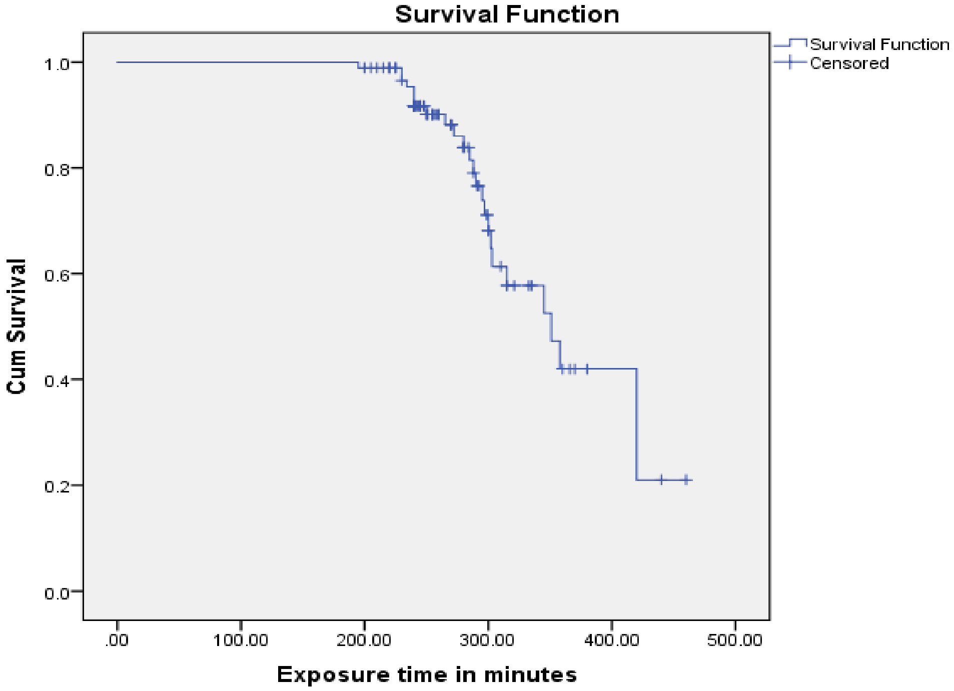

Figure 4.3: Kaplan Meier Survival Function for the Time to Microbial Colonization Intra-operatively

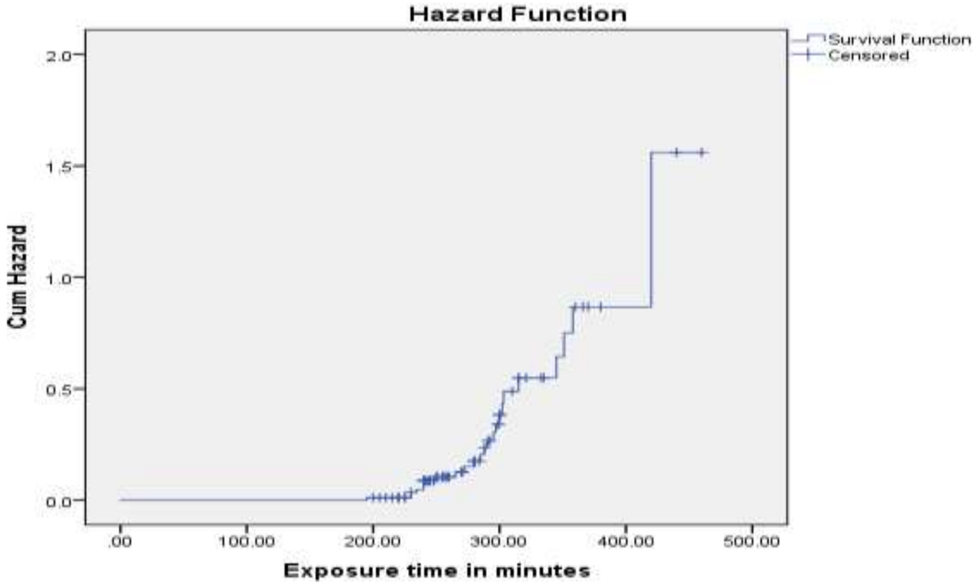

Figure 4.4: Hazard Function for Surgical Site Microbial Colonization Intra-Operatively

The median time for a patient to get microbial colonization was 351 minutes (95%CI: 301 to 401)

Table 4.6: Means and Medians for Survival Time for Surgical Site Microbial Colonization

Means and Medians for Survival Time							
Mean				Median			
Estimate	Std. Error	95% Confidence Interval		Estimate	Std. Error	95% Confidence Interval	
		Lower Bound	Upper Bound			Lower Bound	Upper Bound
358.204	13.224	332.284	384.124	351	25.749	300.532	401.468

a Estimation is limited to the largest survival time if it is censored.

4.3 Types of Microbial Colonization Pre- Surgery on the Surgical Sites

The *staphylococcus* species were predominantly responsible for majority (7.7%) of the microbial colonization on the surgical site pre surgery. The types of species include *staphylococcus aureus, staphylococcus coagulase negative and staphylococcus proteus*. *Bacillus* species was 3.3%, *klebsiella* 2.2% and *Escherichia coli* at 1.1%. This is illustrated in table 4.7 below.

Table 4.7: Types of Microbial Colonization Pre- Surgery on the Surgical Sites

	Frequency	**Percent**
Bacillus Species	1	1.1
Bacillus Species, Coagulase Staphylococci, Staphylococcus Aureus	1	1.1
Bacillus Species, Proteus Species, Klebsiella Species	1	1.1
Coagulase Negative Staphylococcus	3	3.3
Coagulase Negative Staphylococcus Proteus Species	1	1.1
Escherichia Coli	1	1.1
Klebsiella Species	1	1.1
No Growth	82	88.2
Staphylococcus Aureus	2	2.2
Total	93	100

4.4 Types of Microbial Colonization Post-Surgery on the Surgical Sites

Table 4.8 illustrates *Staphylococcus species* formed the majority of microbial colonization of the surgical site postoperatively at *20.6%. Bacillus species* remained the same proportion at 3.3% as at pre-surgery, *micrococcus species 3.3%* and it is noted that it was not present pre surgery. *Klebsiella species 2.2%, Acinetobacter baumannii* and *enterococcus faecalis* each at 1% and were not present pre surgery.

Table 4.8: Types of Microbial Colonization Post-Surgery on the Surgical Sites

	Frequency	Percent
Bacillus Species	3	3.2
Coagulase Negative Staphylococci	1	1.1
Coagulase Staphylococcus Aureus	1	1.1
Micrococcus	1	1.1
Staphylococcus Aureus	15	16.2
Staphylococcus Aureus, Enterococcus Faecalis	1	1.1
Acinetobacter Baumannii	1	1.1
Enterococcus Faecalis	1	1.1
Klebsiella Species	2	2.2
Micrococcus Species	2	2.2
No Growth	64	68.8
Staphylococcus Proteus Species	1	1.1
Total	93	100

4.5 Types of Microbial Colonization on Surgical Instruments at Time Zero

Pre surgery instruments are sterile and assumed to be free from microbial colonization. However, figure 4.9 shows the microbial colonization on instruments at time zero as follows: *Staphylococcus species* was dominant at 9.8%, *candida species was 8.8%, bacillus species 4.4%, Acinetobacter baumanii 3.3%, enterococcus faecalis, micrococcus species and pseudomonas species at 2.2% respectively and klebsiella species at 1%.*

Table 4.9: Types of Microbial Colonization on Surgical Instruments at Time Zero

	Frequency	Percent
Bacillus Species, Acinetobacter Baumanii	1	1.1
Candida Species	7	7.7
Staphylococcus Aureus	5	5.4
Staphylococcus Aureus, Bacillus Species	1	1.1
Acinetobacter Baumannii, Bacillus Species	1	1.1
Acinetobacter Baumannii	1	1.1
Bacillus Species	1	1.1
Coagulase Negative Staphylococcus	3	3.3
Enterococcus Faecalis	2	2.2
Klebsiella Species	1	1.1
Micrococcus Species, Candida Species	1	1.1
Micrococcus Species	1	1.1
No Growth	66	71
Pseudomonas Species	2	2.2
Total	93	100

4.6 Types of Microbial Colonization on Surgical Instrument at 60 Minutes

Table 4.10 illustrates Microbial colonization of surgical instruments at 60 minutes was as follows: *staphylococcus species* was at 13%, *Candida species* was 10%, *bacillus species* was 6.6%, *Acinetobacter baumanii* was 3.3%, *Escherichia coli* and *micrococcus species at* 2.2% respectively*, enterococcus faecalis, proteus species and pseudomonas species* was at 1.1% respectively.

Table 4.10: Types of Microbial Colonization on Surgical Instrument at 60 Minutes

	Frequency	**Percent**
Bacillus Species, Staphylococcus Aureus	2	2.2
Bacillus Species, Escherichia Coli	1	1.1
Candida Species	9	9.9
Staphylococcus Aureus	7	7.5
Staphylococcus Aureus, Bacillus Species	1	1.1
Acinetobacter Baumanii	1	1.1
Bacillus Species	1	1.1
Bacillus Species, Acinetobacter Baumanii	1	1.1
Candida Species, Acinetobacter Baumanii	1	1.1
Coagulase Negative Staphyloccoci	2	2.2
Escherichia Coli	1	1.1
Enterococcus Faecalis	1	1.1
Micrococcus Species	1	1.1
No Growth	61	65.6
Proteus Species	1	1.1
Pseudomonas Species	1	1.1
Micrococcus species	1	1.1
Total	93	100

4.7 Types of Microbial Colonization on Surgical Instrument at 120 Minutes

Table 4.11 illustrates microbial colonization of instruments at 120 minutes as follows: *Staphylococcus species* was at 17.4%, *Candida species* was 9.7%, *bacillus species* was 4.4%, *pseudomonas species* was 4.3%, *acinetobacter baumannii, Escherichia coli, micrococcus species* was at 1.1% respectively *and a new entry of citrobacter species* was at 1.1%.

Table 4.11: Types of Microbial Colonization on Surgical Instrument at 120 Minutes

	Frequency	Percent
Staphylococcus Aureus	5	5.5
Acinetobacter Baumannii, Bacillus Species	1	1.1
Bacillus Species, Coagulase Negative Staphylococci	1	1.1
Candida Species	8	8.6
Candida Species, Gram Negative , Catalase Positive	1	1.1
Citrobacter Species	1	1.1
Coagulase Negative Staphylococci	7	7.5
Coagulase Negative Staphylococci, Klebsiella Species	2	2.2
Escherichia Coli	1	1.1
Micrococcus Species	1	1.1
No Growth	60	64.6
Pseudomonas Species	3	3.2
Pseudomonas Species, Bacillus Species	1	1.1
Staphylococcus Aureus, Bacillus Species	1	1.1
Total	93	100

4.8 Types of Microbial Colonization on Surgical Instrument at 180 Minutes

At 180 minutes the following microorganisms were cultured on surgical instruments as illustrated in table 4.12. *staphylococcus species 14.1%, candida species 11.9%, bacillus species 5.5%, pseudomonas species 4.4%, acinetobacter baumannii, Escherichia coli, micrococcus species at 1.1%* respectively.

Table 4.12: Types of Microbial Colonization on Surgical Instrument at 180 Minutes

	Frequency	**Percent**
Enterobacter Faecalis	2	2.2
Bacillus Species, Pseudomonas Species	2	2.2
Staphylococcus Aureus, Bacillus Species	1	1.1
Acinetobacter Baumannii, Coagulase Negative Staphylococci	1	1.1
Bacillus Species	2	2.2
Staphylococcus Aureus	1	1.1
Candida Species	10	10.8
Candida Species, Enterococcus Faecalis	1	1.1
Catalase Positive	1	1.1
Coagulase Negative Staphylococci	5	5.4
Gram Positive Rods	1	1.1
Escherichia Coli	1	1.1
Gram Negative Rods	1	1.1
Micrococcus Species	1	1.1
No Growth	56	60.3
Pseudomonas Species	2	2.2
Staphylococci Aureus	5	5.4
Total	93	100

4.9 Types of Microbial Colonization on Surgical Instrument at 240 Minutes

At 240 minutes the following microorganisms were cultured on surgical instruments as illustrated in table 4.13. *staphylococcus species 12%, candida species 8.7%, bacillus species 6.6%, pseudomonas species 3.3%, acinetobacter baumannii 3.3%, klebsiella 1.1%, micrococcus species, enterococcus feacalis at 1.1%* respectively. Mc-Lf species at 1.1%

Table 4.13: Types of Microbial Colonization on Surgical Instrument at 240 Minutes

	Frequency	Percent
Bacillus Species	2	2.2
Acinetobacter Baumannii	2	2.2
Bacillus Species, Acinetobacter Baumannii	1	1.1
Bacillus Species, Pseudomonas Species	1	1.1
Candida Species	8	8.7
Staphylococcus Aureus	5	5.5
Staphylococcus Aureus,+Ve Bacillus	1	1.1
Gram Negative Colonies	1	1.1
Enterococcus Faecalis, Bacillus Species	1	1.1
Gram -Ve, Candida Species, Catalase -Ve	1	1.1
Klebsiella Species	1	1.1
Mac¬Lf Species	1	1.1
Micrococcus Species	1	1.1
No Growth	59	63.4
Pseudomonas Species	2	2.2
Pseudomonas Species, Gram positive Bacillus	1	1.1
Staphylococci Aureus -Ve	5	5.4
Total	93	100

4.10 Comparison of Survival Function for Surgery Specialization and Surgical Site Microbial Colonization

There was no statistical significance difference between the (survival functions) time to microbial colonization and the surgery specialization as per the log rank test. All urology patients 100% did not get microbial colonization. 75% of the cardiovascular patients survived microbial colonization by 300 minutes (5 hours). Microbial colonization was evident at 180 minutes for the general patients (90% survived at 180 Minutes) with a median of 300 minutes. 50% of the general surgery patients were colonized by 300 minutes. Half of the orthopedic surgery patients were colonized by 300 minutes. Half of the neuro patients were colonized at 340 minutes. The results are displayed in figure 4.5 and table 4.14. To take care of confounding factors the cox-regression was performed.

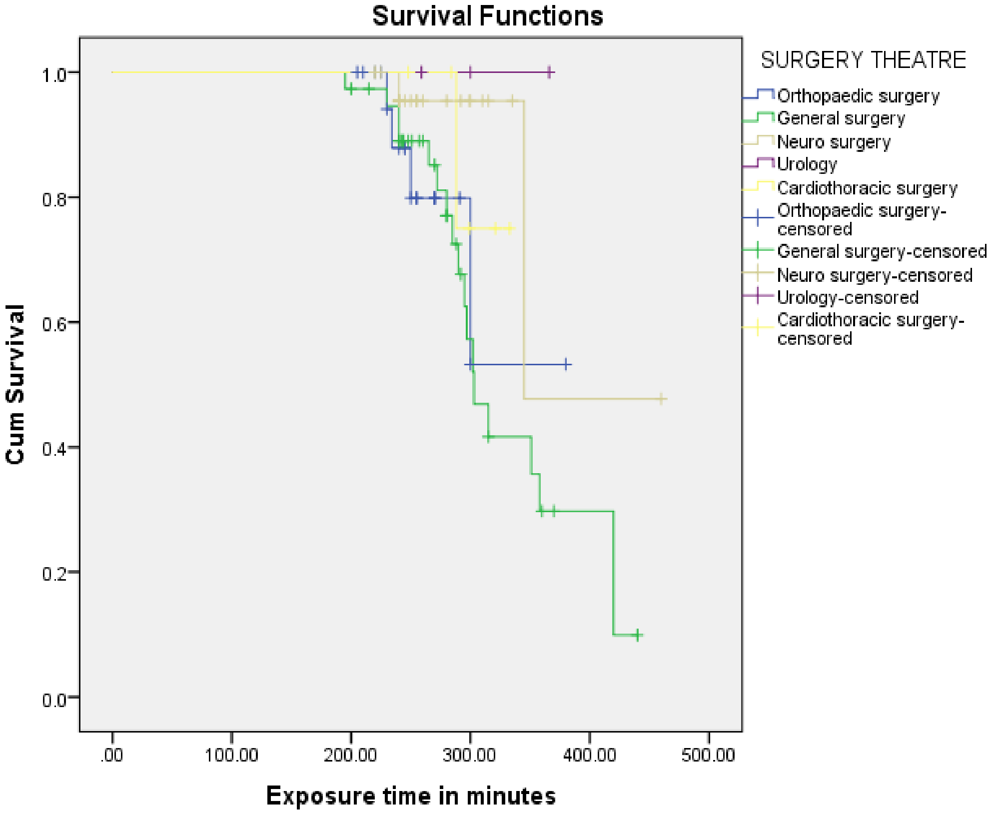

Figure 4.5: Survival Function for Surgery Specialization and Surgical Site Microbial Colonization

Table 4.14: Relationship between Type of Surgery Specialization and Instruments' Microbial colonization Time

Overall Comparisons			
	Chi-Square	**df**	**P-value.**
Log Rank (Mantel-Cox)	4.051	1	0.054
Breslow (Generalized Wilcoxon)	3.542	1	0.06
Tarone-Ware	3.956	1	0.057

There was no statistical association. The colonization was not different for the various surgery specializations meaning the microbial colonization on the instruments was not dependent on the type of surgical instrument set. This is illustrated in table 4.15.

Table 4.15: Cox Regression Table on Relationship between Surgery Specialization and Instrument Microbial Colonization

Variables in the Equation								
	B	**SE**	**Wald**	**df**	**P-value.**	**OR**	**95.0% CI for OR**	
							Lower	**Upper**
Surgery Speciality			2.094	4	0.719			
Orthopaedic	0.301	0.636	0.224	1	0.636	1.352	0.388	4.705
General	-0.129	0.624	0.043	1	0.836	0.879	0.259	2.985
Neuro	-0.15	0.646	0.054	1	0.816	0.861	0.243	3.051
Urology	-0.522	1.155	0.204	1	0.651	0.593	0.062	5.71
Cardiovascular	Reference							

4.11: Relationship between Type of Surgery Specialization and Surgical Site Microbial Colonization Time

There was no statistical association. The microbial colonization on the surgical site was not associated with the type of surgery specialization as illustrated in table 4.16

Table 4. 16: Cox Regression Table on Relationship between Surgery Specialization and Surgical Site Microbial Colonization

Variables in the Equation								
	B	**SE**	**Wald**	**df**	**P-value.**	**OR**	**95.0% CI for OR**	
							Lower	**Upper**
Surgery Speciality			4.43	4	0.351			
Orthopaedic	0.93	1.125	0.684	1	0.408	2.536	0.279	23.022
General	1.023	1.035	0.977	1	0.323	2.782	0.366	21.172
Neuro	-0.414	1.228	0.113	1	0.736	0.661	0.06	7.341
Urology	-12.463	619.195	0	1	0.984	0	0	.
Cardiovascular	Reference							

4.12 Comparison between Type of Surgery Specialization and Instrument Colonization Time

There was no statistical significance difference between the surgery specializations on the issue of instrument microbial colonization. The time to infection was not dependent on the surgery specialization. This is illustrated on table 4.17 below.

Table 4. 7: Means and Medians for Survival Time

Means and Medians for Survival Time								
Surgery Theatre	**Mean**				**Median**			
	Estimate	**Std. Error**	**95% Confidence Interval**		**Estimate**	**Std. Error**	**95% Confidence Interval**	
			Lower Bound	**Upper Bound**			**Lower Bound**	**Upper Bound**
Orthopaedic surgery	165.714	34.834	97.44	233.989	120	68.661	0	254.575
General surgery	240.464	31.315	179.087	301.842	.	.	.	.
Neuro surgery	211.313	29.234	154.014	268.611	.	.	.	.
Urology	200	81.65	39.967	360.033	.	.	.	.
Cardiothoracic surgery	170	50.008	71.984	268.016	180	127.75	0	430.39
Overall	230.33	19.551	192.011	268.649	240	.	.	.

a Estimation is limited to the largest survival time if it is censored.

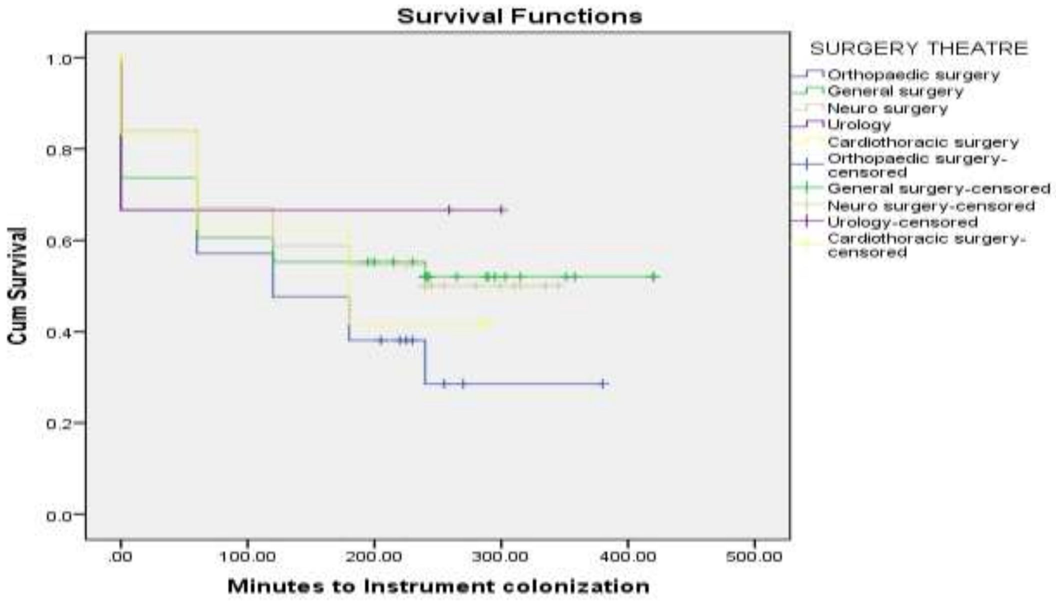

Figure 4.6: Survival Functions

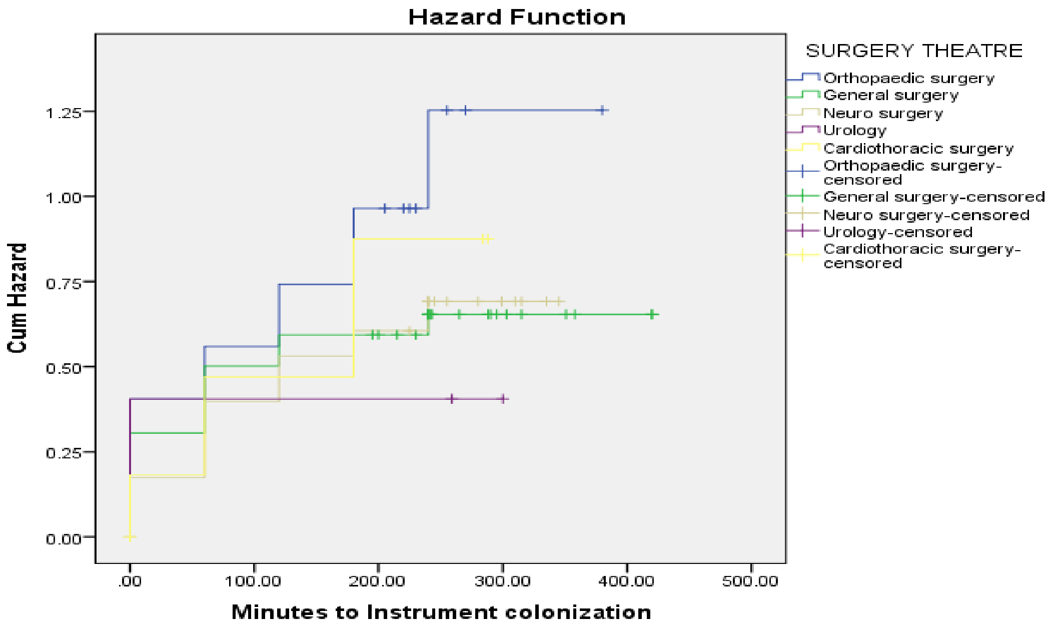

Figure 4.7: Hazard Function

Table 4.18: Overall Comparison

Overall Comparisons			
	Chi-Square	**df**	**Sig.**
Log Rank (Mantel-Cox)	0.987	1	0.32
Breslow (Generalized Wilcoxon)	1.032	1	0.31
Tarone-Ware	1.01	1	0.315

4.13 Strategies to Counter Microbial Colonization on Surgical Instruments and Surgical Sites

The quantitative data results are interdependent to the qualitative data results. The results got from the quantitative data led to the question and answering the qualitative arm. Qualitative data was collected from Key Informants in the Main Theatres of Kenyatta National Hospital. The Key Informants are experts working in the operating theatres and are from three professions to include Perioperative Nurses, Surgeons and Anesthetists. Seven Key Informants were interviewed after having reached saturation from the data collected. The data was analyzed inductively by deriving codes into sub themes and eventually developing themes. Four themes were developed from the data as illustrated below:

Table 4.19: Strategies to Counter Microbial Colonization on Surgical Instruments and Surgical Sites

Themes	Sub themes	Codes	Verbatims	No
Proper sterilization and handling of surgical instruments	Improve sterilization procedure	Sterilization machine maintenance	*"Maybe our sterilization machines need to be recalibrated again" (KII 1)*	*6*
		Recommended load for the machine	*"Sometimes they overload, we need to ensure the load is what is recommended"(KII 6)*	
		Right temperatures to be achieved	*"Do those temperatures really reach the correct parameters. I wii ensure this is achieved" (KII 4)*	
		Proper setting of the machine	*"We may need to re-evaluate our sterilization processes in TSSU. (KII 1, KII 2,KII 3)*	
	Proper handling of sterile sets	Proper handling of the sets	*" some of the trolleys that transport the sets from TSSU to theatres may be contaminated and therefore*	*5*
		Transportation of sets from one floor to the next	*compromise the sterile sets. Those lifts and trolleys shall be decontaminated every morning and when*	
		Sterility of the trolleys and lifts used to transport the instruments	*also when need be" (KII 6,KII 5, KII 4,KII 2, KII 1)*	
	Check on sterilization indicators	Indicators for sterilization inside the sets	*"there should be an indicators inside the sets not outside only" (KII 6)*	*5*
		Recheck the bio indicators	*" We need to recheck those bio indicators if they actually change colour" (KII 1)*	
		The sets should be dry	*"Those sets must be dry before they are considered for use" (KII 2)*	
		The tapes are tight	*"those tapes must be tight on the sets. If they appear loose those sets should not be used" (KII 2, 3)*	
	Reevaluation of sterility process	Recalibration of the machines	*" We will ensure the sterilization machines are servised and recalibrated frequently to ensure sterility is achieved effectively".(KII 5)*	*7*

			"disposable wrappers are the most prefered though sometimes we run short" (KII 3)	
		Set wrapping materials and process of wrapping sets		
		Establishment of washer disinfector machine		
		Double packing of the sets	*" We have established a washer disinfector machine recently this should greatly improve on the*	
		Expired instruments start the sterilization process afresh use of disposable wrappers	*instrument processing and sterilization." (KII 3)*	
Change of instruments	Prevent colonization of instruments	Observe sterility measures to the later	*" new staffs and students need to be given CMEs on sterility measures to avoid breach of sterility during*	*7*
and other surgicals	intraoperatively	Change of gowns	*surgeries"(KII 1,3,5)*	
Intraoperatively		Change of gloves	*" actually by three and a half hours every team member should change their gloves*	
		Change of drapes	*do a fresh scrubbing and change instrument sets"(KII 1,2, 3,4,5,6,7)*	
		Changing instruments where possible (1, 2,3)		
	Time to change instruments and	By 10 to 15 minutes before the fourth hour	*" we need to change instruments, gloves and gowns few minutes before the fouth hour, 10 to 15 minutes"(KII 7)*	7
	other surgicals	By 3.5 hours change	*" actually by three and a half hours every team member should change gowns, gloves and instruments"(KII 3)*	
		By the fourth hour	*" all the surgicals plus instruments need to be changed by the fourth hour" (KII 1,2,4,5,6)*	

Elimination of microbial colonization on surgical sites	Decontamination of the surgical site	Showering of the patient in the ward preoperatively	*" before patients come to theatre, they should take a shower and change the gown" (KII 3)*	*1*
		Change into clean theatre gown		
	Embracing thorough social wash	Social wash should be done to all patients	"*I would suggest that we embrace a thorough social wash before prepping*" (KII 1)	7
		Thorough, skilled and systematic prepping	*"We do a thorough social wash to all patients and there is a way we should do it". (KII 3)*	
		Embrase a thorough social wash before prepping	*" Social wash has not been routinely done to all patients, we are going to ensure that this is done to every patient due for surgery"(KII 1,2,3,4,5,6,7)*	
	Ensuring sterility of the cleaning solution	Covering of the antiseptic solutions when not in use	*" all prepping solutions should be covered immediately after use and we need to use it in 24hours only" (KII 3)*	*5*
		Duration of the antiseptics since the first day of opening		
		Potency of the prepping solutions	*" we also look at our prepping solution, whether they are potent or maybe they are also contaminated" (KII 1)*	
		Check if free of microorganisms	*" we also need to take samples of the solutions for microscopy" (KII 2,4,5)*	
Managing the surgical environment	Avoid overcrowding	Minimizing the number of students coming into the OR	*"the theatre incharges should enforce measures on controlling human traffic in the theatre to only people who are really key in that surgery" (KII 1,2)*	*5*
		Put screens outside the OR for students to watch		
		Take charge by not allowing crowds in OR	*"screens should be placed outside the operating suite that is in the lounges and the classroom for students to watch from there and avoid crowding" (KII 7)*	
		Avoid socialization during surgeries		
		Staff attitude	*" people should avoid socializing during surgeries they need to stay in their designated theatres and this calls*	

			for the staff attitudes" (KII 5,6)	
	Controlling frequency of door opening and foot traffic	Minimal movements once surgery has taken off	*" Make sure you have all your supplies before surgery starts to avoid movement in and out of theatres" (KII 1,2,4)*	*7*
		Availability of adequate supplies	*" As managers we need to ensure supplies are adequate and there is proper preparation of the theatres" (KII 3,5)*	
		Conduct CMEs on the dangers it poses to patients	*" Continous Medical Education should be conducted as a matter of urgency regarding foot traffic and the dagers it poses to the patients. This is a serious eye opener" (KII 6,7)*	
		Proper preparation for surgery		
		Label doors surgery in progress no entry	*" We need to label doors surgery in progress no entry, to avoid foot traffic intraoperatively" (KII 3, 6)*	
		Ensure doors open and close automatically	*" all doors opened should close automatically this will prevent air currents in and out of the theatre" (KII 1)*	
	Competence in scrubbing, gowning and gloving	Proper scrubbing, gowning and gloving	"*CMEs need to be carried out on proper scrubbing, gowning and gloving"(KII 3, 5, 7)*	4
		One colour and design of scrubs to be used in OR to avoid outside traffic	*" Due to the movement in and out of theatres we need establish one colour scrubs to be used in theatres to avoid outside traffic in theatres" (KII 1)*	
	Air controls in theatres	The air is not effective	*" in some theatres Acs are used yet they blow currents, this should be discouraged"(KII 5,6,4)*	*3*
		Use of Acs causes the air currents		

The following strategies emerged from the qualitative results;

Table 4.20: Strategies to Minimize Microbial Colonization

	Strategies to Minimize Microbial colonization
1.	Review and enhancement of the Instruments sterilization process
2.	Change of instruments and other surgical by 4 hours of surgery
3.	Social wash of all surgical sites should be done before the actual surgical prepping
4.	Minimize foot traffic in the operating theatres

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

This chapter discusses the results of this study as per objectives. This is done in view of other authors about their findings on the same subject matter and of which their work has been acknowledged.

5.1.1 Time Taken to Microbial Colonization of Surgical Instruments

Some instruments were colonized at time 0 and were removed from the study as per the exclusion criteria. When surgery begins surgical instruments are presumed to be sterile having gone through the sterilization processes and parameters confirming sterilization reached and confirmed. In this study some instruments (25%; n=23) were found to be colonized at time 0. (Dalstrome et al., 2020) found that the sterilization process may not necessarily produce absolute sterility, even when parameters confirming sterilization have been reached. This cautions that as much as we express confidence of absolute sterility of instruments there are elements which may not be completely free from microorganisms.

More than half of the instruments were colonized by micro-organisms intraoperatively (51.6%; n=48). This result relates to a study done in Tokyo Japan where 31% of the instruments were colonized intraoperatively (Saito et al, 2019). In another study culture positivity correlated directly with the duration of open exposure of the uncovered trays, with culture-positive rates of 22% and 30% at two and four hours, respectively. This was in correlation with light traffic through the operating room intraoperatively (Dalstrome et al, 2020).

Eleven-point eight percent 11.8%; (n=11) patients had microbial colonization on the surgical site pre-surgery. A third of the population got post-surgery microbial colonization on the surgical site (31.2%; n=29). The cumulative incidence of microbial colonization was 269 per 1000 patients (N=25). The prevalence was 34.4% (344 per 1000 patients). Some patients got a secondary microbial colonization intra-operatively. In a study done at Mbarara Uganda 16.4 % of patients had microbial colonization pre surgery (Lubega et al, 2017) while in another study done in Mwanza Tanzania found 27.8% of the patients had microbial colonization post-surgery (Mpogoro et al, 2014).

Regarding the operating-room environment itself as a source of contamination, Ritter et al. found bacterial counts in an empty operating room to increase significantly after the doors were left open and to increase even further when five or more people were added to the room (Ovistgaard et al, 2020). It was observed during the data collection that there was very high foot traffic in and out of the operating room as well as door opening intraoperatively. Following this observation it could contribute to the operating room air contamination.

This study relates that common skin flora appear to be the predominant source of contamination of exposed trays and instruments in the operating room. These findings similarly implicate people as the most likely source of intraoperative contamination of trays. In contrast to the results reported by Ritter et al, their model for generating light traffic in the operating room did not appear to influence the rate of contamination of opened sterile instrument trays (Ovistgaard et al, 2020).

Intraoperatively there are situations where sterile trays are opened but not used immediately such a delay before the start of the operation or multiple procedures performed in the same operative setting. There are no clear guidelines for how long a sterile tray can be exposed to the open environment before the contamination risk becomes unacceptable.

Pre surgery on the surgical site *staphylococcus* species were predominantly responsible (7.7%) of the microbial colonization on the surgical site. The types of species include *staphylococcus aureus*, *staphylococcus coagulase negative and staphylococcus proteus. Bacillus* species was 3.3%, *klebsiella* 2.2% and *Escherichia coli* at 1.1%.

Staphylococcuss species was the commonly isolated microbial colony postoperatively accounting to 20.6%. This is an approximate three times increase as compared to the pre surgery. *Bacillus species* remained the same proportion at 3.3% as at pre-surgery, *micrococcus species 3.3%* and it is noted that it was not present pre surgery. *Klebsiella species 2.2%, acinetobacter baumannii* and *enterococcus fecalis* each at 1% and were not present pre surgery.

Pre surgery instruments are sterile and assumed to be free from microbial colonization following sterilization and all parameters checked and confirmed. However in the study there was microbial colonization on instruments.

Microbial colonization at time 0 was as follows: *Staphylococcus species* was dominant at 9.8%, *candida species was 8.8%, bacillus species 4.4%, acinetobacter baumanii 3.3%, enterococcus faecalis, micrococcus species and pseudomonas species at 2.2% respectively and klebsiella species at 1%.*

Microbial colonization of surgical instruments at 60 minutes was as follows: *staphylococcus species was at 13%, Candida species 10%, bacillus species 6.6%, acinetobacter baumanii 3.3%, Escherichia coli and micrococcus species at 2.2%* respectively*, enterococcus faecalis, proteus species and pseudomonas species at 1.1%* respectively.

In comparison of the findings at 0 time and at 60 minutes *staphylococcus species* increased from 9.8% to 13%, *bacillus species* increased from 4.4% to 6.6%, *acenetobacter baumannii* remained constant at 3.3%. After an hour there was a new entry of microorganisms *Escherichia coli* 2% which were not isolated at the beginning.

Microbial colonization of instruments at 120 minutes was as follows: *Staphylococcus species was at 17.4%.* This is an increase from 13% to 17.4%. *Candida species 9.7%, bacillus species 4.4%, pseudomonas species 4.3%, acinetobacter baumannii, Escherichia coli, micrococcus species at 1.1%* respectively *and a new entry of citrobacter species at 1.1%.*

At 180 minutes, the following microorganisms were cultured on surgical instruments as follows; *staphylococcus species 14.1% there was a slight reduction of 3.3%. candida species 11.9%*, there was an increase from 9.7% to 11.9%. *bacillus species 5.5%,*increased by 1.1% *pseudomonas species 4.4%, acinetobacter baumannii, Escherichia coli, micrococcus species at 1.1%* respectively.

At 240 minutes, the following microorganisms were cultured on surgical instruments as follows; *staphylococcus species 12%, candida species 8.7%, bacillus species 6.6%, pseudomonas species 3.3%, acinetobacter baumannii 3.3%, klebsiella 1.1%, micrococcus species, enterococcus feacalis at 1.1%* respectively. Mc-Lf species at 1.1%

A study by Sadrizadeh (2018) found that *staphylococcus aureus* was the most common organism in SSI. This was largely due to normal flora of skin of the patient and also shedding by the personnel in the operating room. It is generally agreed that airborne pathogens found frequently in surgical sites are primarily *staphylococcus aureus* released from the skin flora. The bacteria is the leading cause of SSI and just a small amount can initiate severe infection at the surgical site.

Pre surgery on the surgical site *coagulase negative staphylococcus* was 3.3%, *staphylococcus aureus* was at 2.2% while post-surgery on the surgical site it was at 16.2%.

On the surgical instruments at time 0 *staphylococcus aureus* was 5.4%, *candida species* was at 7.7%. At 60 minutes it was 7.7% and 9.9% respectively. At 120 minutes *staphylococcus aureus* was 5.5%, negative coagulase staphylococcus was 7.5% and *candida species* was at 8.6%. At 180 minutes *negative coagulase staphylococcus* was 5.4% and *candida species* was at 10.8%. At 240 minutes *staphylococcus aureus* was 5.5% and *candida species* was 8.7%.

There was a statistically significant difference between the (survival functions) time to microbial colonization and the surgery specialization (p-value 0.044). All urology patient did not get microbial colonization. 75% of the cardiovascular patients survived microbial colonization by 300 minutes (5 hours). Microbial colonization was evident at 180 minutes for the general patients (90% survived at 180 Minutes) with a median of 300 minutes (50% of the general surgery patients were colonized by 300 minutes). Half of the orthopedic surgery patients were colonized by 300 minutes. Half of the neuro patients were colonized at 340 minutes. In a study done to compare Microbial colonization of surgical sites, instruments and surfaces in different theatres concluded that microbial colonization is directly influenced by the culture and the general condition of the operating theatres (Ovistgaard et al, 2020). This informs that the culture and way of doing things in a certain operating room may influence the outcomes of microbial colonization of surgical instruments and surgical sites. There was no difference in microbial colonization for the various surgery specializations. Microbial colonization on the instruments was not dependent on the type of surgical instrument set. The microbial colonization on the surgical site and on the surgical instruments was not associated with the type of surgery specialization either. The strategies that emerged from this study led to the discussion as follows; Surgical instrument processing and sterilization to be enhanced. The entire process to include wrapper material. The recommended wrapper materials include muslin towels and nonwoven polypropylene. These materials are chosen for their ability to allow steam penetration for sterilization and promote drying. They also offer good protection and shelf life.

The functionality of the sterilization equipment includes proper and regular servicing of the sterilization machines and equipment. This includes proper calibration of the machines to give accurate readings and values and enhanced services. The sterilization cycles should run through accurately and complete sessions timely.

Post sterilization handling and storage of the instruments is an important stage of handling sterile sets and instruments. They should be handled professionally and stored in clean storage areas to prevent contamination. Expiry dates checked and if there is any expired in the process they should be removed and start the sterilization process afresh and not just sterilizing the pack as it is.

Change of instruments and other surgicals by 4 hours of surgery. More than half of the instruments after surgery had microbial colonization. By the fourth hour of surgery there is significant microbial colonization on the surgical instruments intraoperatively. Following the results as depicted earlier this informed the experts who agreed that by the fourth hour of surgery surgical instruments plus all the other surgicals should be changed.

Social wash should be done to all surgical sites before the actual surgical prepping. This was informed following the result that there was microbial colonization on the surgical sites preoperatively despite surgical prepping having been done. Social wash reduces microorganisms by 50%. This will then be followed by the surgical prepping. It also emerged that the cleaning solutions need to be checked on expiry dates, proper and supervised dilutions and storage and care after use to be enhanced.

Minimize foot traffic in the operating theatres and door opening intraoperatively. A study done in Michigan in a teaching and referral hospital operating theatres the researchers did the study in response to unexplained increase in SSI rates at the institution. One prominent aspect of the review was foot traffic in and out of the OR which was found to be significantly higher than anticipated. This is a vehicle of the operating theatres environment contamination.

Studies have shown that increased crowding on the operating room is associated with a high postoperative surgical site infection rate. The more the human traffic is in an operating theatre the higher the chances of surgical site infection rates.

5.2 Conclusion

A few instruments were positive of microbial colonization at time 0. More than half of the instruments after surgery had microbial colonization. By the fourth hour of surgery there was significant microbial colonization on the surgical instruments intraoperatively. The longer the surgery is, the more the exposure of instruments and the higher was the microbial colonization.

Pre operatively on the surgical site there was microbial colonization despite surgical prepping and post operatively on the surgical site there was microbial colonization.

Staphylococcus aureus is the most common microorganism in Surgical Site Infections. This is attributed to the normal flora of skin of patients and also shed by the personnel in the theatres.

There was no statistical significance of the relationship between surgery specialization and microbial colonization of the surgical sites and surgical instruments. All surgery specialties are equally exposed to microbial colonization. The strategies that emerged in this study included; surgical instrument processing and sterilization to be enhanced, surgical instruments and all other surgicals in use intraoperatively should be changed by the fourth hour, social wash should be done to all the surgical sites before surgical prepping.

5.3 Recommendations

The following recommendations to the perioperative teams in the operating theatres include;

Surgical instrument processing and sterilization to be enhanced. The entire process to include wrapper material, functionality of the sterilization equipment and post sterilization handling and storage of the instruments. Surgical instruments intraoperatively should be changed by the fourth hour of surgery. Social wash should be done to all surgical sites before the actual surgical prepping. Minimize personnel/foot traffic of the non- scrubbed personnel intraoperatively in the operating room.Following the strategies that emerged from this study Kenyatta National Hospital management and Ministry of Health is to in cooperate the strategies and subsequently development of guidelines that will be used by the perioperative teams intraoperatively.

A further study needs to be done on the effectiveness of the strategies which emerged from this study and hence the development of the perioperative guidelines. Another recommendation study is operating theatres air circuits and flow in relation to microbial colonization in the operating theatres.

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APPENDICES

Appendix I: Data Collection Tool

1. Study sample number: __________

2. Week:
   1 2 3 4 5 6 7 8 9 10 11 12

3. Theatre number:
   1 2 3 4 5 6 7 8 9 10 11 12

4. Surgery specialization:
   a. Orthopaedic surgery
   b. Cardiothoracic surgery
   c. Neuro surgery
   d. General surgery
   e. Urology surgery

5. **Surgical Instruments**

Sample obtained	**Time** **0 Minutes Control**	**60 min**	**120 min**	**180 min**	**240 min**	**Total number of swabs**
	1st swabbing	2nd swabbing	3rd swabbing	4th swabbing	5th swabbing	
Surgical instrument						
Total number samples						

6. Results of microbial culture:

a. Bacteria: Yes ☐ No ☐

Specify__________________________

a. Fungi: Yes ☐ No ☐

Specify____________________________

7. Bacterial load (where applicable)____________________________________

8. **Surgical Site**

	Cutting Time Sample	**Closure Time sample**
Surgical site		
Total number of samples		

9. Results of microbial culture:

a. Bacteria: Yes ☐ No ☐

Specify___________________________

b. Fungi: Yes ☐ No ☐

Specify___________________________

10. Bacterial load (where applicable)____________________________

Appendix II: Key Informants Interview Guide

KEY INFORMANTS INTERVIEW GUIDE

INTERVIEW GUIDE FOR PERIOPERATIVE KEY INFORMANTS

This document provides data collection on Key Informants Interview (KII) guide with which to interview Perioperative Experts.

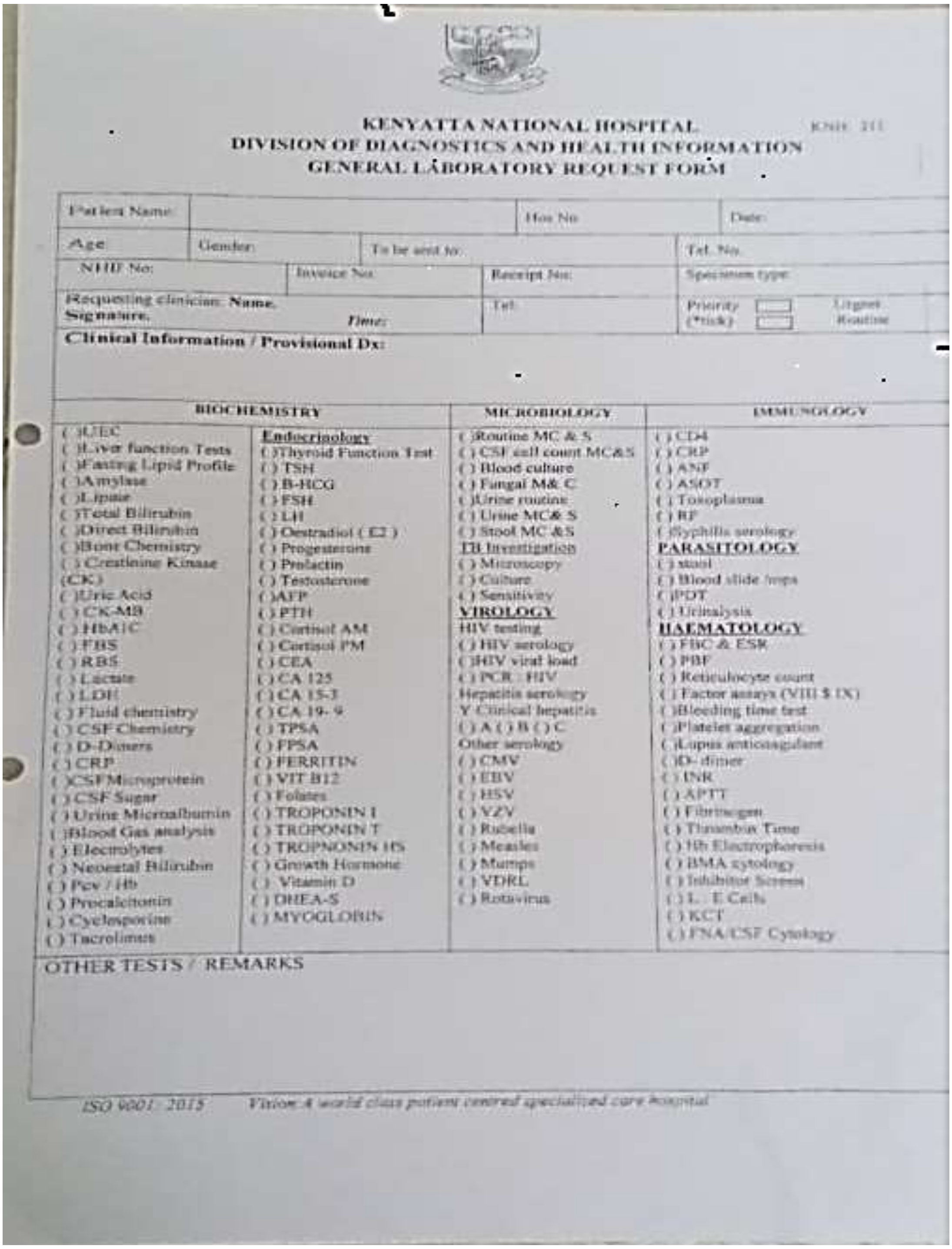
Introduction	Welcome, and thank you for accepting to take part in this Key Informant Interview discussion. You have been asked to participate because your point of view is important. I realize you are busy and I appreciate your time. My name is *Joan Shisoka*, a PhD student at JKUAT currently conducting a study on **Microbial Colonization of Surgical Instruments and Surgical Sites in Main Operating Theatres, Kenyatta National Hospital.** This interview is designed to assess your current thoughts and feelings about the baseline results of the study conducted in the Main theatres KNH. This will take about 15 minutes. The session will be audiotaped to ensure all of your comments are captured. I will also be taking notes during the session. All responses will be kept confidential and anonymous. This means that your interview responses will only be shared with the research team and we will ensure that any information we include in our report does not identify you as the respondent. The audio recordings will be destroyed after transcribing. Remember, you do not have to talk about anything you do not want to and you may end the interview at any time. Are there any questions about what I have just explained?

	Are you willing to participate in this interview? Sign consent form: ______________________ Date: ________________________
Demographic characteristics	Date: _______________ Signed consent: ___________________ 1. Sex: ☐ Male ☐ Female 2. Age (*Completed Years*):_______________ 3. Designation (Tick all that apply) ☐ Perioperative Nurse ☐ Surgeon ☐ Anaesthetist Other (Specify) _____________________ 4. Years of practice: ___________ 5. Duration worked in operating Theatres: _____(mm/yy)
KII Questions	
• Keep the questions open-ended without leading • Use probes when necessary: • *Would you give me an example?* • *Can you elaborate on that idea?* • *Would you explain that further?*	The study Microbial Colonization of Surgical Instruments and Surgical Sites in Main Operating Theatres, Kenyatta National Hospital. The quantitative data was collected in a period of 10 months and the baseline data was as follows; • *There was no absolute sterility of surgical instruments on opening of the sets for surgery despite the sets passing all the sterilization checks.* • *There was microbial colonization on the surgical site after surgical prepping* • *By the fourth hour of surgery more than fifty percent of instruments were colonized.*

• *I'm not sure I understand what you are saying.* • *Is there anything else you'd like to share about that?*	• *High frequency of door opening and foot traffic was observed* Following the baseline results above; 1. Would you kindly share your thoughts on the outcomes of the study • *There was no absolute sterility of surgical instruments on opening of the sets for surgery despite the sets passing all the sterilization checks.* • *There was microbial colonization on the surgical site after surgical prepping* • *By the fourth hour of surgery more than fifty percent of instruments were colonized.* • *High frequency of door opening and foot traffic was observed* 2. What measures do you say should be put in place so as to ensure absolute instruments sterility from TSSU? 3. What measures do you say should be put in place so as to ensure absolute elimination of microbial colonization on the surgical sites? 4. What would you suggest be done on the outcome of by the fourth hour more than half of the instruments were colonized? 5. What would you suggest to be done on High frequency of door opening and foot traffic that was observed intraoperatively? 6. Of all the things we've discussed today, what would you say are the most important issues you would like to express about this results? 7. Would you be willing to adopt the suggestions you have given after completion of the study? Yes: No: Kindly elaborate on your response:

Wrap-up	Is there anything else that you would like to add or discuss here that you think would be relevant to the issue? Do you have any questions or concerns? If you would like to follow-up with anything, please do not hesitate to contact me at ***0722310257*** Thank you very much for your time.

Appendix III: Standard Laboratory Request Form



KENYATTA NATIONAL HOSPITAL KNH 211
DIVISION OF DIAGNOSTICS AND HEALTH INFORMATION
GENERAL LABORATORY REQUEST FORM

Patient Name:		Hos No	Date:
Age	Gender:	To be sent to:	Tel. No.
NHIF No:	Invoice No:	Receipt No:	Specimen type:
Requesting clinician: **Name.** **Signature.** *Time:*		Tel	Priority (*tick) ☐ Urgent ☐ Routine

Clinical Information / Provisional Dx:

BIOCHEMISTRY

( ) UEC
( ) Liver function Tests
( ) Fasting Lipid Profile
( ) Amylase
( ) Lipase
( ) Total Bilirubin
( ) Direct Bilirubin
( ) Bone Chemistry
( ) Creatinine Kinase (CK)
( ) Uric Acid
( ) CK-MB
( ) HbAIC
( ) FBS
( ) RBS
( ) Lactate
( ) LDH
( ) Fluid chemistry
( ) CSF Chemistry
( ) D-Dimers
( ) CRP
( ) CSF Microprotein
( ) CSF Sugar
( ) Urine Microalbumin
( ) Blood Gas analysis
( ) Electrolytes
( ) Neonatal Bilirubin
( ) Pcv / Hb
( ) Procalcitonin
( ) Cyclosporine
( ) Tacrolimus

Endocrinology
( ) Thyroid Function Test
( ) TSH
( ) B-HCG
( ) FSH
( ) LH
( ) Oestradiol (E2)
( ) Progesterone
( ) Prolactin
( ) Testosterone
( ) AFP
( ) PTH
( ) Cortisol AM
( ) Cortisol PM
( ) CEA
( ) CA 125
( ) CA 15-3
( ) CA 19- 9
( ) TPSA
( ) FPSA
( ) FERRITIN
( ) VIT B12
( ) Folates
( ) TROPONIN I
( ) TROPONIN T
( ) TROPNONIN HS
( ) Growth Hormone
( ) Vitamin D
( ) DHEA-S
( ) MYOGLOBIN

MICROBIOLOGY

( ) Routine MC & S
( ) CSF cell count MC&S
( ) Blood culture
( ) Fungal M& C
( ) Urine routine
( ) Urine MC& S
( ) Stool MC &S
TB Investigation
( ) Microscopy
( ) Culture
( ) Sensitivity
VIROLOGY
HIV testing
( ) HIV serology
( ) HIV viral load
( ) PCR : HIV
Hepatitis serology
Y Clinical hepatitis
( ) A ( ) B ( ) C
Other serology
( ) CMV
( ) EBV
( ) HSV
( ) VZV
( ) Rubella
( ) Measles
( ) Mumps
( ) VDRL
( ) Rotavirus

IMMUNOLOGY

( ) CD4
( ) CRP
( ) ANF
( ) ASOT
( ) Toxoplasma
( ) RF
( ) Syphilis serology
PARASITOLOGY
( ) stool
( ) Blood slide /mps
( ) PDT
( ) Urinalysis
HAEMATOLOGY
( ) FBC & ESR
( ) PBF
( ) Reticulocyte count
( ) Factor assays (VIII $ IX)
( ) Bleeding time test
( ) Platelet aggregation
( ) Lupus anticoagulant
( ) D- dimer
( ) INR
( ) APTT
( ) Fibrinogen
( ) Thrombin Time
( ) Hb Electrophoresis
( ) BMA cytology
( ) Inhibitor Screen
( ) L . E Cells
( ) KCT
( ) FNA/CSF Cytology

OTHER TESTS / REMARKS

ISO 9001: 2015 *Vision: A world class patient centred specialized care hospital*

Appendix IV: Patients Consent

UNIVERSITY OF NAIROBI (UoN)

COLLEGE OF HEALTH SCIENCES

KNH-UoN ERC

KENYATTA NATIONAL HOSPITAL (KNH)

P O BOX 19676 Code 00202

Email: uonknh_erc@uonbi.ac.ke

Website: http://www.erc.uonbi.ac.ke

PARTICIPANT INFORMATION AND CONSENT FORM

FOR ENROLLMENT IN THE STUDY

Title of Study: Microbial Colonization Time of Surgical Instruments Intra-operatively In Relation to Surgical Site Infections in Main Theatres, Kenyatta National Hospital

Principal Investigator\and institutional affiliation: Joan Shisoka

/ Jomo Kenyatta University of Agriculture and Technology

Introduction:

I would like to tell you about a study I am conducting. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When I have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research:

i) Your decision to participate is entirely voluntary
ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal
iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. I will give you a copy of this form for your records.

May I continue?

Yes [ ] No [ ]

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No ____________________________

What is this study about?

I am taking 2 swab samples on the surgical site of the patient during surgery in the main theatres of Kenyatta National Hospital. The purpose of taking these samples is to take them the microbiology laboratory of the University of Nairobi for analysis to ascertain if there will be any microbial colonies. There will be approximately 55 participants in this study purposefully selected. I am asking for your consent to consider participating in this study.

What will happen if you decide to be in this research study?

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

I will take 2 swab samples from your surgical site. The first one will be at the beginning of surgery and the second one will be at the end of surgery. These samples will be taken while under general or spinal anaesthesia and therefore there will be no pain or any form of discomfort. The results of the samples will be used only by people working for this study and will not be shared with others. I may need to contact you after surgery in case we need further information and in case of intervention.

Are there any risks, harms discomforts associated with this study?

One potential risk of being in the study is loss of privacy. I will keep all the information as confidential as possible. I will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

Are there any benefits being in this study?

There is no direct monetary benefit in participating in this study. However, the results we get after the laboratory analysis will guide if you require an intervention which will be provided. It provides a base to help us improve on the protocols of the surgical environment. It will also guide us on improvement of our treatment modalities hence informing policies and interventions if necessary.

Will being in this study cost you anything?

The study participation will not cost you anything.

Will you get refund for any money spent as part of this study?

You will not get any monetary compensation for your participation in this study.

What if you have questions in future?

If you have further questions or concerns about participating in this study, please call or send a text message to the researcher;

Researchers name: Joan Shisoka **Phone No**: 0722 310 257

Email: joan.shisoka@jkuat.ac.ke

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

P. O. Box 19676 Code 00202 Nairobi.

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

E-mail: uonknh_erc@uonbi.ac.ke

What are your other choices?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

Consent form (Statement of consent)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No

I agree to provide contact information for follow-up: Yes No

Participant name: ____

Participant signature _______________________ **Date** _______________

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher‘s Name: Joan Shisoka

Email address: joan.shisoka@jkuat.ac.ke

Cell phone number: 0722310257

For more information contact my supervisors;

Dr. Drusilla Makworo

dmakworo@jkuat.ac.ke

0721262355

Dr. Kyalo Mutisya

amutisya@jkuat.ac.ke

0721484869

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

P. O. Box 19676 Code 00202 Nairobi.

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

E-mail: uonknh_erc@uonbi.ac.ke

Appendix V: Kiswahili Consent Version

FOMU YA KUKUBALI KUSHIRIKI KATIKA UTAFITI

Mimi, **JOAN SHISOKA** mwanafunzi katika chuo kikuu cha Jomo Kenyatta. Ninafanya utafiti katika Hospitali kuu ya Kenyatta unaochunguza matokeo baada ya kuchukua sampuli kutoka kwa kidonda cha upasuaji.

Nitakueleza kuhusu kuchukua sampuli kutoka kwa kidonda cha upasuaji kisha nitapeleka katika maabara kwa shughuli za huu utafiti. Bali na utafiti huu matibabu yataendelea kama yalivyo pangwa.

Uelewe kwamba hakuna malipo ya kushiriki na habari yote utakayopeana itawekwa siri. Unaweza kujiondoa wakati wowote katika utafiti huu, na hali hiyo haitaathiri matibabu ya ugonjwa ulionao kwa vyovyote vile.

Jina lako halita andikwa pahali popote katika makaratasi ya utafiti ila nambari ya utafiti tu.

Mimi………………………………………………………………………………
(majina kamili kwa herufi kubwa) nimeelewa maelezo yote ambayo nimepewa. Nimekubali kushiriki katika huu utafiti kama mgonjwa kwa hiari yangu.

Sahihi/kidole gumba…………………………………………………………..

Tarehe ………………………

MTAFITI

JOAN SHISOKA

Sahihi………………………………………………

NAMBARI YA SIMU: 0722 310 257

Appendix VI: Letter to KNH / UON ERC

Joan M. Shisoka,

School of Nursing Sciences,

College of Health Sciences,

Jomo Kenyatta University of Agriculture and Technology

The Chairman,

KNH/UON Ethics Research Committee,

P.O. Box 20723,

Nairobi.

Dear Sir/Madam,

RE: PERMISSION TO CONDUCT A STUDY ON:

Microbial Colonization of Surgical Instruments and Surgical Sites Intraoperatively in Main Theatres, Kenyatta National Hospital

I am a postgraduate student at the Jomo Kenyatta University of Agriculture and Technology.

I seek permission to carry out the above stated study. Your kind consideration will be highly appreciated and it will go a long way in facilitating completion of my study. The research findings will be presented, published and utilized both locally and internationally in improving health care service delivery.

Attached please find three (3) copies of my research proposal.

Yours Faithfully,

JOAN M. SHISOKA.

Appendix VII: Letter to KNH Anaesthesia and Theatres Department

Joan M. Shisoka,
School of Nursing Sciences,
College of Health Sciences,
Jomo Kenyatta University of Agriculture and Technology

The Chairman,

KNH ANAESTHESIA AND THEATRES DEPARTMENT,

P.O. Box 20723,

Nairobi.

Dear Sir/Madam,

RE: PERMISSION TO CONDUCT A STUDY ON:

Microbial Colonization of Surgical Instruments and Surgical Sites Intraoperatively in Main Theatres, Kenyatta National Hospital

I am a postgraduate student at the Jomo Kenyatta University of Agriculture and Technology.

I seek permission to carry out the above stated study. Your kind consideration will be highly appreciated and it will go a long way in facilitating completion of my study. The research findings will be presented, published and utilized both locally and internationally in improving health care service delivery.

Yours Faithfully,

JOAN M. SHISOKA.

Appendix VIII: NACOSTI Research License

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR
SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **166233**

Date of Issue: **05/August/2021**

RESEARCH LICENSE

This is to Certify that Ms.. Joan Matendechere Shisoka of Jomo Kenyatta University of Agriculture and Technology, has been licensed to conduct research in Nairobi on the topic: MICROBIAL COLONIZATION OF SURGICAL INSTRUMENTS AND SURGICAL SITES INTRA-OPERATIVELY IN MAIN THEATRES, KENYATTA NATIONAL HOSPITAL (P65/02/2021) for the period ending : 05/August/2022.

License No: **NACOSTI/P/21/12174**

166233

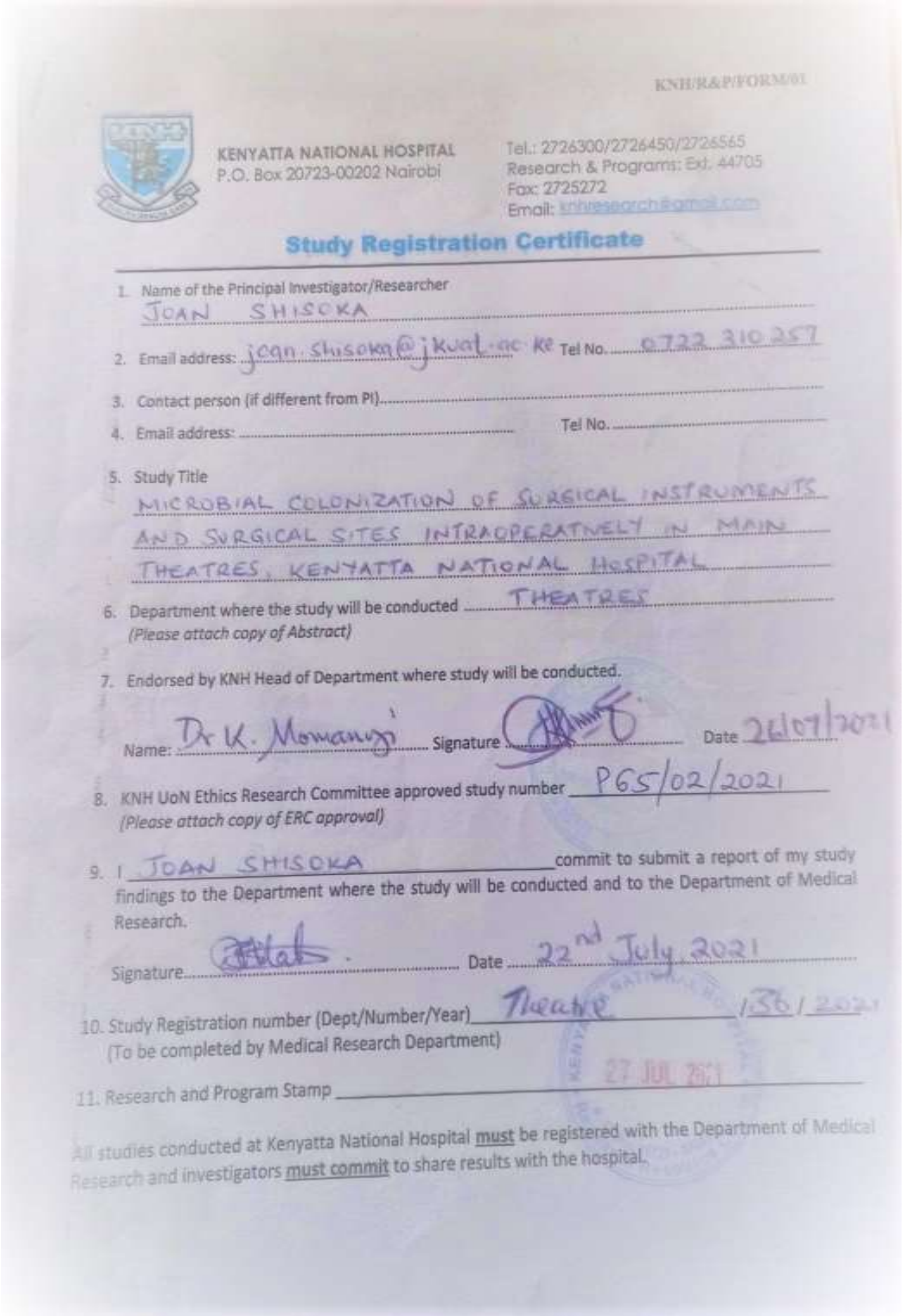
Applicant Identification Number

Director General
NATIONAL COMMISSION FOR
SCIENCE,TECHNOLOGY &
INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document,
Scan the QR Code using QR scanner application.

Appendix IX: Study Registration Certificate



KNH/R&P/FORM/01

KENYATTA NATIONAL HOSPITAL
P.O. Box 20723-00202 Nairobi

Tel.: 2726300/2726450/2726565
Research & Programs: Ext. 44705
Fax: 2725272
Email: knhresearch@gmail.com

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
JOAN SHISOKA

2. Email address: joan.shisoka@jkuat.ac.ke Tel No. 0722 310 257

3. Contact person (if different from PI)

4. Email address: Tel No.

5. Study Title
MICROBIAL COLONIZATION OF SURGICAL INSTRUMENTS AND SURGICAL SITES INTRAOPERATIVELY IN MAIN THEATRES, KENYATTA NATIONAL HOSPITAL

6. Department where the study will be conducted THEATRES
(Please attach copy of Abstract)

7. Endorsed by KNH Head of Department where study will be conducted.

Name: Dr K. Momanyi Signature Date 26/07/2021

8. KNH UoN Ethics Research Committee approved study number P65/02/2021
(Please attach copy of ERC approval)

9. I JOAN SHISOKA commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Medical Research.

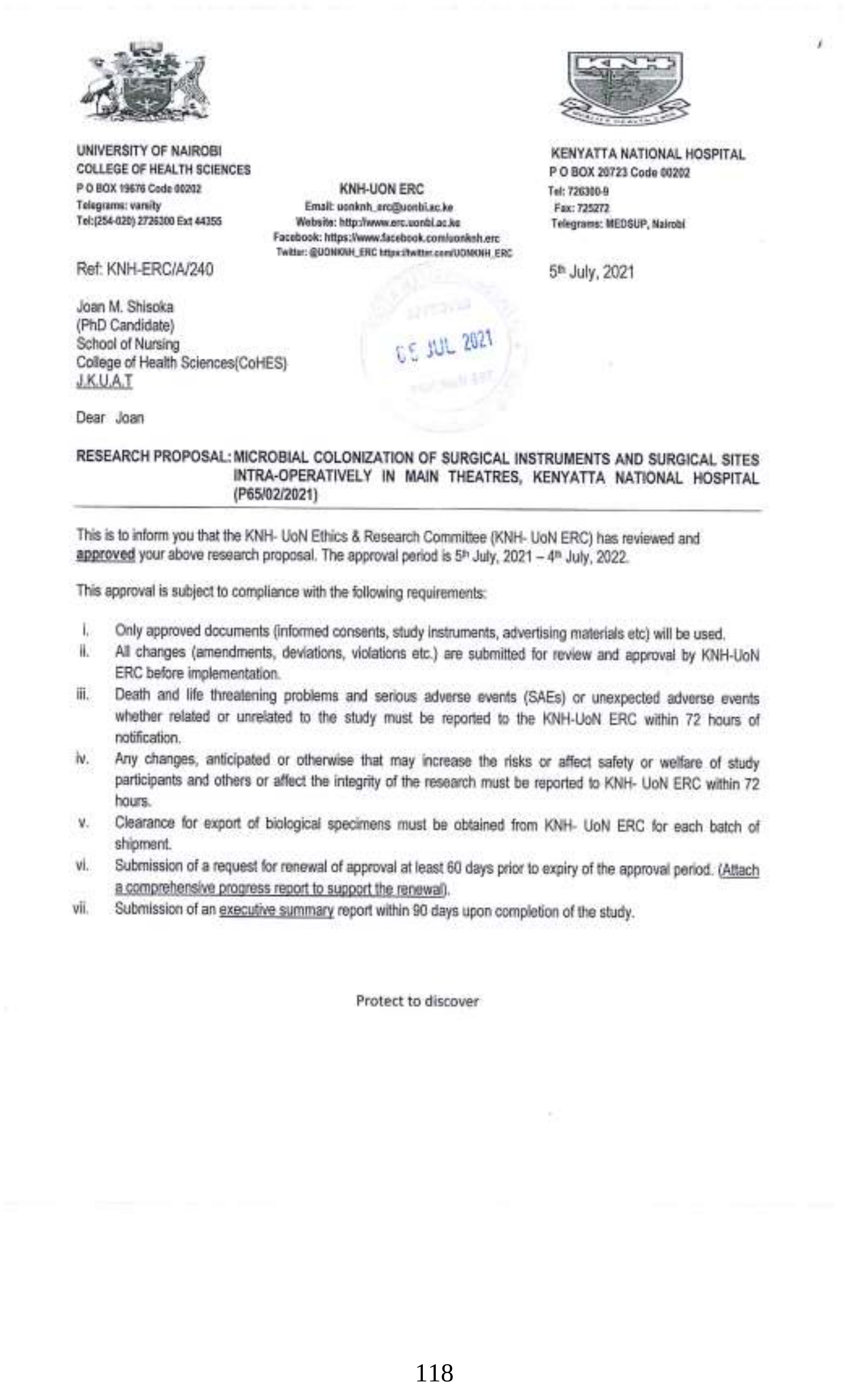
Signature Date 22nd July 2021

10. Study Registration number (Dept/Number/Year) Theatre/36/2021
(To be completed by Medical Research Department)

11. Research and Program Stamp 27 JUL 2021

All studies conducted at Kenyatta National Hospital <u>must</u> be registered with the Department of Medical Research and investigators <u>must commit</u> to share results with the hospital.

Appendix X: KNH/UoN-ERC Letter of Approval



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
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Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

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5th July, 2021

05 JUL 2021

Joan M. Shisoka
(PhD Candidate)
School of Nursing
College of Health Sciences(CoHES)
J.K.U.A.T

Dear Joan

RESEARCH PROPOSAL: MICROBIAL COLONIZATION OF SURGICAL INSTRUMENTS AND SURGICAL SITES INTRA-OPERATIVELY IN MAIN THEATRES, KENYATTA NATIONAL HOSPITAL (P65/02/2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 5th July, 2021 – 4th July, 2022.

This approval is subject to compliance with the following requirements:

i. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
ii. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
iii. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
vii. Submission of an executive summary report within 90 days upon completion of the study.

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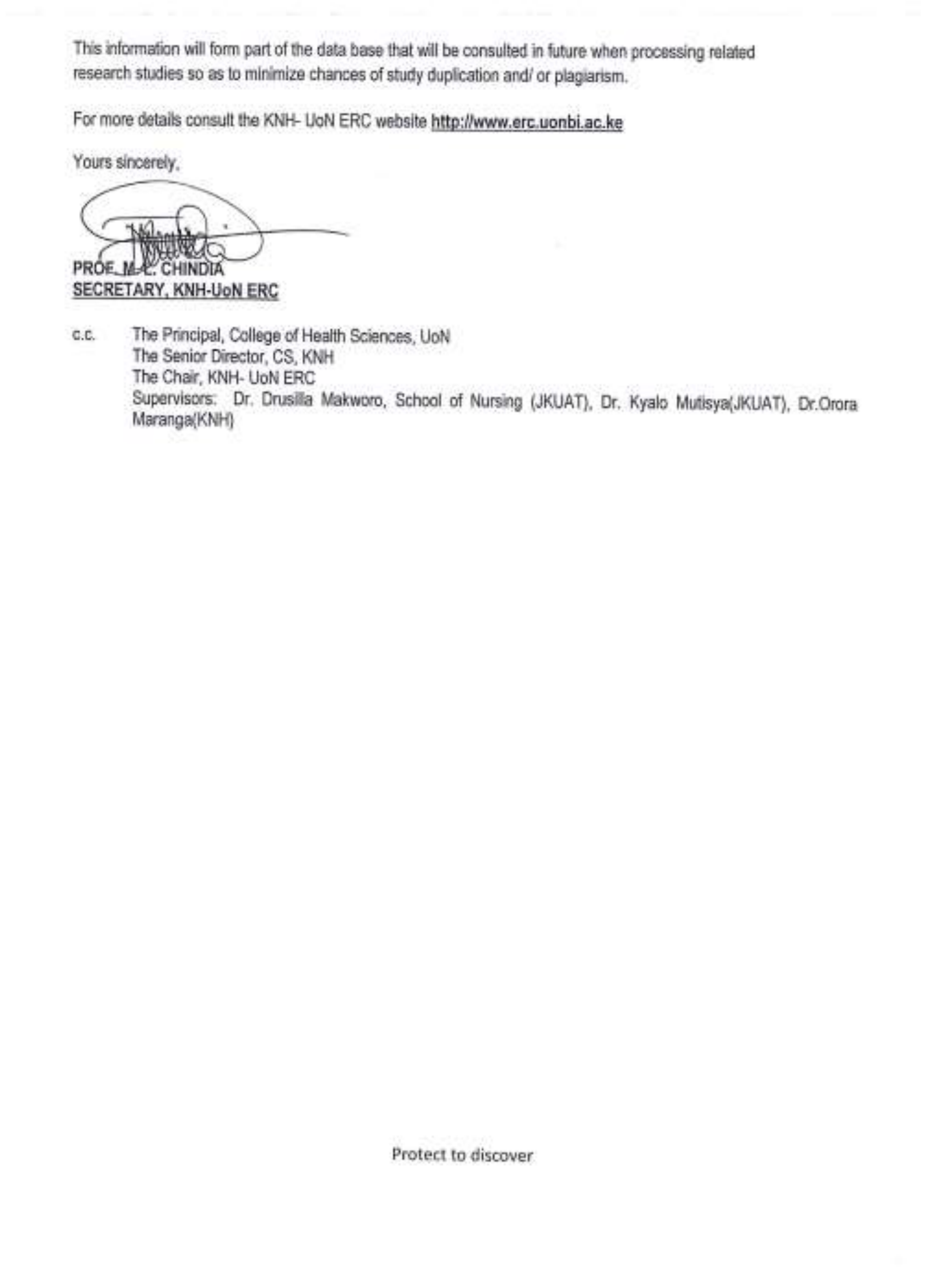

This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

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

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chair, KNH- UoN ERC
Supervisors: Dr. Drusilla Makworo, School of Nursing (JKUAT), Dr. Kyalo Mutisya(JKUAT), Dr.Orora Maranga(KNH)

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Appendix XI: Publications

East African Medical Journal Vol. 100 No. 9 November, 2023

DURATION OF TIME TO MICROBIAL COLONIZATION ON SURGICAL INSTRUMENTS AND SURGICAL SITES INTRAOPERATIVELY AT A PUBLIC REFERAL HOSPITAL, KENYA

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DURATION OF TIME TO MICROBIAL COLONIZATION ON SURGICAL INSTRUMENTS AND SURGICAL SITES INTRAOPERATIVELY AT A PUBLIC REFERAL HOSPITAL, KENYA

J. Shisoka, A. Mutisya, and D. Makworo

ABSTRACT

Background: Surgical site infections have the highest frequency of postsurgical complications and an impact on health or illness process of the patient. The absolute sterility of surgical instruments is often assumed. Though other surgicals are usually changed and the surgical instruments are rarely or not changed hence high chances of surgical wounds contamination. There are no guidelines on how long instruments be exposed to the open environment before the contamination risk becomes unacceptable.

Materials and Methods: Analytical cross-sectional design. The study subjects were 93 surgical patients pre and post wound swabs and instruments swabs hourly x5. Check lists and laboratory forms were used for data collection. Sample size was 651 (93x7). SPSS used to analyze descriptive statistics and Kaplan-Meier estimation for survival analysis.

Results: 51.6%; N=48 instruments were colonized by micro-organisms intra-operatively. 75% of the instruments survived microbial colonization at zero minutes. Pre-surgery 11.8% and post-surgery 31.2% surgical sites had microbial colonization. The cumulative incidence of microbial colonization was 269 per 1000 patients.

The mean survival time for the microbial colonization was 230 Minutes 95%CI: 192 to 269 and the median time was 240 minutes. The median time for a surgical site to get microbial colonization was 351 minutes 95%CI: 301 to 401.

Conclusion: Enhance instrument sterilization, social wash of surgical sites before prepping and microbial colonization occurs by 4 hours.

INTRODUCTION

Various types of surgeries are carried out in the OR of KNH ranging from simple surgeries to complex and specialized surgeries. Time taken varies from as short as 15 minutes to hours and the longest time on record is 23 hours 20 minutes of the successful separation of the Siamese twins in November 2016. The current practice in surgeries is that the surgical team may change the gowns, linen and gloves as a measure of infection control, but the instruments are not changed. Following this observation, the researcher developed interest as to why the instruments are not changed despite them having been exposed in the same measure as the other surgicals.

There are no guidelines to inform the surgical teams after how long they should change the surgicals and instruments when presumed to be contaminated.

While we often take great care in addressing factors that are perceived as readily modifiable, other factors may be overlooked, be thought to be uncontrollable or be taken for granted as already being ideal. Specifically, the absolute sterility of surgical trays and instruments is often assumed. There are no clear guidelines for how long an operating room tray can be exposed to the open environment before the contamination risk becomes unacceptable (6).

The burden and suffering posed by surgical site infections (SSIs) on patients' safety globally in terms of pain, delayed surgical site healing, increased use of antibiotics, revision surgery, increased length of hospital stay, morbidity and mortality rates, which are also reflected in excess health care costs (1).

Globally, surgical site infection rates have been reported to range from 2.5% to 41.9%. In the United States, approximately 2% to 5% of the 16 million patients undergoing surgical procedures each year have postoperative surgical site infections. (2).

(3) Found out that an infection rate of between 0.5 % and 6.5 % is accepted as normal in elective surgery among surgeons. In another study they found a much higher total surgical site infection rate (15.3 %) which was much higher

than that accepted as normal by these authors.

Surveillance programs focused on healthcare-associated infections (HAI) including SSI are essential tools to prevent their incidence and reduce their adverse effects, thereby allowing for the reduction of patients’ risk of infection. As widely shown in the literature from high income countries, including the U.S., the incidence of HAI can be reduced by as much as 30%, and by 55% in the case of SSIs (5).

The surgical field is considered to remain aseptic during operation. However, microbes gradually recover in the surgical field and could cause microbial contamination of sterilized surgical instruments. The relatively high incidence of contamination of surgical instruments sheds light on the mechanisms of SSI development. The study also suggests that surgical gloves play a role as fomites in the surgical field by transportation of microbes. (6)

There is a possibility that skin drapes and meticulous surgical skills may be far more important for decreasing the risk of SSI than we previously considered. Change of surgical instruments after prolonged exposure should be recommended even more strongly as basic practice (6).

Several studies have shown that 80 to 90 % of bacterial contaminants found in the wounds after surgery emanate from air contaminated with microbes present in operating theatres. (7). This indicates that as other surgicals are changed and the surgical instruments are not changed there is high chances of surgical wounds contamination since they are all exposed in the same measure.

A survey conducted in 14 countries by WHO attributed 8.7% prevalence of nosocomial infections mainly acquired from poorly controlled operating theatres environment. This originated from the use of medical devices and procedures.

Modern surgical procedures and therapeutic invasive techniques are a source of surgical site infections. The equipment and instruments in most hospitals are limited and this leads to prolonged use and overuse of the equipment posing contamination risks to the surgical patients. (8).

A study done in Michigan at a high-volume teaching and referral hospital operating

rooms, the aspect of foot traffic in and out of the OR intraoperatively was found to be significantly higher than anticipated. Frequent opening of the OR door disrupts air flow systems and thus may limit the effectiveness of measures for prevention of contamination of surgicals and open instrument tray intraoperatively. (9).

In a study done in Mwanza, Tanzania it was clear that overall standard for cleaning the operating theatre environment, decontamination and sterilization of surgical instruments and trays must be raised to effect reduction risk of the surgical site contamination and iatrogenic transmission (10)

MATERIALS AND METHODS

This study used analytical cross-sectional design. It was carried out at the main operating theatres of Kenyatta National Hospital, Nairobi County. The study population comprised of 93 surgical patients who were selected from the following specialties; Orthopaedics, Neuro surgery, Cardiothoracic surgery, General surgery and Urology. Sterile surgical instruments picked from the instrument trays intraoperatively but were not used during surgery. Stratified random sampling was used to capture the five specialties. The surgical patients were free from any infections and swabs were obtained from the surgical site just before incision and immediately after wound closure before dressing, the specialized surgery lasted a minimum of four hours and sterile surgical instruments randomly selected from sterile surgical trays were swabbed at 0 minute then hourly until four hours. A total of 651 (93x7) samples were collected. Data collection check lists were used to verify obtained samples and standard lab request forms for culture and sensitivity. Data was entered in SPSS version 26 for analysis. Research permit was obtained from Kenyatta National Hospital University of Nairobi ethics research committee *P65/02/2021* and NACOSTI *166233*.

Voluntary and informed consent of the patients was sought after explaining the aim of the study and the procedures involved. Confidentiality of the data collected was observed and the identities of the patients was protected by using numbers to ensure the principle of anonymity.

RESULTS

Microbial Colonization

Instrument Colonization

More than half of the instruments were colonized by micro-organisms intra-operatively (51.6%; n=48). Table 4.1 displays the results.

Table 1

Surgical Instrument Colonization

	Frequency	Percent	Cumulative Percent
Not Colonized	45	48.4	48.4
Colonized	48	51.6	51.6
Total	93	100	

Table 2

Time to microbial colonization on the surgical instrument

Time in minutes	Colonization status	% of colonization status	% of survival from colonization
0	Colonized	25%	75%
60	Colonized	38%	62%
120	Colonized	45%	55%
180	Colonized	49%	51%
240	Colonized	53%	47%

Seventy five percent (75%) of the surgical instruments survived microbial colonization at zero minutes (a quarter of the instruments were colonized at zero minute). Sixty two percent of the surgical instruments survived microbial colonization at 60 minutes. Fifty five percent of the surgical instruments survived microbial colonization at 120 minutes. Fifty one percent (half) of the surgical instruments survived the microbial colonization at 180 minutes. Forty seven percent of the surgical instruments survived microbial colonization at 240 minutes. The median time to colonization was 230 minutes while the mean was 240 minutes.

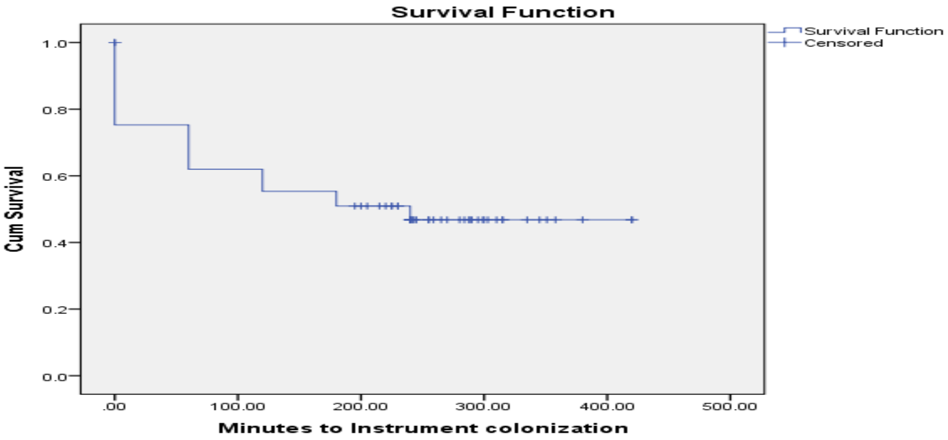

Figure 1: Survival Function for the Surgical Instruments

The mean survival time for the microbial colonization of the instruments was 230 Minutes (95%CI: 192 to 269). The median time was 240 minutes (Four hours). Meaning 50% of the surgical instruments were colonized at 4 hours. The longer the surgery the higher the risk of microbial colonization.

Table 3

Mean and Median Survival Time

Means and Medians for Survival Time							
Mean				Median			
Estimate	Std. Error	95% Confidence Interval		Estimate	Std. Error	95% Confidence Interval	
		Lower Bound	Upper Bound			Lower Bound	Upper Bound

230.33	19.551	192.011	268.649	240	.	.	.
aEstimation is limited to the largest survival time if it is censored							

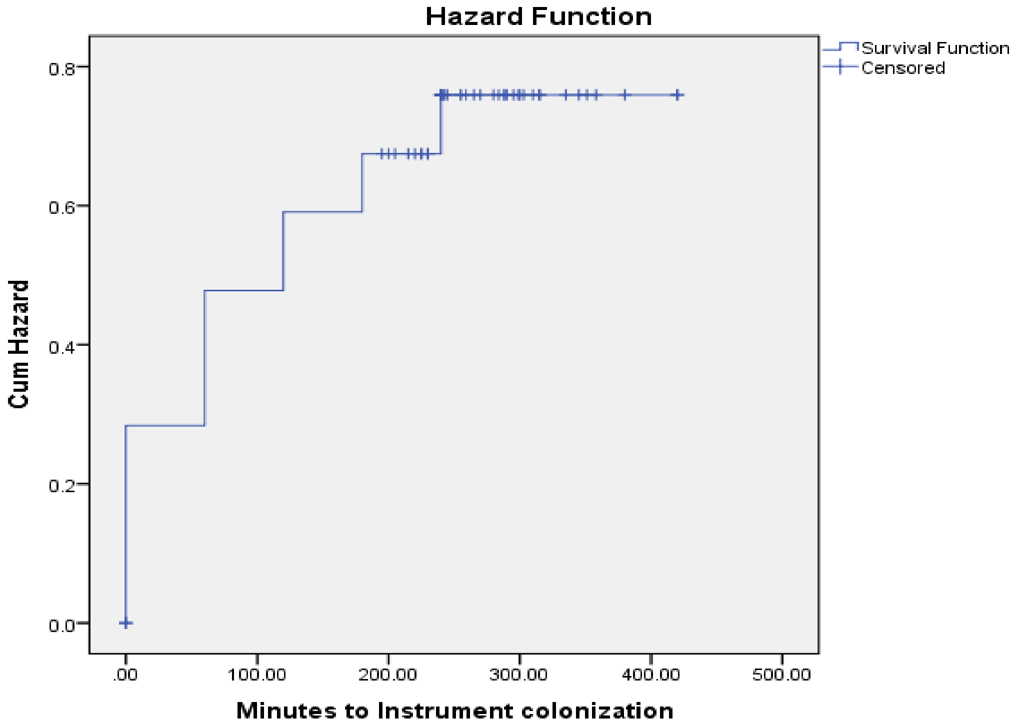

Figure 2: Hazard Function for the Surgical Instruments

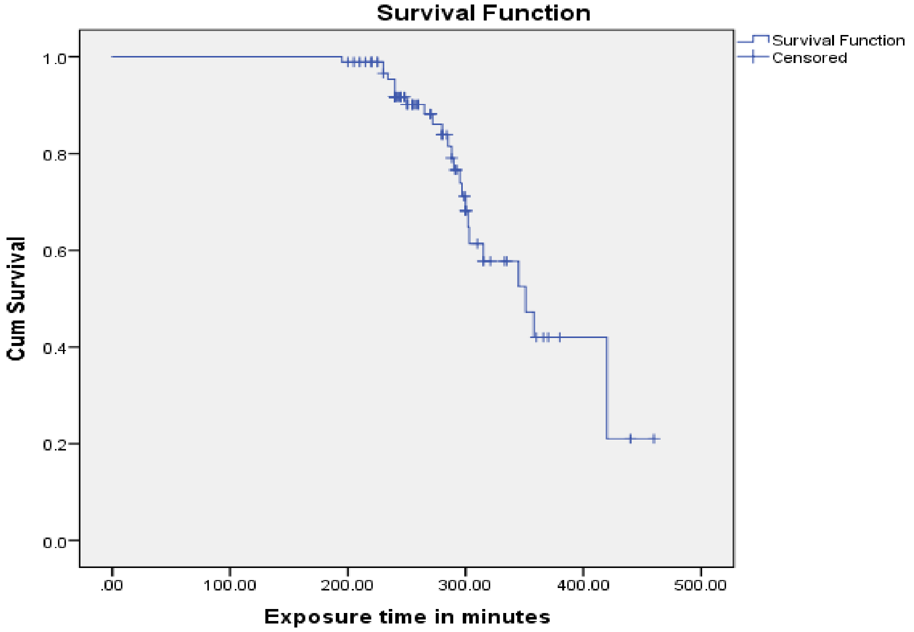

Figure 3: Kaplan Meier survival function for the time to microbial colonization intra-operatively.

Surgical Site Microbial colonization

11.8%; (n=11) patients had microbial colonization on the surgical site pre-surgery. A third of the population got post-surgery microbial colonization on the surgical site (31.2%; n=29). The cumulative incidence of microbial colonization was 269 per 1000 patients (N=25).

Table 4

Occurrence of Surgical Site Microbial Colonization

		Frequency	**Percent**
Pre-surgery patient status	No growth	82	88.2
	Colonized	11	11.8
Post-surgery patient status	No growth	64	68.8
	Colonized	29	31.2
Incidence	NO	68	73.1
	YES	25	26.9
Prevalence	NO	61	65.6
	YES	32	34.4

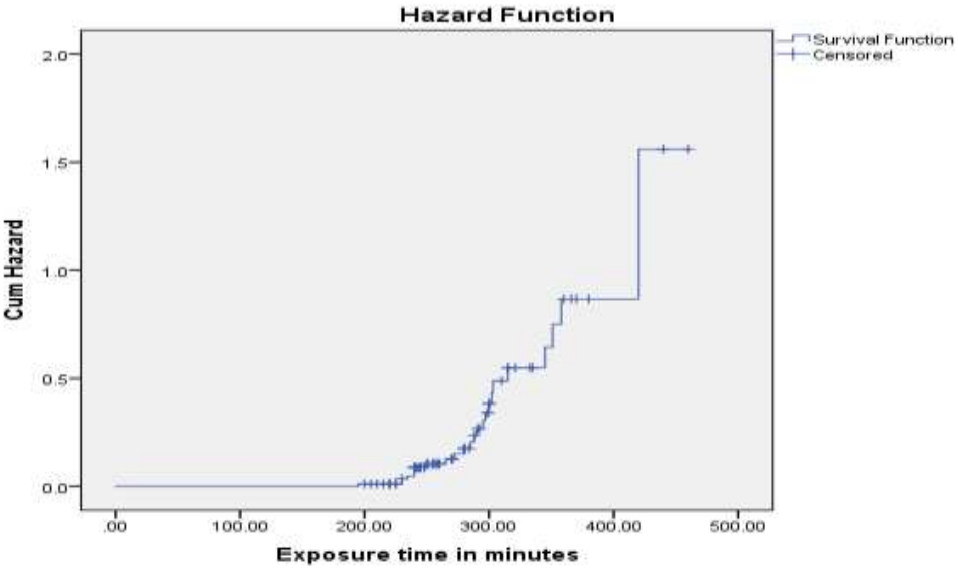

Figure 4: Hazard function for surgical site microbial colonization intra-operatively

The median time for a patient to get microbial colonization was 351 minutes (95%CI: 301 to 401)

Table 5

Means and Medians for Survival Time for Surgical Site Microbial colonization

Means and Medians for Survival Time							
Mean				Median			
Estimate	Std. Error	95% Confidence Interval		Estimate	Std. Error	95% Confidence Interval	
		Lower Bound	Upper Bound			Lower Bound	Upper Bound
358.204	13.224	332.284	384.124	351	25.749	300.532	401.468
a Estimation is limited to the largest survival time if it is censored.							

DISCUSSION

Some instruments were colonized at time 0. (6) Found that the sterilization process may not necessarily produce absolute sterility, even when parameters confirming sterilization have been reached.

More than half of the instruments were colonized by micro-organisms intraoperatively (51.6%; n=48). In a study done in Tokyo Japan where 31% of the instruments were colonized intraoperatively (6). Culture positivity correlated directly with the duration of open exposure of the uncovered trays, with culture-positive rates of 22% and 30% at two and four hours, respectively. 11.8%; (n=11) patients had microbial colonization on the surgical site pre-surgery. A third of the population got post-surgery microbial colonization on the surgical site (31.2%; n=29). The cumulative incidence of microbial colonization was 269 per 1000 patients (N=25). The prevalence was 34.4% (344 per 1000 patients). Some patients got a secondary microbial colonization intra-operatively. In a study done at Mbarara Uganda 16.4 % of patients had microbial colonization pre surgery (12) while in another study done in Mwanza found 27.8% of the patients had microbial colonization post-surgery (13).

Regarding the operating-room environment itself as a source of contamination, Ritter et al. found bacterial counts in an empty operating room to increase significantly after the doors were left open and to increase even further when five or more people were added to the room (1)

During surgery there are situations such as a delay before the start of the operation or multiple procedures performed in the same operative setting where sterile trays are opened but not immediately used. There are no clear guidelines for how long a sterile tray can be exposed to the open environment before the contamination risk becomes unacceptable.

CONCLUTION

A few instruments were positive of microbial colonization at time 0. More than half of the instruments after surgery had microbial colonization. The longer the surgery the more the exposure of instruments and the higher the microbial colonization rate.

Pre operatively on the surgical site there was microbial colonization despite prepping and post operatively on the surgical site there was microbial colonization.

RECOMMENDATIONS

Surgical instrument processing and sterilization to be enhanced. Surgical instruments need to be changed after 4 hours of surgery. Social wash should be done to all surgical sites before surgical prepping

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ORIGINAL RESEARCH ARTICLE

Microbial colonies isolated on surgical sites and surgical instruments intraoperatively at a public referral hospital, Kenya

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Abstract

Background: The surgical field is considered to remain aseptic during operations. This may change with time as surgery progress, microbes eventually settle in the surgical field and cause contamination of sterilized surgical instruments and surgical sites. Microbial contamination of surgical sites and instruments leads to the development of Surgical Site Infection (CDC, 2019). Researchers have demonstrated intraoperative contamination of surgical instruments and surgical sites was common in spite of various means of preventing Surgical Site Infections, such as skin preparation preoperatively, prophylactic antibiotics, and intraoperative aseptic technique. Different types of microorganisms have been isolated on surgical instruments mainly postoperatively (Saito et al, 2014). This study dwelled on the intraoperative sessions of surgery. Change of surgical instruments and drapes after prolonged exposure is recommended strongly as basic practice.

Materials and Methods: Analytical cross-sectional design was used. The study subjects were 93 surgical patients pre and post-surgery wound swabs were done. Instruments swabs was done at intervals from 0 minute then hourly up to 4 hours.

Check lists and laboratory forms were used for data collection. Sample size was 651 (93x7) 2 samples on the surgical site and 5 samples from the instruments. SPSS was used to analyze descriptive statistics.

Results: *Staphylococcus species* had the highest frequency and percentage both on the surgical site pre and post-surgery as well as instrument swabs at all levels of time from time 0 then hourly up to 4 hours. The *staphylococcus species* infection range was 7% to 20%. Others included *Bacillus* species, *klebsiella* and *Escherichia coli* at minimal percentages.

Conclusion: In surgical site infections, the study demonstrates that the frequently occurring organism is *Staphylococcus aureus*. This is due to normal flora of skin of patients and also shed by the personnel in the theatres. There was evidence of microbial colonization on the surgical sites and instruments.

Recommendation: Change of surgical instruments and drapes, enhanced surgical prepping and enhance instrument processing and sterilization.

Key words: Surgical Site Infections, Intraoperative Contamination

1.0 Introduction

The surgical field is considered to remain aseptic during operation. This may change with time as surgery progress microbes eventually settle in the surgical field and cause contamination of sterilized surgical instruments and surgical sites.

The burden and suffering posed by surgical site infections (SSIs) on patients' safety globally in terms of pain, delayed surgical site healing, increased use of antibiotics, revision surgery, increased length of hospital stay, morbidity and mortality rates, which are also reflected in excess health care costs (Richmond et al., 2015).

In a study done in Mwanza, Tanzania it was clear that overall standard for cleaning the operating theatre environment, decontamination and sterilization of surgical instruments and trays must be raised to effect reduction risk of the surgical site contamination and iatrogenic transmission (Mpogoro et al., 2014).

Despite good practices incorporation and improvements in operating room practices, instrument decontamination and sterilization methods, improved surgical technique, and best practices of infection prevention and control strategies, surgical site infections remain a major cause of hospital-acquired infections (Lubega et al., 2017)

In surgical oncology patients, the efficacy of negative pressure therapy (NPT) in preventing SSIs has been tested with (Blackham et al., 2013) actually proving that it decreases SSIs in oncology patients.

Patients with SSI have a significantly higher overall comorbidity burden, higher perioperative mortality rates, longer length of stay, and higher complication rates. In their evaluation (Poultsides et al., 2013) found that the average cost of in-hospital care was double for SSI versus non-SSI patients

Several researchers have demonstrated that intraoperative contamination of surgical instruments was common in spite of various means of preventing Surgical Site Infections, such as skin preparation preoperatively, prophylactic antibiotics given, and intraoperative aseptic technique. The study sought to identify microbial colonies found on the surgical instruments and surgical sites intraoperatively.

2.0 Materials & methods

This study used analytical cross-sectional design. Quantitative observational approach to data collection, analysis and presentation was adopted. It was carried out in operating theatres at a public referral hospital. The study population comprised of 93 surgical patients. Sterile surgical instruments picked from the instrument trays intraoperatively but were not used during surgery however were exposed within the same environment till end of surgery. The surgical patients were free from any infections and swabs were obtained from the surgical site after prepping just before incision and immediately after wound closure. Sterile surgical instruments randomly selected from sterile surgical trays were swabbed at 0 minute then hourly until four hours. A total of 651 (93x7) samples were collected. Data collection check lists were used to verify obtained samples and standard lab request forms for culture and sensitivity. Data was entered in SPSS version 26 for analysis. Research permit was obtained from Kenyatta National Hospital University of Nairobi ethics research committee *P65/02/2021* and NACOSTI *166233*. Voluntary and informed consent of the patients was sought after explaining the aim of the study and the procedures involved. Confidentiality of the data collected was observed and the identities of the patients was protected by using numbers to ensure the principle of anonymity.

3.0 Results

3.1 Types of organism colonization Pre- surgery on the surgical sites

The *staphylococcus* species were predominantly responsible for majority (7.7%) of the microbial colonization on the surgical site pre surgery. The types of species include *staphylococcus aureus, staphylococcus coagulase negative and staphylococcus proteus. Bacillus* species was 3.3%, *klebsiella* 2.2% and *Escherichia coli* at 1.1%. This is illustrated in table 1 below.

Table 1. Types of Organism colonization Pre- Surgery on the Surgical Sites

	Frequency	Percent
Bacillus Species	1	1.1
Bacillus Species, Coagulase Staphylococci, Staphylococcus Aureus	1	1.1
Bacillus Species, Proteus Species, Klebsiella Species	1	1.1
Coagulase Negative Staphylococcus	3	3.3
Coagulase Negative Staphylococcus Proteus Species	1	1.1
Escherichia Coli	1	1.1
Klebsiella Species	1	1.1
No Growth	82	88.2
Staphylococcus Aureus	2	2.2

3.2 Type of organism colonization post-surgery on the surgical sites

Table 2 Illustrates *Staphylococcuss species* formed the majority of microbial colonization of the surgical site postoperatively at *20.6%. Bacillus species* remained the same proportion at 3.3% as at pre-surgery, *micrococcus species 3.3%* and it is noted that it was not present pre surgery. *Klebsiella species 2.2%, acinetobacter baumannii* and *enterococcus fecalis* each at 1% and were not present pre surgery.

Table 2. Type of Organism colonization Post______-Surgery on the Surgical Sites

	Frequency	Percent
Bacillus Species	3	3.2
Coagulase Negative Staphylococci	1	1.1
Coagulase Staphylococcus Aureus	1	1.1
Micrococcus	1	1.1
Staphylococcus Aureus	15	16.2
Staphylococcus Aureus, Enterococcus Faecalis	1	1.1
Acinetobacter Baumannii	1	1.1
Enterococcus Faecalis	1	1.1
Klebsiella Species	2	2.2
Micrococcus Species	2	2.2
No Growth	64	68.8
Staphylococcus Proteus Species	1	1.1

3.3 Organisms cultured on surgical instruments at time zero

Pre surgery instruments are sterile and assumed to be free from microbial colonization. However Table 3 shows the microbial colonization on instruments at time zero as follows: *Staphylococcus species* was dominant at 9.8%, *candida species was 8.8%,* *bacillus species 4.4%, acinetobacter baumanii 3.3%, enterococcus faecalis, micrococcus species and pseudomonas species at 2.2% respectively and klebsiella species at 1%.*

Table 3. Organisms Cultured on Surgical Instruments at Time Zero

	Frequency	Percent
Bacillus Species, Acinetobacter Baumanii	1	1.1
Candida Species	7	7.7
Staphylococcus Aureus	5	5.4
Staphylococcus Aureus, Bacillus Species	1	1.1
Acinetobacter Baumannii, Bacillus Species	1	1.1
Acinetobacter Baumannii	1	1.1
Bacillus Species	1	1.1
Coagulase Negative Staphylococcus	3	3.3
Enterococcus Faecalis	2	2.2
Klebsiella Species	1	1.1
Micrococcus Species, Candida Species	1	1.1
Micrococcus Species	1	1.1
No Growth	66	71
Pseudomonas Species	2	2.2

3.4 Organisms cultured on surgical instrument at 60 minutes

Table 4 illustrates Microbial colonization of surgical instruments at 60 minutes was as follows: *staphylococcus species was at 13%, Candida species 10%, bacillus species 6.6%, acinetobacter baumanii 3.3%, Escherichia coli and micrococcus species at 2.2%* respectively*, enterococcus faecalis, proteus species and pseudomonas species at 1.1%* respectively.

Table 4. Organisms Cultured on Surgical Instrument at 60 Minutes

	Frequency	Percent
Bacillus Species, Staphylococcus Aureus	2	2.2
Bacillus Species, Escherichia Coli	1	1.1
Candida Species	9	9.9
Staphylococcus Aureus	7	7.5
Staphylococcus Aureus, Bacillus Species	1	1.1
Acinetobacter Baumanii	1	1.1
Bacillus Species	1	1.1
Bacillus Species, Acinetobacter Baumanii	1	1.1
Candida Species, Acinetobacter Baumanii	1	1.1
Coagulase Negative Staphyloccoci	2	2.2
Escherichia Coli	1	1.1
Enterococcus Faecalis	1	1.1
Micrococcus Species	1	1.1
No Growth	61	65.6
Proteus Species	1	1.1
Pseudomonas Species	1	1.1
Micrococcus species	1	1.1

3.5 Organisms cultured on instrument at 120 minutes

Table 5 illustrates microbial colonization of instruments at 120 minutes as follows: *Staphylococcus species was at 17.4%, Candida species 9.7%, bacillus species 4.4%, pseudomonas species 4.3%*, *acinetobacter baumannii, Escherichia coli, micrococcus species at 1.1%* respectively *and a new entry of citrobacter species at 1.1%.*

Table 5 Organisms cultured on Instrument at 120 Minutes

	Frequency	Percent
Staphylococcus Aureus	5	5.5

Acinetobacter Baumannii, Bacillus Species	1	1.1
Bacillus Species, Coagulase Negative Staphylococci	1	1.1
Candida Species	8	8.6
Candida Species, Gram Negative , Catalase Positive	1	1.1
Citrobacter Species	1	1.1
Coagulase Negative Staphylococci	7	7.5
Coagulase Negative Staphylococci, Klebsiella Species	2	2.2
Escherichia Coli	1	1.1
Micrococcus Species	1	1.1
No Growth	60	64.6
Pseudomonas Species	3	3.2
Pseudomonas Species, Bacillus Species	1	1.1
Staphylococcus Aureus, Bacillus Species	1	1.1

3.6 Organisms cultured on surgical instrument at 180 minutes

At 180 minutes the following microorganisms were cultured on surgical instruments as illustrated in Table 6. *staphylococcus species 14.1%, candida species 11.9%*, *bacillus species 5.5%, pseudomonas species 4.4%*, *acinetobacter baumannii, Escherichia coli, micrococcus species at 1.1%* respectively.

Table 6. Organisms Cultured on Surgical Instrument at 180 Minutes

	Frequency	Percent
Enterobacter Faecalis	2	2.2
Bacillus Species, Pseudomonas Species	2	2.2

Staphylococcus Aureus, Bacillus Species	1	1.1
Acinetobacter Baumannii, Coagulase Negative Staphylococci	1	1.1
Bacillus Species	2	2.2
Staphylococcus Aureus	1	1.1
Candida Species	10	10.8
Candida Species, Enterococcus Faecalis	1	1.1
Catalase Positive	1	1.1
Coagulase Negative Staphylococci	5	5.4
Gram Positive Rods	1	1.1
Escherichia Coli	1	1.1
Gram Negative Rods	1	1.1
Micrococcus Species	1	1.1
No Growth	56	60.3
Pseudomonas Species	2	2.2
Staphylococci Aureus	5	5.4

3.7 Organisms Cultured on Surgical Instrument at 240 Minutes

At 240 minutes the following microorganisms were cultured on surgical instruments as illustrated in Table 7. *staphylococcus species 12%, candida species 8.7%, bacillus species 6.6%, pseudomonas species 3.3%, acinetobacter baumannii 3.3%, klebsiella 1.1%, micrococcus species, enterococcus feacalis at 1.1%* respectively. Mc-Lf species at 1.1%.

Table 7. Organisms cultured on surgical instrument at 240 minutes

	Frequency	Percent
Bacillus Species	2	2.2
Acinetobacter Baumannii	2	2.2
Bacillus Species, Acinetobacter Baumannii	1	1.1
Bacillus Species, Pseudomonas Species	1	1.1
Candida Species	8	8.7
Staphylococcus Aureus	5	5.5
Staphylococcus Aureus,+Ve Bacillus	1	1.1
Gram Negative Colonies	1	1.1

Enterococcus Faecalis, Bacillus Species	1	1.1
Gram -Ve, Candida Species, Catalase -Ve	1	1.1
Klebsiella Species	1	1.1
Mac¬Lf Species	1	1.1
Micrococcus Species	1	1.1
No Growth	59	63.4
Pseudomonas Species	2	2.2
Pseudomonas Species, Gram positive Bacillus	1	1.1
Staphylococci Aureus –Ve	5	5.4

4.0 Discussion

In this study staphylococcus species had the highest frequency and percentage both on the surgical site pre and post-surgery as well as instrument swabs at all levels of time as is depicted above. In a study by (Sadrizadeh et al,. 2018) *staphylococcus aureus* is the most common organism in Surgical Site Infections (SSI) due to normal flora of skin of patients and also shed by the personnel in operating theatres. It is generally agreed that airborne pathogens found frequently in surgical sites are primarily *staphylococcus aureus* released from the skin flora. The bacteria is the leading cause of SSI and just a small amount can initiate severe infection at the surgical site. (Dreikausen et al 2023), found that microbial contamination of surgical instruments only play a minor role as a potential exogenious source of microbial contamination compared to the high microbial load in the air. In their study the most common microorganisms were *coagulase negative staphylococcus* followed by *bacillus and micrococcus* species which is in accordance with literature.

The air remains an important exogenous source of microorganisms potentially leading to surgical site infections. Therefore analysis of microbial contamination during use and reprocessing of surgical instruments and sterile packaging systems is of importance. In this study microbial contamination was isolated at time 0 minute when instruments are presumed to be absolutely sterile.

Regarding the operating-room environment itself as a source of contamination, Smith et al (2013) found bacterial counts in an empty operating room to increase significantly after the doors were left open and to increase even further when five or more people were added to the room. This study indicates that *staphylococcus aureus* which is the commonest skin flora is the dominant indicator of microbial growth on surgical instruments and instrument sets in the operating theatres. The study findings implicate the operating theatre staff and patients to be the most likely source of contamination of the instruments by microbes shed from the skin. In contrast (Smith et al,. 2013) in their study where they generated light traffic in the operating theatres did not influence the contamination rate.

5.0 Conclusion

The longer the surgery the more the exposure of instruments and the higher the microbial colonization rate. Despite prepping before incision there was evidence of microbial colonization on the surgical site. Staphylococcus aureus is the most common organism in SSI. This is due to normal flora of skin of patients and also shed by the personnel in the theatres.

6.0 Recommendations

Change of surgical instruments and drapes intraoperatively, enhanced surgical prepping and enhance instrument processing and sterilization.

7.0 References

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