UNIVERSITY OF NAIROBI, COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF ANAESTHESIA

PATTERNS OF HEALTHCARE-ASSOCIATED INFECTIONS IN PATIENTS AT KENYATTA NATIONAL HOSPITAL MAIN INTENSIVE CARE UNIT.

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JUNE, 2023

DECLARATION

I, **Dr. Elly Thathi,** do hereby declare that this proposal is my original work and has not been presented before, either in whole or part, to this institution or any other institution elsewhere for academic qualification. I further declare that all material cited in this report which are not my own, has been duly acknowledged.

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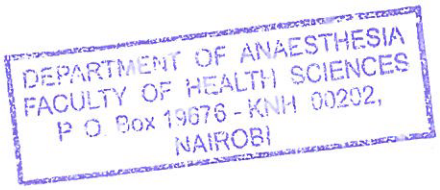

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LIST OF ABBREVIATIONS

AMR	Antimicrobial Resistance
AMS	Antimicrobial Stewardship
BSI	Bloodstream Infection
CAUTI	Catheter-Associated Urinary Tract Infection
CDC	Center for Disease Control and Prevention
CFU	Colony Forming Units
CLABSI	Central Line-Associated Blood Stream Infection
CLSI	Clinical and Laboratory Standard Institute
ECDC	European Centre for Disease Prevention and Control
EPIC	Extended Prevalence of Infection in Intensive Care
ESBL	Extended- spectrum beta-Lactamases
EUCAST	European Committee on Antimicrobial Susceptibility Testing
HAI-Net	Healthcare-associated Infections Surveillance Network
HCAI	Healthcare-Associated Infections
ICU	Intensive Care Unit
IPC	Infection Prevention and Control
KNH	Kenyatta National Hospital
LRTI	Lower Respiratory Tract Infections
MRSA	Methicillin-resistant Staphylococcus
NHSN	National Healthcare Safety Network
NI	Nosocomial Infections
PEEP	Positive End Expiratory Pressure
PI	Principal Investigator
RA	Research Assistant
SIRS	Systemic inflammatory response syndrome
SPP	Species
SSI	Surgical Site Infection
VAP	Ventilator-Associated Pneumonia
WHO	World Health Organization
WHO	World Health Organisation

DEFINITION OF OPERATIONAL TERMS

Admission Date:	The day of the patient's entry into a Critical Care Unit
Antibiotic stewardship:	This is the optimal selection, dosage, and duration of antimicrobial treatment that results in the best clinical outcome for the treatment or prevention of infection, with minimal toxicity to the patient and minimal impact on subsequent resistance.
Central line (CL):	An intravascular catheter that terminates at or close to the heart or in one of the great vessels utilized for infusion, withdrawal of blood, and hemodynamic monitoring.
Critical Care Unit:	Refers to acute care units in the hospital, namely, the Intensive Care Unit, Coronary Care Unit, High Dependency Unit, and Cardiothoracic –Intensive Care Unit
Developed Countries:	These are high-income countries according to the World Bank Classification 2009.
Developing Countries:	These are low- and middle-income countries according to the World Bank Classification 2009.
Device-associated HAI:	Is an infection in a patient with a (relevant) device used within the 48 hours before the onset of illness (even if used only intermittently)
Discharge Date:	The day of release from the hospital or unit by a patient on follow-up; it also marks the day of the patient's demise or transfer to another ward
Indwelling urinary catheter:	Drainage tubes inserted into the urinary bladder through the urethra, left in place and connected to a collection system.
Length of Stay:	Duration between patient's admission and discharge
Nosocomial Infection:	Infection that occurs in a patient while admitted to a hospital
Systemic Inflammatory Response Syndrome:	This is an exaggerated defense response of the body to a noxious stressors (infection, trauma, surgery, acute inflammation) to localize and eliminate the endo/exogenous stressors.

ABSTRACT

Background: Healthcare-Associated Infections refer to those infections that occur 48 hours after admission to healthcare facilities. Such infections are related to the use of invasive devices and procedures. Intensive Care Unit patients are at an increased risk of acquiring HCAIs, possibly due to inherent patient disease factors such as underlying co-morbidities and extremes of age. HCAIs create a three-pronged challenge to global health systems; first, by increasing patient mortality and morbidity; next, by contributing to increased health care costs; and finally, by worsening antimicrobial resistance (AMR). Prevention of HCAIs through evidence-based interventions and surveillance is of paramount importance.

Objectives: To determine the incidence, etiology, and risk factors associated with HCAIs in patients admitted to Kenyatta National Hospital Main ICU.

Materials and Methods: Using a prospective cohort study model and a consecutive convenience sampling approach, all patients regardless of age admitted at the KNH Main ICU during the study period (February to April 2023) were enrolled and followed up for seven days. The patients were screened daily for any HCAI starting 48 hours after admission, as defined by the Centre for Disease Prevention and Control guidelines 2022. A structured data collection tool was used for data collection and stored in a Microsoft Excel 2016 database that was password protected. The data collected included age, gender, admitting diagnosis, surgical intervention, length of surgery, co-morbidities, patients' vitals, presence of invasive devices, and medication history.

Data Analysis: Patients' demographic and clinical data were cleaned and analyzed using the Stata Statistics software version 15. Continuous variables were presented in the form of mean, median, and interquartile ranges and tested for normality with the Shapiro-Wilk test. Categorical variables were submitted in the form of tables, and a comparison of distribution between these groups was tested using the Chi-square test. The time to occurrence of infection was presented using Kaplan- Meier Survival curve. Multivariate logistic regression analyses were used to predict the association between risk factors and HCAIs.

Significance of the Study: The study revealed the incidence of HCAIs, and the microorganisms involved and highlighted the risk factors associated with these infections. This information will form the basis for assessing our infection prevention protocols and guiding improvements to our current therapy modalities.

1.0 CHAPTER ONE: INTRODUCTION

No one should acquire an infection while receiving health care for an unrelated ailment, yet it's among the most common complications arising during care delivery. Healthcare-associated infection (HCAI) refers to infections acquired by patients while receiving medical care after 48 to 72 hours of admission, up to 3 days after discharge, or up to 30 days in the case of surgical site infection (1). This definition applies to hospitals, ambulatory clinics, or long-term healthcare facilities like nursing homes (2).

HCAIs encompass several subtypes as highlighted by the WHO report on HCAIs, such as Blood Stream Infection (BSI), Central Line-Associated Blood Stream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Surgical Site Infection (SSI), Hospital-acquired Pneumonia (HAP) and Ventilator-Associated Pneumonia(VAP). These infections account for 80% of all HCAIs (3),(4). Infrequently, the remaining 20% of infections occur in joints, skin, and soft tissues (3).

The World Health Organization (WHO) HCAI report disclosed that hundreds of millions of patients are affected yearly (5),(6), with at least half of these HCAIs occurring in the ICU setup (7). In developing countries, the frequency of HCAIs in ICUs is 2-3-fold higher compared to developed countries (6), thought to be a result of poor infection control practices, understaffing of healthcare facilities, and overcrowding of hospitals (8). 10% of those affected with HCAIs succumb to these infections (2),(9).

HCAI incidence in the ICU is estimated to be up to 5 times higher than in the general wards (4) due to the use of invasive devices, the presence of surgical incisions, immobility, and the need for mechanical ventilation (10). HCAIs are propagated further by significant antimicrobial resistance rates seen due to the haphazard use of antimicrobial agents to treat infections in the ICU (11).

The strategies adopted to ease HCAIs effects include the "*WHO Clean Care is Safer Care"* program which aims to reduce HCAIs by emphasizing hand hygiene in the healthcare system (9), and the CDC campaign to prevent antimicrobial resistance through the advocacy of wise use of antimicrobials(12).

HCAIs still create a three-pronged challenge to global health systems, despite the application of various mitigation strategies. Firstly, by increasing patient mortality and morbidity. The increased morbidity is due to prolonged mechanical ventilation, ICU stays (between 5 and 29. 5 days), and the creation of long-term disability (6). The increased mortality is due to the development of antimicrobial-resistant organisms, including Methicillin-resistant

Staphylococcus (MRSA) and those that produce Extended-spectrum beta-Lactamases (ESBL) that are challenging to treat (11),(13). Secondly, worsening antimicrobial resistance, where more than 70% of bacterial HCAIs have been shown, can be resistant to existing antimicrobials (12), creating an imminent crisis in healthcare systems. Thirdly, causing an increased cost implication for patients' families and healthcare systems. This cost can be as high as $6.5 billion/year in the USA, and 13–24 billion Euros annually in Europe (12) as a result of increased use of drugs, need for dialysis, and inotropic support, laboratory, and diagnostic services, and increased length of stay (3). Medico-legal issues can also arise due to litigation by the patients or relatives blaming the hospital for the infection acquired and demanding compensation (13). HCAIs are preventable with current evidence-based policies for Infection Prevention and Control (IPC) and continuous health surveillance activities (14), whose adherence results in improved health outcomes, avoidance of litigation, decrease in healthcare costs, and prevention of morbidity and mortality. Such policies include screening those at risk, hand hygiene by all staff and patients, use of personal protective equipment, environmental and equipment hygiene, respiratory hygiene, sharps safety (15), public health surveillance, and antibiotic stewardship(9). Whereby; strict conformance to good hand-hygiene practices has been shown to effectively reduce the rates of HCAI by 40% (2),(9).

Most of the published studies on HCAIs have been carried out in developed countries compared to developing countries, especially in Africa, as only a few have established national surveillance systems. This study assessed the HCAIs in a busy ICU by determining the incidence, etiological basis, and risk factors for developing HCAIs showing the current infection burden. This would inform the change in practice and strategies to ensure hospital safety and the prevention of HCAIs in the ICU.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1. Background

An intensive care unit is a specialized unit that provides care for critically ill patients (13) in a hospital. An ideal ICU comprises a myriad of highly specialized health personnel in appropriate numbers and complex equipment to provide invasive hemodynamic monitoring and ventilatory support. An ICU should function round the clock with trained health workers to deal with all emergencies as they arise, ICU-acquired infection is the acquisition of a new infection 48 hours after admission to the ICU (16). The high incidence of these infections is associated with the use of invasive devices in the ICU, particularly central lines, urinary catheters, and ventilators (5). A WHO Report on the Burden of HCAIs showed that at least a third of patients admitted to an ICU will be affected by a minimum of one episode of HCA. Ultimately results in increased morbidity in the way of lengthy hospital stays and susceptibility to further infections (5).

2.2 Incidence, Etiology, And Risk Factors of HCAIs

2.2.1 The incidence of HCAIs

HCAI incidence refers to all new infections acquired while undergoing unrelated treatment in a health facility followed up for a defined period (5).

HCAIs in developing countries ranged from 5 to 19% compared to 3 to 12% in developed countries (5),(6),(17). This greater burden in developing countries is also seen in a different WHO systematic review that showed HCAIs incidence density in adult ICUs was three times as high as in the developed countries (13).

A multicentric international study reported at least one ICU-acquired infection in the patients admitted to the ICUs across the centers (18). Most studies on HCAIs have reported an incidence range of 9% to 37% (1), depending mainly on the populations studied (2). Globally, this can be appreciated explicitly by various studies and surveys (4),(7),(17), and (19) on the incidence rates of HCAIs.

Closer home, most reports on the burden of HCAIs in Sub-Saharan Africa focus on prevalence. A few examples of the prevalence of HCAIs in African countries were 19% in Mali,11% in Senegal, 7% in Ghana, 13% in Botswana,7% in South Africa, and 14% in Tanzania (5) with a recent addition in Ethiopia in 2020 by Alemu et al. review that showed a prevalence of 17%. (20).

2.2.2 The Microbiological Organisms Associated With The Development of HCAIs

The microbial agents can be bacterial, viral, fungal, or parasitic. They can be acquired from one person to another (cross-infection) or from a patient's flora (endogenous infection), or from contaminated objects or substances that come into contact with the individual (environmental infection).

Recent years have witnessed swings in the etiologic pathogen pattern of Gram-positive bacterial organisms. Nonetheless, Gram-negative bacteria still cause ICU HCAIs in more than half of the cases, which is in tandem with the EPIC II study (1) that also showed *Acinetobacter* isolates having a high incidence in African ICUs due to their presence in the water supplies of hospitals. Thus, believed to potentially contaminate resuscitation equipment and reusable ventilator circus (13). Fungal pathogens are also shown to become increasingly common, especially *Candida species* (1).

Today, most HCAIs are caused by ubiquitous organisms, including *Staphylococcus aureus, enterococci, enterobacteriaceae* (3)*, pseudomonas species,* and *acinetobacter species* have been shown to give rise to approximately 70% of all HCAIs in ICU patients (13). Various studies have globally noted similar causative organisms' patterns (4),(7),(19),(21),(17),(22).

Closer home; the same pattern is repeated (13) as seen in an African systematic review of HCAI by Irek et al., where roughly 60% of the data were from East Africa, which showed the most common pathogens identified were *Klebsiella species., Staphylococcus aureus, Escherichia coli, Pseudomonas spp, and Acinetobacter species* (8). Supported further by a local study done by Ngumi et al. at KNH ICU (23).

2.2.3 The Risk Factors Associated With The Development of HCAIS

The risk factors for developing HCAI include environmental, patient susceptibility, and pathogen resistance in the ICU setup (6). Among these three factors, greater severity of illness by the patient, an immunocompromised state, premedication with antibiotics, and the use of invasive procedures and devices were found to be the most significant in all the studies (10).

The patient factors associated with HCAI include extremes of age (<1 year and > 65 years), immunity status, disease severity, underlying comorbid conditions, malnutrition, and diagnostic and therapeutic interventions, including chemotherapy and radiation therapy (3). This is supported by various studies (4),(11),(13), and (21) that highlighted the above as the significant host factors that predispose to the development of HCAIs.

The environmental factors associated with HCAI include the concentration of patients susceptible to infections in the ICU, long duration of stay, failure of health workers to adhere to handwashing practices, and prolonged and inappropriate use of invasive devices (6) like central venous catheters, urinary catheters, prolonged endotracheal intubation with mechanical ventilation, tracheostomy tube, nasogastric tube placement and invasive procedures (7),(19),(21). Bacterial resistance occurs due to widespread overuse and misuse of antimicrobial drugs with poor antimicrobial stewardship (3),(7),(19).

2.3 Sub-Types of Healthcare-Associated Infections

The important subtypes of HCAIs include;

a) Surgical site infection
b) Ventilator-acquired pneumonia
c) Catheter-associated urinary tract infection
d) Central line bloodstream infection

SSI is the leading cause of HCAIs in developing countries, while CAUTI is the most frequent in developed countries (2),(6).

2.3.1 Surgical Site Infections in The Intensive Care Unit

Surgical site infection (SSI) is a complication of a surgical intervention where an infection occurs involving the surgical incision site. The infection can be within the skin, subcutaneous fat, muscular, fascial layer, or in an organ or cavity within 30 from the operation (24).
SSIs management cost is estimated to be $3.3 billion annually in the USA, contributing to extended hospital length of stay and loss of income due to disability. SSIs are associated with a several-fold increase in mortality risk, with three-quarters of SSI-associated deaths directly attributable to SSI(24).

Diagnosis of an SSI is a combination of both clinical and laboratory criteria vis;

1. Clinical criteria include at least one of the following within 30 days of surgery
    - fever $>38^0$
    - sign of inflammation: localized tenderness, warmth, erythema, induration
    - purulent discharge at the incision site/wound/drain
    - abscess identified by direct examination or during reoperation by a surgeon or physician who declares the wound infected

2. Laboratory criteria include a positive culture from a swab taken from a surgical incision site/wound (16),(24).

2.3.1.1 Incidence of SSI

SSI is the most common complication in post-operative patients (5). SSIs account for up to 20% of all HCAIs in general(24). SSI incidence density ranges from 1.2 - 23.6 for every 100 surgical procedures in developing countries, in contrast to 1.2- 5.2 per 100 surgical procedures in developed countries. The incidence rate of SSI is 5-25% in ICU patients, as represented in various studies (5). For example: In a systematic review by Ling et al. in 2015 on the burden of HCAIs; showed the incidence rate of SSI to be at 7.8% (21) as well as a local study by Njiru et al. in 2015 on Craniotomy SSI in KNH showed a rate of 7.5%, with the majority occurring within the first seven days postoperatively(25).

2.3.1.2 Microbiological Organisms Causing SSI

The patient's endogenous skin flora is regarded as the most common cause of SSI. A study by Cheadle et al. (2006) on SSIs supported this assertion, whereby the gram-positive infection could be inoculated from the patient's skin during a surgical incision (26).
In a systemic review in South East Asia, Ling et al. showed that the most common microorganisms implicated in SSI in ICU were *S. aureus, E. coli, Acinetobacter baumannii,* and *Pseudomonas species* (21). These organisms have been mirrored in studies and reviews done in India (4) and Africa (8).

2.3.1.3 Risk Factors of SSI

According to numerous studies, the common risk factors for developing SSI are either patient or procedure-related, as well as the choice of antimicrobial prophylaxis used. The factors for SSI found to be statistically significant by a Systematic Literature Review in 2015 by Ling et al. were; the type of surgery with the highest risk seen in orthopedic, cardiac, and intraabdominal surgery (2), and the length of surgery, wound type, and age (21). In addition to smoking, obesity, and the presence of surgical drains by a study done by Njiru et al (25).

2.3.2 Ventilator-Associated Pneumonia In The Intensive Care Unit

Ventilator-associated pneumonia is a respiratory infection that occurs after using an invasive airway device, i.e., an endotracheal tube or tracheostomy for mechanical ventilation 48 hours before the onset of illness (16).

VAP accounts for more than 90% of cases of pneumonia in the ICU (21). VAP significantly worsens the patient's prognosis, causes the excessive use of antibiotics, increases treatment costs, and prolongs hospitalization time (27).

Diagnosis is made using a combination of clinical, laboratory, and radiological criteria.

a. Clinical: at least two of the following: cough, purulent sputum, worsening signs of gas exchange such as increased oxygen requirements by at least 20%, or increased ventilation demand (increase in PEEP by at least 3 cm H2O), and fever > 38 °C with no other cause.
b. Laboratory: a positive culture from sputum or tracheal aspirates with a threshold of 10^6 CFU/ml obtained after 48 hours of admission and either leukopenia or leucocytosis.
c. Radiological: progressive new infiltrate on chest x-ray not present on admission (16),(28).

2.3.2.1 Incidence of VAP

VAP accounts for up to 25% of all HCAIs (28). WHO compared incidence densities of VAP between low- and high-income countries, and the results were overwhelming for the lower-income countries at 23.9 vs. 7.9 per 1000 ventilator days (5).

The incidence rate of VAP ranged from 10-35% in ICU patients, as represented in various studies (4),(7),(27) supported further by a local survey by Kinuthia et al. on the patterns of VAP in KNH ICU during the four-month study period (29).

2.3.2.2 Microbiological Organisms Causing VAP

Identifying the microbiological basis is the key to selecting appropriate antimicrobial therapy for VAP. These microorganisms vary depending on factors such as patient characteristics, duration of mechanical ventilation, prior antimicrobial administration, and geographical location.

The most common bacteria known to cause VAP include the following, which have been mirrored in various studies and reviews across the globe and locally (4),(8),(21),(29);

1. *Pseudomonas aeruginosa,*
2. *Klebsiella pneumoniae,*
3. *Acinetobacter species,*
4. *Staphylococcus aureus,*
5. *Enterobacter group and*
6. *Citrobacter species.*

2.3.2.3 Risk factors of VAP

The risk of VAP varies with the infecting organism and patient population. According to a retrospective study in Krakow, patients at an increased risk for VAP had co-morbidities such as diabetes, chronic obstructive pulmonary disease, alcoholism, and obesity (27).

The main risk factors known for VAP include intubation and mechanical ventilation, which are associated with a 21-fold increase in VAP incidence, extremes of age, abdominal or thoracic surgery, and the previous use of broad-spectrum antibiotics (27).

Other risk factors found to be significant include the use of enteral feeds, paralytic agents and antacids, neurological injury, trauma, reintubation, and sepsis (29).

2.3.3 Catheter-Associated Urinary Tract Infection In The Intensive Care Unit

Catheter-associated urinary tract infection (CAUTI**)** is a primary infection associated with indwelling urinary catheter use in the 48 hours preceding the onset of the infection (30).

Urinary catheter insertion is among the most performed procedures in healthcare settings. In developing countries, CAUTIs are the most prevalent cause of gram-negative bacteremia. CAUTIs affect all age groups and are linked with higher rates of antibiotic resistance. This assertion was confirmed by Chuang et al. (31) in their paper on microbiological surveillance. Therefore the impact and significance of CAUTI in global health systems are seen in hospital costs, morbidity, and mortality.

Diagnosis is based on a combination of clinical and laboratory parameters, which include;

- Clinical: at least one of the following symptoms developing after 48 hours of admission with no other recognized cause:
    a) High body temperature is often greater than 38 °C,

b) Tenderness in the suprapubic region,
c) Hematuria,
d) Flank and back angle pain or tenderness at the costovertebral angle,
e) If the catheter is removed: urgency, frequency, and dysuria

- Laboratory: Urine culture that grows more than $\geq 10^5$ CFU/ml of not more than two species isolated (16),(30).

2.3.3.1 Incidence of CAUTI

CAUTIs are a significant cause of HCAIs across the globe and contribute up to 40 % in the acute care setting (30). Three-quarters of these are attributable to an indwelling urinary catheter (31).

The incidence rate of CAUTI in ICU patients varies and ranges from 15-40% (4)(17),(19), and (32) across the various studies. The incidence densities of CAUTI in developing countries was 6.3 CAUTIs per 1000 urinary catheter days, in contrast to 3.3 per 1000 catheter days in developed countries (31), as shown in a 6-year study by the International Nosocomial Infection Control Consortium involving 422 ICUs in 36 countries in Europe, South America, Asia, and Africa.

2.3.3.2 Microbiological Organisms Causing CAUTI

According to multiple global studies, *E. coli* is the most common uropathogen isolated with short-term catheterization (2),(4),(32). Other microorganisms implicated in CAUTI in various studies include; *Pseudomonas spp., Klebsiella spp.,* and *Enterococcus spp*. (8),(21), *Proteus* and *Candida species* (31),(33).

2.3.3.3 Risk Factors of CAUTI

The most critical risk factor for CAUTI identified in prospective observational studies is prolonged urinary catheter use (30).

Others include;

- female gender (short and wide urethra),
- extremes of age,
- breaks in closed drainage while handling urinary catheters/ aseptic technique,

- structural abnormalities of the urinary tract and
- diabetes mellitus (31).

2.3.4 Central Line-Associated Bloodstream Infection In The ICU

Bloodstream infection (BSI) is an infection that elicits an inflammatory response caused by the presence of viable bacterial and fungal microorganisms in the bloodstream.

2.3.4.1 Incidence of Bloodstream Infection

BSI has been shown to account for about 7% of the HCAIs in all ICU admissions within the first month (34) and has an incidence density ranging from 5 to 19 per 1,000 patient days (35). The presence of BSI in a patient has been used as a marker of illness severity.

2.3.4.2 Central line-associated bloodstream infection

CLABSI refers to a primary BSI associated with using a central vein catheter within 48 hours before the onset of the infection (16).
BSI and CLABSI are shown to significantly worsen the prognosis, cause the excessive use of antibiotics, increase hospital costs, and prolong the duration of ICU stay (34),(35).

Diagnosis of BSI/CLABSI is based on a combination of both clinical and laboratory criteria.

a) Clinical parameters are;
    i. Documented high body temperatures of >38 °C,
    ii. Chills/rigors and
    iii. Persistent hypotension.
b) Laboratory reports of at least one positive blood culture with or without central venous catheterization were obtained 48 hours after hospitalization (16),(36).

2.3.4.3 Incidence of CLABSI

CLABSI has been shown to cause up to 10% of HCAIs in the acute care setting (36). Across the various studies and reviews, the incidence rate of CLABSI in ICU patients ranged from 9-20% (4),(7),(17),(19).

The incidence density of CLABSI in low and middle-income countries was 12.2 compared to high-income countries at 3.5 per 1000 catheter days (5), replicated in surveys across the globe (2),(21).

2.3.4.4 Microbiological Basis of CLABSI

The median time until the first positive blood culture in those who acquired BSI/CLABSI was seven days (35). Haque et al. (2018) conducted a cross-sectional study and found the most common causative organisms were Gram-negative at 40%, Gram-positive at 33%, and *Candida* spp. at 27% (2). The most prevalent organisms causing CLABSI isolated in ICUs across the globe, according to several studies; were *Klebsiella spp., S. aureus* (4)*, Acinetobacter spp* (21)*, Enterococci, Candida species* (35), *E. coli, and Pseudomonas species* (8)*.*

2.3.4.5 Risk Factors of CLABSI

CLABSI is more common in patients who've had surgical intervention, whose immunity was compromised, who developed multiorgan dysfunction, and who required mechanical ventilation or dialysis (2). Ling et al. systematic review showed the significant risk factors of CLABSI were cancer, steroid use, prolonged duration of stay of the central catheter, and overt sepsis (21).

2.4 Study Justification

KNH is a resource-limited public national referral facility for patients requiring ICU care. The profile of patients admitted to KNH's main ICU is quite diverse, including children, adults, and the elderly, who have different indications for ICU care. Based on monthly mortality audits, the average monthly mortality rate for 2021 was 53%, and a significant number of these mortalities were directly attributable to HCAIs. No one should catch an infection while receiving health care as the expectation is to get better; thus, prevention is the first step toward avoiding ICU-acquired conditions. In hospitals with a robust program for HCAI surveillance, the infection rates are reduced by about 30% (4), potentially reducing these high mortality rates. Thus an active surveillance program for HCAIs will serve as the first step toward a better infection control strategy.

Implementing such a robust surveillance system requires intimate knowledge of the infection rates, the potential modes of acquiring the infections, and the pathogens involved. This understanding was addressed by conducting this study. Knowledge of local epidemiology is crucial as it suggests the empirical antibiotic choice pending microbiological confirmation, which guides definitive treatment. Our proposed study was able to evaluate those at the highest risk of HCAIs as we believe that the ability to define these patients may help clinicians institute appropriate potential interventions. This will, in total, enable better healthcare resource utilization and patient outcomes via reduced patient morbidity and mortality, which are the key objectives of the hospitals' mandate. There is little published literature concerning HCAIs in ICUs in developing countries; thus, the study would provide results from which it will inform further related studies.

2.5 Study Question

What are the patterns of healthcare-acquired infections in the patients admitted to the main intensive care unit in Kenyatta National Hospital?

2.6 Objectives

2.6.1. Broad Objective

To determine the incidence, etiological organism, and risk factors associated with healthcare-acquired infections in patients admitted to the main intensive care unit in Kenyatta National Hospital.

2.6.2 Specific Objectives

a) To determine the incidence of healthcare-acquired infections among patients admitted to the main intensive care unit at Kenyatta National Hospital
b) To identify the etiological organisms in patients with healthcare-acquired infections admitted to the main intensive care unit at Kenyatta National Hospital
c) To determine the risk factors associated with healthcare-acquired infections among patients admitted to the main intensive care unit at Kenyatta National Hospital

3.0 CHAPTER THREE: MATERIALS AND METHODS

3.1 Study Design

A prospective cohort study.

3.2 Study Area and Site Description

KNH is the largest public and tertiary hospital in Nairobi, Kenya, with a total bed capacity of 1800, offering specialized medical, surgical, research, and rehabilitative health care services to patients from within the country, Eastern, Southern, and Central African regions. It's also the teaching hospital for the University of Nairobi, College of Health Sciences. KNH has eight critical care units, the largest being the Main ICU which is the focus area for the study.

The Main ICU has a 21 bed-capacity that serves critically ill acute trauma, surgical and medical patients of all ages who require specialized treatment and round-the-clock care with close supervision. Governed by a highly trained multidisciplinary care team that includes intensivists, critical care nurses, specialist physicians, pharmacists, physiotherapists, nutritionists, and other support staff. Each bed can offer mechanical ventilation and other ventilatory support. The unit has a wide array of monitoring equipments, fluids, and drugs that provide hemodynamic support to the patients admitted. The average monthly admissions for 2021 was 82 patients with an average length of stay (ALOS) of 7 days and an average bed occupancy of 87 % based on the KNH's main ICU records.

3.3 Study Population

The study population was patients of all ages who were critically ill and admitted at the KNH main ICU requiring specialized treatment services. On admission to the unit, participants were screened for eligibility after they had dully consented to take part and signed the consent forms. Once eligible; the recruited patients were assessed daily from day 2 to 7 to determine the presence or absence of an infection.

3.4 Eligibility Criteria

3.4.1 Inclusion Criteria:

- All newly admitted patients in the main ICU with no signs and symptoms of infection
- All newly admitted patients in the main ICU regardless of age
- All patients who have proved written consent to participate in the study

3.4.2 Exclusion Criteria:

- Patients who have declined consent to participate in the study
- Patients who stay less than 48 hours in the main ICU
- Patients with signs and symptoms of infection within 48 hrs of admission

3.5 Sample Size Determination and Formula

The Main CCU records indicate a monthly average of 82 patients admitted to the unit.
The sample size will be calculated using Fisher's (1) formula;

$$n = \frac{Z^2 x\ P(1-P)}{d^2}$$

Where,

n = Desired sample size

Z = Constant, Standard deviation (SD) at 95% Confidence interval (CI) is 1.96

d = precision desired for the study set at 0.05

P = expected true proportion (estimated at 12%, from a prospective observational study conducted by Dasgupta et al. (2015) over six months at a public tertiary teaching hospital ICU in Eastern India, looking at 29 cases amongst 242 patients (4).)

Substituting the formula above:

$$n_0 = \frac{1.96^2 x\ 0.12(1-0.12)}{0.05^2} = 163$$

A sample size of 163 patients was used for the study.

3.6 Sampling Method and Procedure

The study used a consecutive convenience sampling method. All patients meeting the eligibility criteria were included at admission to the main intensive care unit until the desired sample size of 163 participants was achieved. This was done over three months.

3.7 Consenting Procedures

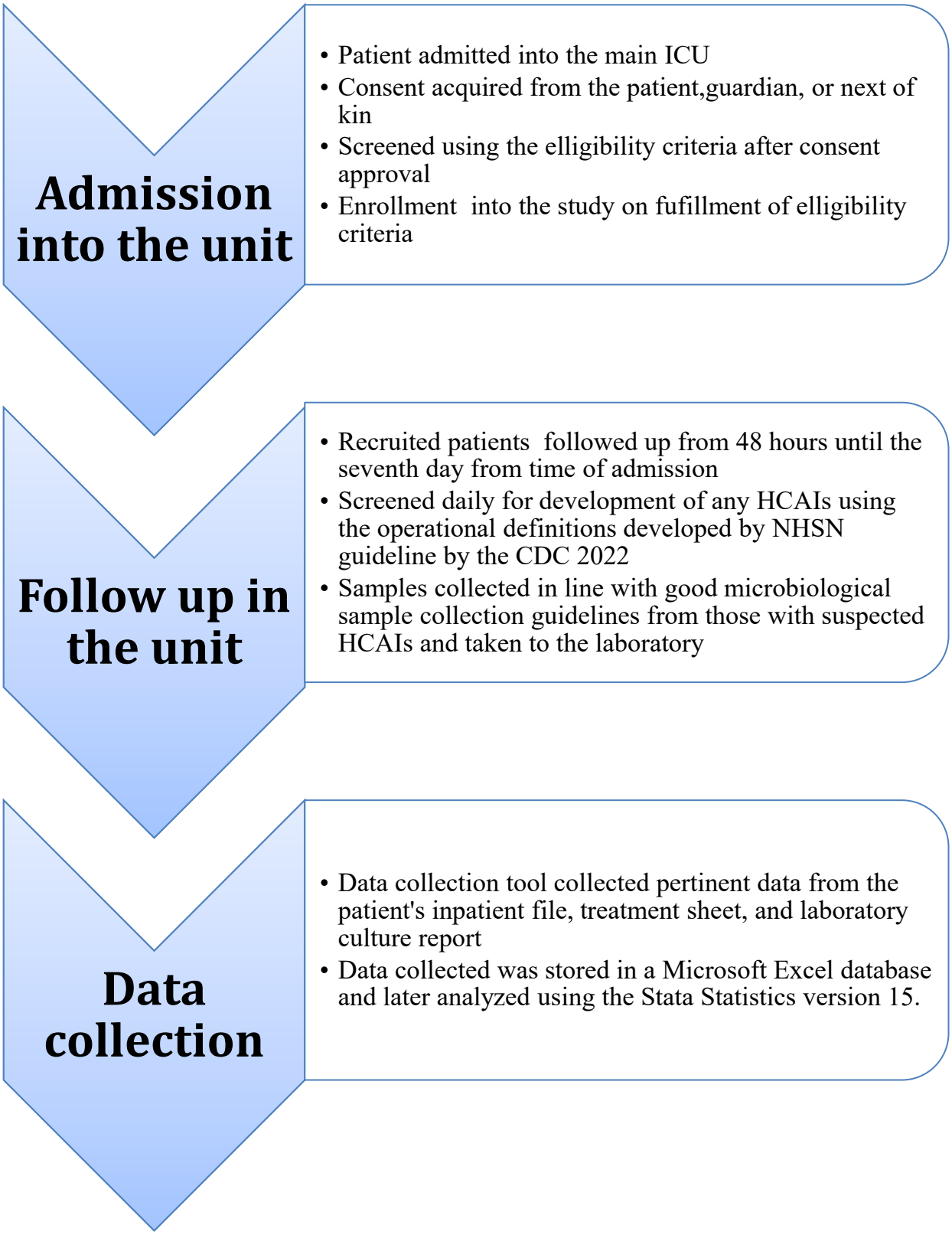
After admission into the Main ICU by the ICU team, an informed consent form was administered to patients or their next of kin at admission by the principal investigator (PI) in the unit. For underage participants, consent was sought from their guardians. This was done in a language that they understood (Swahili or English). The study purpose, procedure, benefits, process of final results dissemination, and the possible risks of the project were fully explained to the patients, guardians, or next of kin. Any clarifications were made, and finally, they were enrolled in the study. Voluntary participation in the study was emphasized.

3.8 Study Procedure and Recruitment

Ethical approval and consent to carry out the study was obtained from the Kenyatta National Hospital - University of Nairobi(UON) Ethics and Research Committee (ERC). All patients after admission into the Main ICU by the ICU team of the day were administered an informed consent by the PI in the unit. After approval of the consent, the patients were then screened using the eligibility criteria by the PI. Those who meet the study eligibility criteria were enrolled in the study via consecutive convenience sampling until the desired sample size of 163 participants was achieved. Each participant engaged in the study only once and was assigned unique serial numbers for identification. The recruited patients were then followed up while in the unit by the PI or trained research assistant (RA) from 48hrs until the seventh day from the day of admission. They were screened every morning for the development of suspected HCAIs using the operational definitions developed by the National Healthcare Safety Network(NHSN) guideline by the CDC in 2022 to identify and qualify the infections. Samples were collected in line with good microbiological sample collection guidelines from those with a suspected HCAI and taken to the laboratory for microscopy, culture, and sensitivity by the trained RA.

The data collection tool (Appendix III) collected pertinent data from the patient's inpatient file, treatment sheet, and laboratory culture report by the PI with the help of a trained RA. The data collected was stored in a Microsoft Excel database and later analyzed using the Stata Statistics version 15.

3.8.1 Flow Diagram



3.8.2 Sample Collection, Handling, and Processing

The PI and RA used the standard screening protocol daily for diagnosis of infection based on clinical and radiological parameters throughout the study duration to identify those with suspected HCAIs in the ICU as well as the site of the infection. Those patients that meet the clinical criteria from day two to seven for any of the suspected HCAIs had a sample taken in reference to the type of infection by the trained RA. The microbiological sample taken was either from the lower respiratory tract, bloodstream, urinary tract, or from the surgical site in line with good microbiological sample collection (37), (38)as described below.

Generally, an aseptic technique was observed and appropriate sterile containers were used. The sample was collected by the trained RA only when clinically indicated after diagnosis of a suspected infection. It was taken at the time of patients' clinical presentation of the suspected HCAIs and before the administration of any antibiotics. For each type of HCAI diagnosed only one sample was taken from the corresponding source of the infection during the entire study duration for each patient. This was in alignment with standard patient care that would have been offered to those with suspected HCAIs to confirm the presence, cause, and antimicrobial susceptibility of the said infection in accordance with the KNH management protocol(38).

Endotracheal aspirates were obtained by suctioning using a sterile suction catheter in the endotracheal tube or tracheostomy tube. The secretions in the catheter received were flushed with sterile water and placed in a sterile container. The sample was labeled with the identification number, date, time, and source of the specimen and taken to the laboratory within 1 hour. The most purulent part of the aspirate was used to inoculate plates of blood, chocolate, and MacConkey agar by the laboratory technician. Chocolate and blood plates were incubated in carbon dioxide at 35–37 °C and MacConkey in ambient air for 24 h. Positive cultures with isolates were identified using colonial morphology, gram stain, and biochemical tests.

Mid-stream urine or from a sampling port on an indwelling catheter was collected in a sterile container using an aseptic technique. The sample was labeled with the identification number, date, time, and source of the specimen and taken to the laboratory within 1 hour. The samples were then inoculated with blood agar and incubated in carbon dioxide at 35–37°C for 24-48 hours and MacConkey agar in ambient air for 24 hours. Positive cultures were identified using colonial morphology, gram stain, and biochemical tests.

Surgical site swabs from septic wounds; were collected aseptically after cleaning the wound with normal saline, and excess saline blotted from the wound bed using sterile cotton swabs. A swab was done at the center and base of the wound for 5 seconds which was then immediately

dipped into a sterile tube containing two drops of sterile water or a tissue specimen for culture was taken. The sample was labeled with the identification number, date, time, and source of the specimen and taken to the laboratory within 1 hour. The samples were then inoculated with blood and chocolate agar and incubated aerobically at 37 ^{0}C for 18-24 hours and MacConkey agar in ambient air for 24 hours. Positive cultures were identified using colonial morphology, gram stain, and biochemical tests.

Blood culture sampling; was taken from two sites, e.g., a peripheral site and a central line or two peripheral sites. The area selected was swabbed with 70% alcohol and allowed to dry for 30 seconds before the puncture. For adults, a draw of 10-15ml of blood was done, and 1-5ml for children under five years from the site and collected in bactec bottles. The central venous catheter tip cultures were accompanied by blood for culture. The samples were labeled with the identification number, date, time, and source of the specimen and taken to the laboratory within 1 hour. The samples were then inoculated with blood agar and incubated at 35–37°C for 18–24 h and MacConkey agar in ambient air for 24 hours in the laboratory. Positive cultures were identified using colonial morphology, gram stain, and biochemical tests.

Bacterial isolates were identified by their morphology and colonies gram-stained, and where necessary, selective media and specific biochemical tests followed standard protocols and with the assistance of the microbiologists. Positive bottles were tested for antibiotic susceptibility using the Kirby-Bauer disk-diffusion technique on the Mueller Hinton agar using different antimicrobial agents according to Clinical and Laboratory Standard Institute (CLSI) guidelines. The antimicrobial susceptibility testing and analysis aligned with the European Committee on Antimicrobial Susceptibility Testing (EUCAST) standards.

3.8.3 Data Collection Procedures

On admission, the PI and RA documented the baseline data of the eligible patients, such as sociodemographic and clinical characteristics: gender, age, primary diagnosis, co-morbidities, and antimicrobial use in the data collection tool. Patients were considered to have HCAIs only when they had met the clinical, laboratory, and radiological criteria for each type of infection. Once the results for the organism isolated were available from the microbiology laboratory, the information was extracted and entered into the data collection tool. The organism isolated from the first screening sample was the one recorded. The data was periodically evaluated for consistency and completeness. The data collected was stored on the tablet's Microsoft Excel database and backed up on separate external hard drives kept in different locations. Access to data was username and password protected.

3.8.4 Role of the Research Assistant, Laboratory Technologist, and the Principal Investigator

The principal investigator was in charge of patient identification, recruitment, and screening of those with HCAIs using the ECDC criteria, collection of both clinical and laboratory data, and accurate data input into the Microsoft Excel database for storage. As well as sharing the data with the statistician for analysis, interpretation of the analyzed data, and dissemination of results in appropriate channels. The research assistant assisted in patient screening, collection of clinical and laboratory data, and entry of data into the Microsoft Excel database. The laboratory technologist was in charge of receiving, testing, and disseminating the results of the collected samples. The statistician and the principal investigator did quality control checks on the data to ensure that all the data collected and dissemination protocols were followed; this was done tentatively before embarking on data analysis and interpretation.

3.9 Quality Assurance of Procedures

The research assistants were trained before the beginning of the study and during the study. A pilot study was conducted on 30% of the required sample size to give general insights and expectations of the main research. This also entailed the testing of the data collection tool.
All KNH safety guidelines protocols were adhered to throughout the study to prioritize patients' well-being(37)(38) as highlighted in the following statements. Microbiological sample collection Good practices were observed during sample collection. Patients were sampled for microbial culture and sensitivity before the start of a new antimicrobial. The laboratory procedures for microscopy, culture, and sensitivity were done by qualified personnel. Quality control measures were carried out at each step of the specimen processing where the date of preparation for each reagent and stain was indicated and culture media was prepared as per the manufacturer's instructions with control strains cultured to assess the media quality.

There was daily data cleaning and entry with periodical evaluation for consistency. Data was backed up in several external hard disks to enable reference in case of data loss. Data protection was enhanced to maximize confidentiality, whereby access was username and password protected, and the tablets for the data collection were stored in locked steel cupboards only accessible to the principal investigator. The principal investigator closely monitored the progress of the study.

3.10 Ethical considerations

Approval was sought from the Kenyatta National Hospital - University of Nairobi(UON) Ethics and Research Committee (ERC). Written informed consent administration played a significant role in the enrolment of patients in the study. The administration of consent forms was in both English and Swahili. The patient or their next of kin if incapacitated at the time of recruitment or their guardian for minors were briefed about the study's purpose, significance, risk, and benefit. The participants had the right to opt out of the study at any stage with no expected cost or penalty as the participation was voluntary. No additional costs were incurred, and no direct benefits or allowances were given to those participating in the study. The study had minimal risks incurred by the patient which included mild pain, discomfort, or bleeding during sample collection. This was clearly explained as well as ways to alleviate the risks when administering the consent forms to the participants.

Standard patient care was maintained for all participants even if they opted out of the study. Once a patient was found to have a suspected HCAI, the primary doctor was informed if not aware, antimicrobial therapy was administered as necessary, and cultures requisitioned for definitive diagnosis. The COVID-19 protocols and guidelines were strictly followed to avoid risking the patient's health. Patient privacy and confidentiality were guaranteed by limiting persons with access to the study data via username and password protection. Patient identifiers such as names were not collected in the data collection sheets. Instead, a unique identification or serial number was used, ensuring patient confidentiality and data safety.

3.11 Data Management

3.11.1 Data Storage and Security

Data from the data collection tool was entered into Microsoft Excel 2016 data entry sheet for cleaning and storage. The laboratory reports were collected after the analysis of samples by the laboratory, and copies were placed in locked steel cupboards to ensure patient information privacy and for future reference, if needed. These tablets were password protected to ensure that the data was only accessible to the designated study staff. Participant anonymization was done, and the identifier information was removed to ensure the confidentiality of the participants was maintained. The data was backed up in password-protected hard disks to ensure availability in case of data loss in the tablet due to technical constraints.

3.11.2 Study Variables

The dependent study variable was the presence or absence of the HCAI and etiological organisms. The independent study variables included age, gender, admitting diagnosis, and, if post-surgical intervention: whether (elective/emergency) and preceding antimicrobial therapy, co-morbidities, medications: prescribed steroids, sedatives, and stress ulcer preventive therapy.

3.11.3 Data Analysis Plan

Upon the completion of the data collection exercise, consistency checks were done on the data to ensure quality. The data quality aspects that were checked included missing values, duplicates, and outliers. The data corresponding to the missing cases were further collected and checked for completeness and accuracy. The data was then coded and fed into Stata Statistics version 15 and analyzed, with the primary analysis being descriptive. The study population was then described by summarizing the demographic and clinical characteristics. Incidence: calculated as a proportion(%) of patients with HCAI out of the sample. For continuous variables, the data were presented as means, medians, standard deviation, and interquartile ranges and tested for normality using the Shapiro-Wilk test. For the data that was non-parametric, the Mann-Whitney U test was used to compare the variables between the independent groups. The summarized data for categorical variables were submitted as tables or percentages. A comparison of distribution between these groups was tested using the Chi-square test. The time to occurrence of infection was presented using Kaplan- Meier Survival curve. Multivariate logistic regression analysis was used to analyze the association between risk factors and HCAIs to predict the occurrence of an infection and those at risk. The statistical significance level was set at $\alpha=0.05$ with the confidence level at 95%.

3.11.4 Data Presentation

Data presentation for determining the incidence of HCAIs and the various subtypes was recorded as a frequency of isolation expressed as a percentage. The findings, where appropriate were presented using frequency distribution tables.

Data presentation for determining the etiological organisms of HCAIs included the five commonest organisms causing the different types of HCAIs with their primary location and the frequency of isolation expressed as a percentage. The findings, where appropriate were presented using frequency distribution tables. Data presentation for determining risk factors associated with HCAIs was considered statistically significant for the association between variables if the P-value is equal or <0.5.

4.0 CHAPTER FOUR: RESULTS

4.1 Patient recruitment characteristics

The study was conducted from February to April 2023. During this period there was a total of 254 admissions to the main critical care unit. Out of these; 165 were enrolled after having met the inclusion criteria. 39 of the study participants (24%) developed a HCAI.

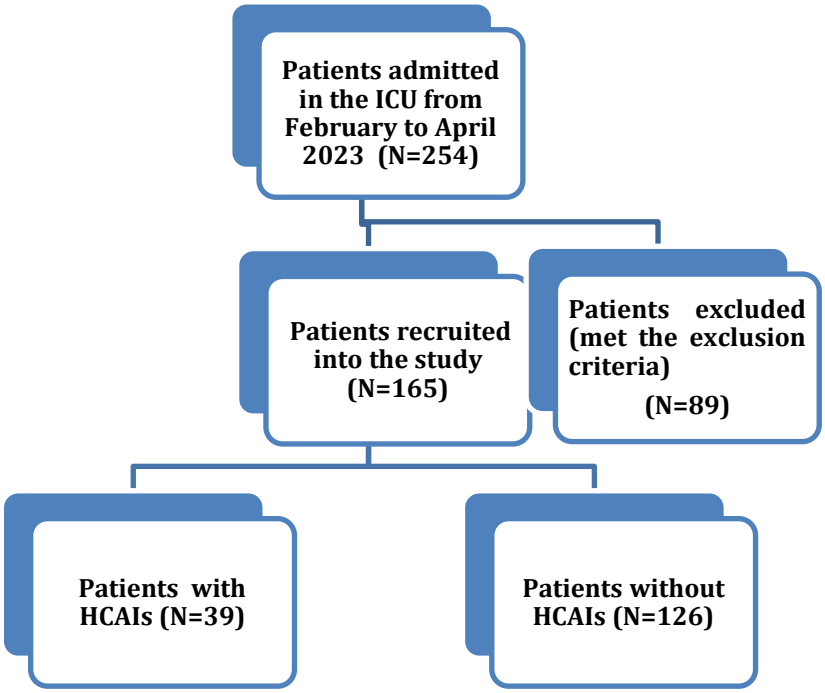


Figure 4.1.1 The flowchart

89 patients were excluded due to the following reasons:

- **40** patients had signs and symptoms of infection on admission
- **33** patients died in <48hours
- **16** patients transferred out of ICU in <48 hours

4.2 Patient baseline characteristics

Table 4.2.1 shows the summaries of the patient baseline characteristics.

Variable	Description	Frequency	Percentage
Sex	Female	69	41.8%
	Male	96	58.2%
Age-Group	0 to 10 years	36	21.8%
	11 to 20 years	17	10.3%
	21 to 30years	21	12.7%
	31 to 40 years	31	18.8%
	41 to 50 years	17	10.3%
	51 to 60 years	18	10.9%
	Greater than 60 years	25	15.2%
Diagnosis at Admission	Traumatic brain injury	104	63%
	Shock with Acute Kidney Injury	16	9.7%
	Abdominal trauma	13	7.9%
	Neoplasms	12	7.3%
	Intracranial Haemorrhage	10	6.1%
	Others	10	6.1%
Comorbidities	Hypertension	20	12.1%
	Diabetes Mellitus	14	8.5%
	Convulsive Disorder	8	4.9%
	HIV	5	3%
	None	118	71.5%
Surgical Intervention	Emergency	79	47.9%
	Elective	45	27.3%
	No intervention	41	24.9%
Duration of surgery (hours)	Mean (SD),	4.92	(5.65)
	Min-Max hours	0-15	
Antimicrobial prophylaxis	Yes	108	87%
	No	16	13%

Table 4.2.1: Patient characteristics summaries

The majority of the study participants were male at 58% (n=96) with a male-to-female ratio of 1.3:1. Their mean age (SD) was 32 (22.25) years. The most common age group was 0 to 10 years at 22%(n=36), followed by 31 to 40 at 19% (n=31), and the least represented group was 11-20 and 41-50 at 10.3% (n=17).

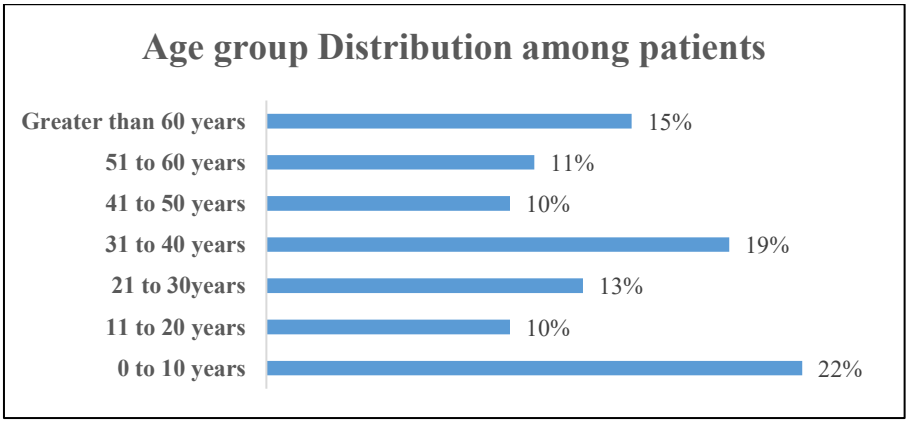


Figure 4.2.2: Age-Group distribution

The most common diagnosis among the participants was traumatic brain injury representing 63% (n=104) of all the admissions. This was followed by shock with acute kidney injury at 9% (n=16), neoplasms at 7% (n=12), abdominal trauma at 8% (n=13), intracranial hemorrhage at 6% (n=10) and others at 6%(n=10). Figure 4.2.3 shows the diagnosis distribution of the participants.

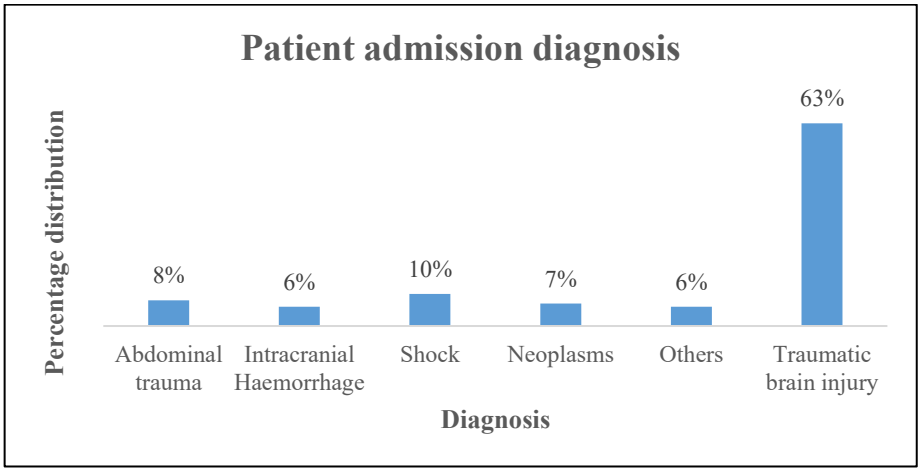


Figure 4.2.3: Patient diagnosis

The majority of the patients admitted into the unit were post-surgical intervention at 75% (n=124), of whom 64% (n=79) were on an emergency basis. The mean (SD) time of surgery was 4.92(5.65) hours with a range between 0 to 15. Antimicrobial prophylaxis was administered to 87% (n=108) of the patients taken to the theatre.

Comorbidities were observed among 28.5% (n=47) of the study participants, with the most common being hypertension at 12% (n=20). The other comorbidities observed were diabetes mellitus at 8.4% (n=14), convulsive disorder at 5% (n=8), and HIV at 3% (n=5). Figure 4.2.4 shows the comorbidity distribution of the participants.

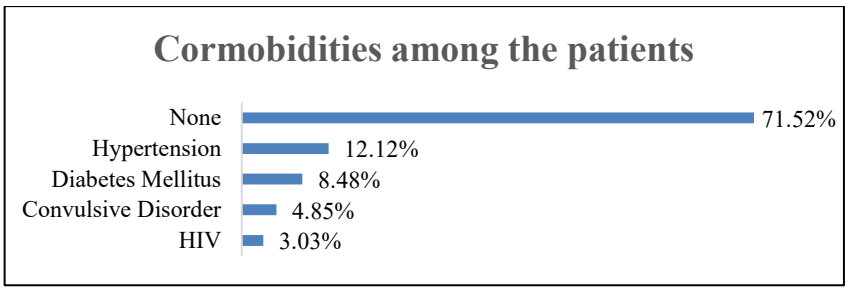


Figure 4.2.4: Patient cormobidities

4.3 The incidence of HCAIs in patients at the main ICU in KNH

The SIRS (Systemic Inflammatory Response Syndrome) scores were used to screen for infection. The SIRS criteria were met when at least 2 of the following were positive; body temperature was >38.3 or <36 degrees Celsius, heart rate >90 beats/minute, respiratory rate >20 breaths/minute, and leucocyte count >12000 or <4000 *10^9/L. In the pediatric population, the value considered for heart rate and respiratory rate were 25% above the baseline for the expected age.

The following table shows the SIRS scores distribution among the study participants.

SIRS Score	Frequency	Percentage
0	37	22.4%
1	30	18.2%
2	54	32.7%
3	40	24.2%
4	4	2.4%

Table 4.3.1 SIRS distribution scores

The SIRS score of 2, 3, and 4 were 33% (n=54), 24% (n=40), and 2% (n=4) respectively. Thus the participants who met the criteria of a positive SIRS score were 59% (n=98).

The CDC guideline screening tool was then used as a clinical criteria to identify the source in those with a suspected healthcare-associated infection. The participants who met the criteria of an HCAI likelihood were 56% (n=92). Based on the CDC criteria for HCAIs; the likelihood of SSI, VAP, CAUTI, and CLABSI/BSI was 25%, 18%, 9%, and 4% of the study participants respectively.

Variable	Description	Frequency (N=165)	Percentage
SSI likelihood	**Yes**	**42**	25.5%
	Inflammation, tenderness, warmth	39	23.6%
	Purulent discharge at the incision site	12	7.3%
	Abscess Identified	15	9.1%
VAP likelihood	**Yes**	**29**	17.6%
	Ventilatory support	26	15.8%
	Cough/ increased work of breathing	9	5.5%
	Purulent sputum?	22	13.3%
	Worsening gas exchange	15	9.1%
CAUTI likelihood	**Yes**	**15**	9.1%
	Haematuria	15	9.1%
	Suprapubic/ costoverbral angle pain or tenderness	4	2.4%
	Pyuria, sediments along the catheter	15	9.1%
	Urgency/ frequency/ dysuria following catheter removal	6	3.6%
	Discharge, redness, or leakage at the catheter site	9	5.5%
CLABSI/BSI likelihood	**Yes**	**6**	3.6%
	Chills/rigors	4	2.4%
	Hypotension	6	3.6%
	Discharge, redness, leakage of CVC	3	1.8%
	Hypothermia or HR < 80 in infants	5	3%

Table 4.3.2: HCAI likelihood among the study participants

Appropriate samples were taken from 92 out of the 165 study participants due to their HCAI likelihood to identify the causative organism. The specimens were mainly from wound swabs. 46 microorganisms were isolated in 39 patients. 4.2% of the study participants developed two or more types of HCAIs at the same time.

Following the fulfillment of the SIRS scores, CDC guideline likelihood criteria, and the presence of isolates on culture and microscopy; 39 (24%) study participants met the criteria for a healthcare-associated infection.

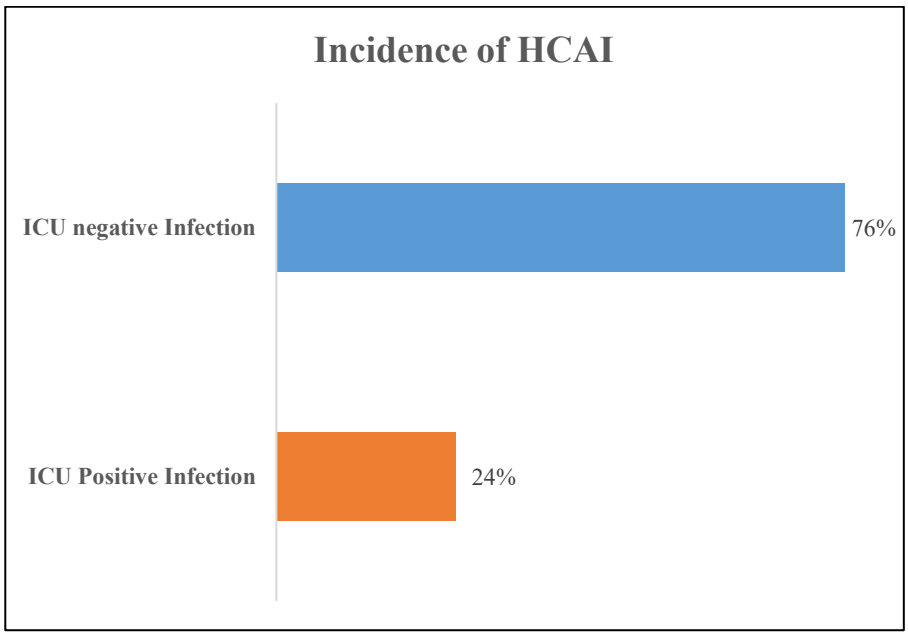


Figure 4.3.3: HCAI Incidence

4.4 The etiological organisms in patients with HCAIs at the main ICU in KNH

Overall, 46 microorganisms were isolated from 99 specimens which gave a 46% culture positivity rate . Of these, 39 (84%) were Gram-negative and 7 (16%) were Gram-positive bacteria. The most common organism identified was *Escherichia coli* at 9% (n=15). *Pseudomonas aeruginosa, Klebsiella pneumonia,* and *Staphylococcus aureus* were recorded in 8,%, 4%, and 3% of study participants.

Table 4.4.1 shows the microorganisms observed among the study participants.

Microorganism	Frequency	Percentage of study participants
Escherichia coli	15	9.1%
Pseudomonas aeruginosa	13	7.9%
Klebsiella pneumonia	7	4.2%
Staphylococcus aureus	5	3.1%
Enterococcus	2	1.2%
Acinetobacter	2	1.2%
Serratia marcescenes	1	0.6%
Proteus mirabilis	1	0.6%

The overall incidence of SSI among the study participants was 10% (n=16); constituting 42% of the HCAIs. The commonest organism was *Escherichia coli* causing 39% of SSI infections.

The overall incidence of VAP among the study participants was 8%(n=13); constituting 33% of the HCAIs. The commonest organism was *Klebsiella pneumonia* causing 44% of VAP infections.

The overall incidence of CAUTI among the study participants was 6% (n=8); constituting 21% of the HCAIs. The commonest organism was *Escherichia coli* causing 50% of CAUTI infections.

The overall incidence of CLABSI/BSI among the study participants was 1%(n=2); constituting 5% of the HCAIs.

Table 4.3.2: Microorganisms based on types of HCAIs

Type of Infection	**Description/micro-organisms**	**Frequency**	**Percentage**
Surgical Site Infection	**Overall patients**	**16**	**10%**
	Escherichia coli	7	38.9%
	Pseudomonas aeruginosa	5	27.8%
	Staphylococcus aureus	4	22.2%
	Acinetobacter	1	5.6%
	Enterococcus	1	5.6%
Ventilator Acquired Pneumonia	**Overall patients**	**13**	**8%**
	Klebsiella pneumonia	7	43.8%
	Pseudomonas aeruginosa	4	25.1%
	Escherichia coli	3	18.8%
	Proteus mirabilis	1	6.2%
	Acinetobacter	1	6.2%
Catheter Associated Urinary Tract Infection	**Overall patients**	**8**	**5%**
	Escherichia coli	5	50%
	Pseudomonas aeruginosa	3	30%
	Serratia marcescenes	1	10%
	Enterococcus	1	10%
Blood Stream Infection	**Overall patients**	**2**	**1%**
	Staphylococcus aureus	1	50%
	Pseudomonas aeruginosa	1	50%

4.5 The risk factors associated with HCAIs in patients at the main ICU in KNH

a. The Kaplan-Meier Curve

The time from admission to the occurrence of infections in the study participants was analyzed using the Kaplan-Meier curve to check the time taken for the occurrence of an infection to occur.

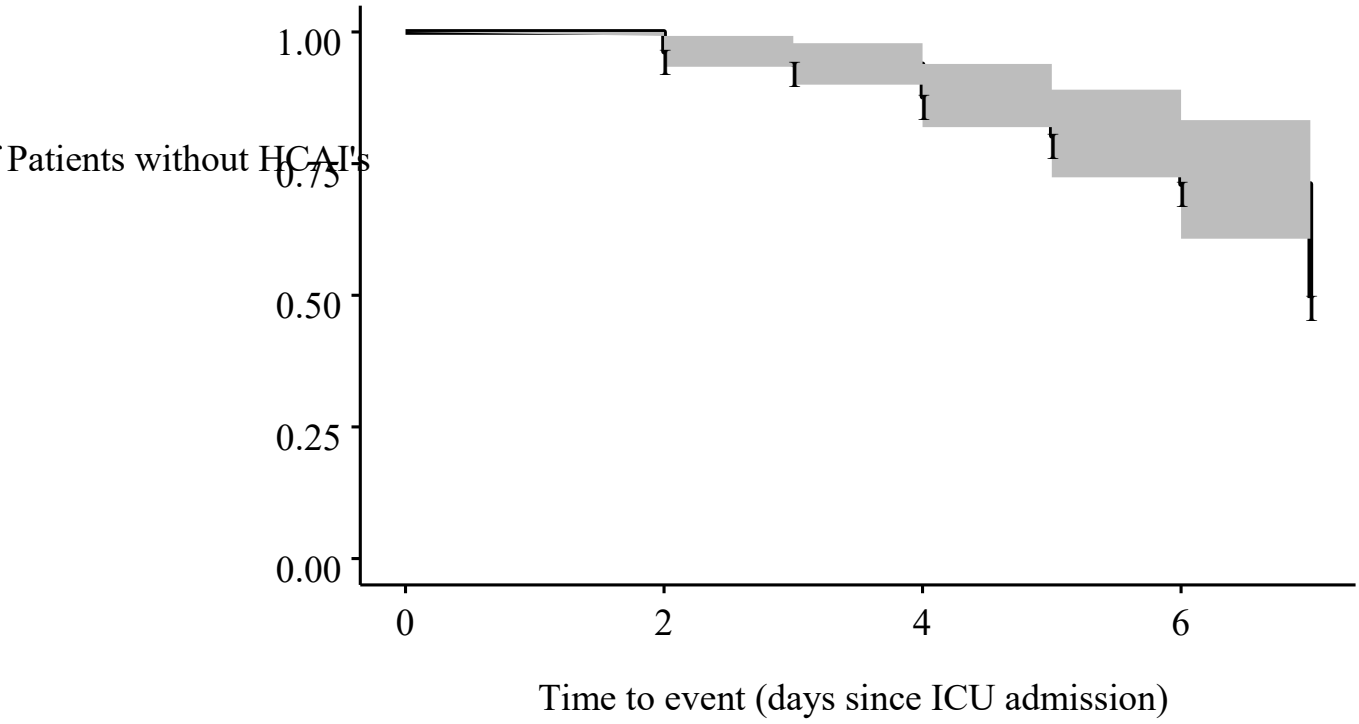


Figure 4.5.1: Kaplan-Meir Curve for the occurrence HCAIs

The Kaplan-Meir curve; Y axis represents the "Proportion of Patients without HCAIs" while the X axis represents "Time to event (days since ICU admission)." Whereby the proportion of patients without HCAI decreases from 100 to about 75% from the time of admission to the seventh day in the ICU.

b. Comparison of participants with HCAI and those without HCAI

The demographic and baseline clinical characteristics were compared between patients who developed HCAIs and those who did not to check for the association between the groups using Mann–Whitney U-test for the continuous variables and the Chi-Square test for the categorical variables.

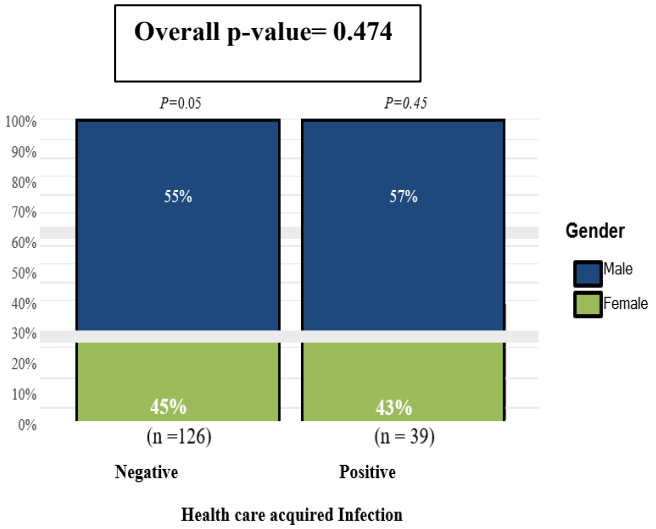


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Figure 4.5.2: HCAIs based on Gender

The majority of the study participants with HCAIs were male at 57% with a similar male-to-female ratio of 1.3:1. The overall p-value was 0.474 showing there was no statistical significance between gender and the occurrence of HCAIs. The median age for the development of a HCAI was 25 years.

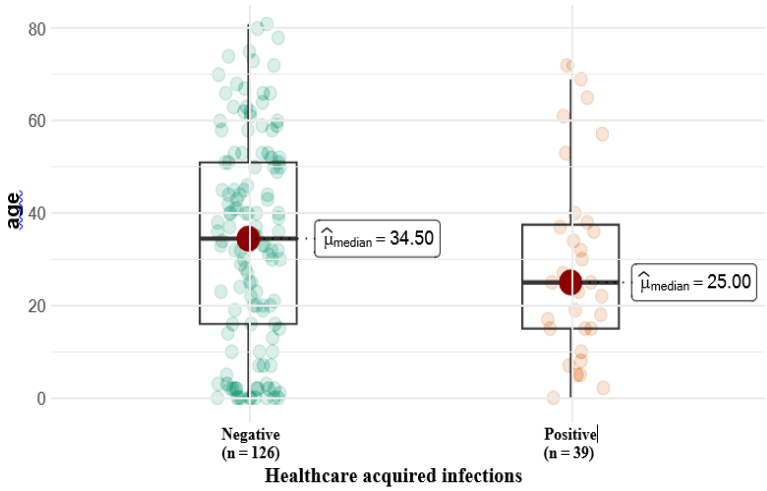


Figure 4.5.3: HCAIs based on age

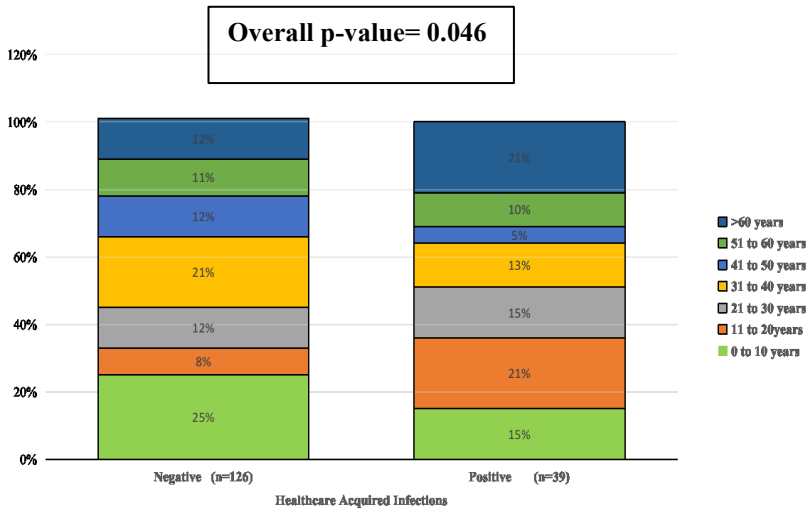


Figure 4.5.4: HCAIs based on Age-groups

The majority of the study participants with HCAIs were between the age group of 11-20 years and > 60 years at 21% each. The p-value was **0.046** showing there was a statistical significance between the age groups to the occurrence of HCAIs.

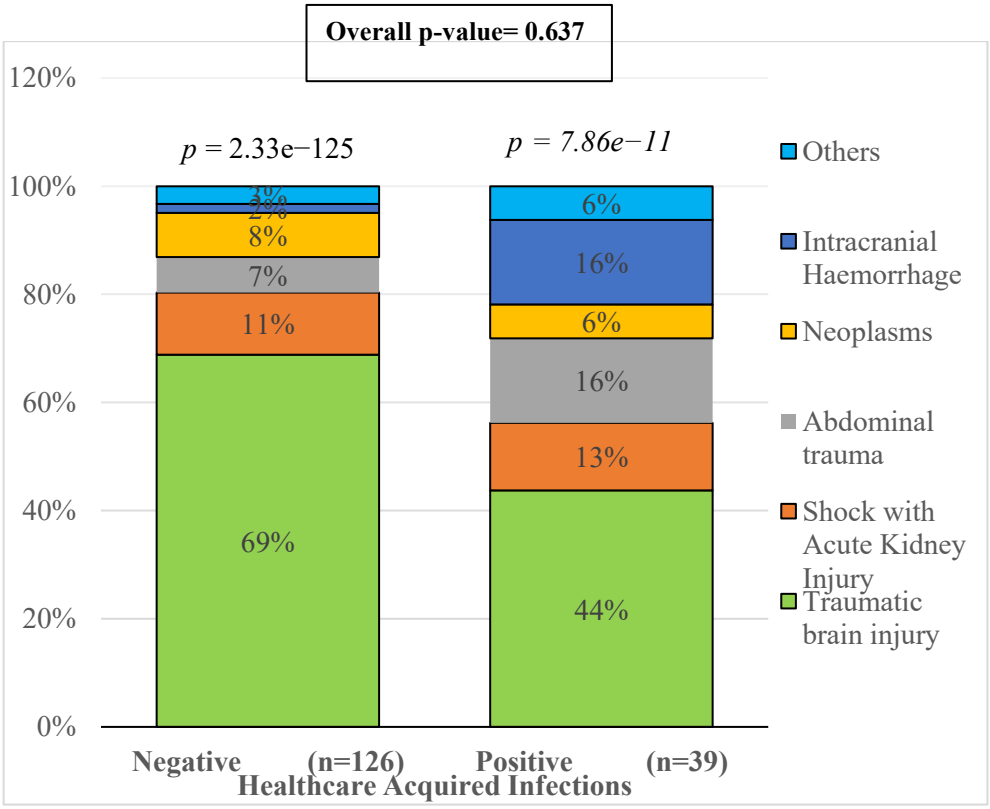


Figure 4.5.5: HCAIs based on Diagnosis

The majority of the study participants with HCAIs had a diagnosis of Traumatic brain injury 44%. The p-value was 0.637 showing there was no statistical significance between diagnosis and the occurrence of HCAIs.

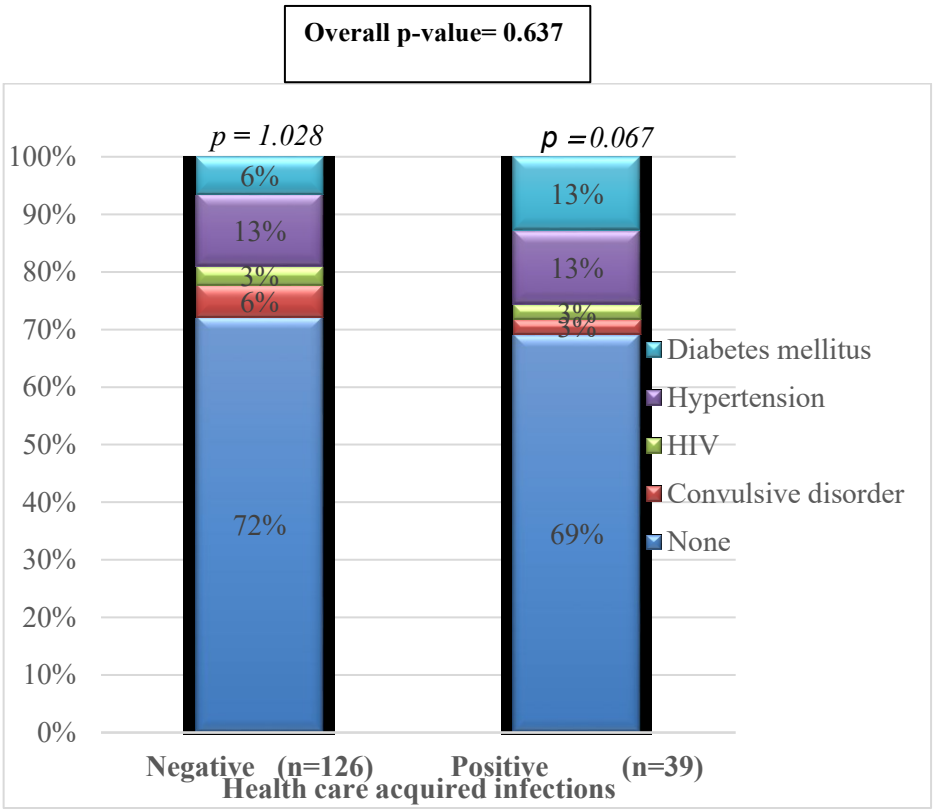


Figure 4.5.6: HCAIs based on Comorbidities

The majority of the study participants with a HCAI did not have comorbidities at 69%. The p-value was 0.067 showing there was no statistical significance between comorbidities and the occurrence of HCAIs.

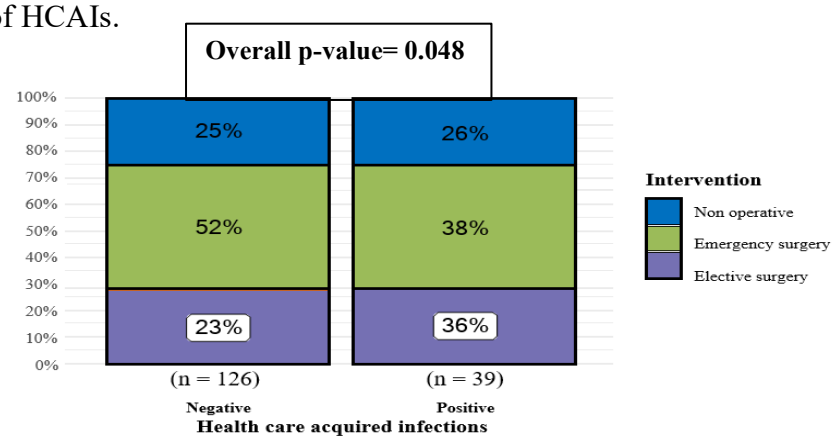
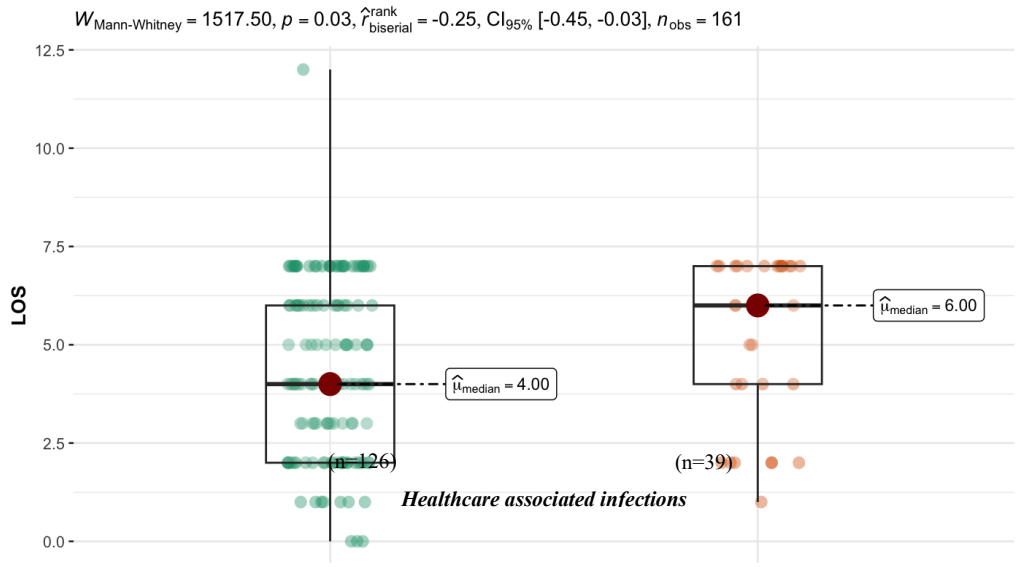


Figure 4.5.7: HCAIs based on Intervention

The majority of the study participants with a HCAI were post-emergency surgery at 38%. The p-value was **0.048** showing there was statistical significance between post-surgical intervention and the occurrence of a HCAI.

Figure 4.5.6: HCAIs based on Length of stay



The median length of stay to the development of HCAI was 6 days. The p-value was **0.03** showing there was statistical significance between the length of stay and the occurrence of HCAIs.

c. Logistic regression analysis for the predictors of HCAIs

Logistic regression analysis was performed to identify characteristics with an increased risk of developing HCAIs and their relative weighting.

Table 4.5.7 illustrates the multivariate logistic regression for the predictor of the occurrence of HCAI among the study participants. The significant overall predictors for the development of HCAI among the study participants were;

1. Age between 11 and 20 years (OR: 4.13, 95% CI : [1.15-14.81], p=**0.029**),
2. Length of ICU (OR: 1.01, 95% CI : [1.00-1.02], p=**0.003**), and
3. Emergency surgical intervention (OR: 2.32, 95% CI : [0.99-5.42], p=**0.041**).

Table 4.5.7: multivariate logistic regression for the occurrence of HCAI

Variable	Description	Odds Ratio(OR)	Confidence interval(PI)	P-Value
Age Group	Ref: <10 years	1	1	1
	11 to 20years	4.13	[1.15-14.81]	**0.029**
	21 to 30 years	2.07	[0.57-7.50]	0.270
	31 to 40 years	0.99	[0.27-3.63]	0.992
	41 to 50 years	0.69	[0.12-3.83]	0.670
	51 to 60 years	1.48	[0.36-6.07]	0.589
	>60 years	2.76	[0.81-9.38]	0.105
Gender	Ref: Male	1	1	1
	Female	0.76	[0.36-1.59]	0.475
Comorbidities	Ref: No comorbidity	1	1	1
	Convulsive disorder	0.48	[0.06- 4.09]	0.503
	HIV	0.84	[0.09-7.86]	0.881
	Hypertension	1.05	[0.35- 3.14]	0.926
	Diabetes Mellitus	2.11	[0.64- 6.97]	0.223
Surgical intervention	Ref: No intervention	1	1	1
	Emergency	2.32	[0.99-5.42]	**0.041**
	Elective	1.50	[0.60-3.75]	0.388
Duration of surgery in hours	Time in hours	0.99	[0.91-1.06]	0.726
Antimicrobial prophylaxis	Not given antimicrobial prophylaxis	1.12	[0.77- 1.64]	0.552
Length of ICU stay	Length in days	1.01	[1.00-1.02]	**0.003**
Corticosteroids	Given corticosteroids	0.19	[0.10-0.56]	0.678
Stress ulcer prophylaxis	Given prophylaxis	0 .53	[0.23- 1.19]	0.122

5.0 CHAPTER FIVE: DISCUSSION

5.1 The incidence of HCAIs in patients at the main ICU in KNH

The diagnosis for a HCAI is a combination of both clinical and laboratory criteria. In the study; a confirmed infection was made on fulfillment of positive SIRS scores, CDC guideline likelihood criteria, and the presence of isolates on culture and microscopy. Thus the overall incidence of HCAI in the study participants at KNH Main ICU was found to be 24% (n=39).

The study finding is in keeping with the global pattern whereby most studies and surveys on HCAIs have reported an incidence range of 9% to 37% (1), depending mainly on the populations studied (2),(4),(7),(17),(19). This is supported further by the WHO Report on the Burden of Endemic HCAIs Worldwide that showed at least 30% of patients admitted to an ICU will be affected by a minimum of one episode of HCAIs (6).

The study's incidence correlates with those of developing countries which are 2-3 fold higher; as opposed to the 3 to 12% observed in developed countries (5),(6),(17). This greater burden in developing countries could be explained by the higher patient load, overcrowding, poor infrastructure, and design of the hospital layout.

When compared to other incidence reports done in Sub-Saharan Africa, the finding of this study is higher than those observed in Mali at 19%,11% in Senegal, 7% in Ghana, 13% in Botswana,7% in South Africa, and 14% in Tanzania (5)(39). This might be associated with the comprehensive nature of this study which involved all critically ill patients in the ICU.

5.2 The microbiological organisms associated with the development of HCAIs

Of the 46 microorganisms isolated, 39 (84%) were Gram-negative and 7 (16%) were Gram-positive bacteria. Globally; gram-negative bacteria are shown to contribute more than half of the HCAIs in ICU patients, which is in tandem with the study findings as well as the EPIC II study (1). This is a concern as gram-negative bacteria are more resistant to the available antibiotics due to their outer membrane and can pass genetic materials that allow other bacteria to become drug-resistant (40); thus higher associated morbidity and mortality(41). These organisms as well might have colonized the medical devices or the hospital environment to cause an infection when the patients' immunity was compromised.

The most common organism isolated was *Escherichia coli* constituting 32 % of the isolates and affecting 9% of study participants. *Escherichia coli* is normally a commensal found on the skin, mucous membranes, and gastrointestinal tract. But the organism may become pathogenic when the body's immunological defenses are compromised(42) as in the case of critically ill patients.

The other organisms isolated included; *Pseudomonas aeruginosa, Klebsiella pneumonia, Staphylococcus aureus, Acinetobacter baumanii, and Enterococcus spp*. A similar pattern is repeated in several studies across the globe (4),(7),(17),(21). Closer home, in an African systematic review of HCAI by Irek et al., where roughly 60% of the data were from East Africa, showed the most common pathogens identified were *Klebsiella species., Staphylococcus aureus, Escherichia coli, Pseudomonas spp, and Acinetobacter species* (8). Supported further by a local study done by Ngumi et al. at KNH ICU (23).

5.3 The types of HCAIs among the study participants

1. Surgical Site Infections

SSI was the most prevalent infection accounting for 42 % of the HCAIs; with an incidence of 10% among the study participants. This is in line with the incidence rates of SSI in ICU patients in various global studies which were between 5-25% (5), (21). This shows we still have some room for improvement in our postoperative care and hand hygiene.

The microorganisms implicated in the development of SSI in the ICU were *Escherichia coli, Pseudomonas species, Staphylococcus aureus, and Acinetobacter baumannii;* which were among the microorganisms identified in various studies in low and middle-income counties including Africa, India, and Asia (4), (8), (21).

2. Ventilator-Associated Pneumonia

VAP accounted for 33 % of the HCAIs with an incidence of 8% among the study participants. This is much lower than the global studies whose overall incidence among patients in the ICU was between 10 to 35% (4), (7), (27). Locally; it's still lower than those observed in previous studies conducted at KNH on ICU patients by Kinuthia et al where the prevalence of VAP was 12.2% (29) and Wangari-Siika et al whose incidence of VAP was 20.6%. This could be attributed to awareness and compliance with VAP prevention bundles.

The microbiological organisms implicated in the development of VAP in this study include; *Klebsiella pneumonia, Pseudomonas aureginosa, Escherichia coli, and Acinetobacter*. Similar organisms constitute some of the most identified among VAP patients in studies conducted worldwide (4), (8), (21), (29).

3. Catheter-Associated Urinary Tract Infection

CAUTI accounted for 21% of the HCAIs with an incidence of 5 % among the study participants. In other studies conducted worldwide; CAUTI was seen to have an incidence of between 15 to 40% (4), (17), (19); which is significantly higher than what we found in our study. Locally; it's still lower than those observed in previous studies conducted at KNH on ICU patients by Inyama et al whose incidence of CAUTI was 18% (32). This could be attributed to preventive efforts and compliance with CAUTI prevention bundles.

The microorganisms implicated in the development of CAUTI in the ICU were *Escherichia coli, Pseudomonas aeruginosa, Enterococcus, and Serratia marcescenes.* This mimics multiple global and local studies, where *Escherichia coli* is the most common uropathogen isolated with short-term catheterization (2)(4),(32), and other similar gram-negative organisms were observed (8) and (21).

4. Central Line-Associated Bloodstream Infection

CLABSI/BSI accounted for 5% of the HCAIs with an incidence of 1% among the study participants. The low proportion observed in our study contrasts with other studies and reviews from high, low, and middle-income countries conducted where the incidence of CLABSI was between 9 to 20 % (4),(7),(17), and (19). This can be attributed to the time taken to get an infection as the median time until the first positive blood culture in those who acquired BSI/CLABSI was seven days (35). Locally it's still lower than that observed in a previous study conducted at KNH on ICU patients by Seko et al in 2007 whose incidence of CLABSI was 12%(43). Showing the incidence has decreased over time; likely due to major preventative efforts as well as increased education on CLABSI prevention bundles.

Only *Staphylococcus aureus and Pseudomonas aeruginosa* were observed as microorganisms causing CLABSI/BSI infections; which are among those isolated in ICUs across the globe, according to several studies; *Klebsiella spp., Staphylococcus aureus* (4), *Acinetobacter spp* (21), *Enterococci, Candida species* (35), *E. coli, and Pseudomonas species* (8).

5.4 The risk factors associated with the development of HCAIs

Gender: The study showed a predominance of males at 58%. This is in agreement with the gender distribution in intensive care units as they are consistently found to be around 60% men and 40% women(44). There are more males with infection than females as estrogen has been shown to have a protective effect in critical illness(45), but there was no significant difference in gender predisposition toward HCAIs in the study population.

Traumatic brain injury accounted for 63% of all ICU admissions**.** This can be correlated to the fact that on average; every single day, a patient with a TBI-related incident gets admitted to the CCU (46). TBI affected approximately half of the infected study participants which could be explained by the fact that TBI alters the systemic immune response in a way that renders TBI patients more vulnerable to infections in the acute post-injury period (47)(48), but this was found to be insignificant with the association of HCAIs in the study population.

Comorbidities were observed among 32% of those patients who developed HCAIs; with the most common being hypertension and diabetes at 12% each. Underlying comorbid conditions have been demonstrated to have a critical influence on the clinical course and complications in the ICU (3), (4),(11),(13),(49); but there was no significant difference in comorbidities predisposition towards HCAIs in the study population.

In the study; duration of surgery, antimicrobial prophylaxis, corticosteroids, and stress ulcer prophylaxis did not influence the occurrence of HCAIs among the study population.

Overall: The significant predictors for the development of a HCAI among the study participants were;

1. Age between 11 and 20 years (OR: 4.13, 95% CI : [1.15-14.81], p=**0.029**),
2. Length of ICU stay (OR: 1.01, 95% CI : [1.00-1.02], p=**0.003**), and
3. Emergency surgical intervention (OR: 2.32, 95% CI : [0.99-5.42], p=**0.041**).

a) The age group 11-20 years and > 60 years contributed the most (21% each) to those patients who developed HCAIs. Most studies show that patients with advanced age (>65 years) tend to have a weaker immune response and underlying comorbidity thus more vulnerable to the development of HCAIs (4),(11),(13). But only the age group 11-20 years showed a significant association as the odds ratio was 4.13 with a p-value of 0.029; showing being in this particular age group increased the likelihood of developing HCAIs. It is possible to speculate that this particular group of patients had greater severity of illness or some chronic underlying disease before admission that might have potentially exposed them to development of HCAIs.

b) Those who had emergency surgery before admission constituted 38% of those patients who developed HCAIs. There was a significant association as the odds ratio was 2.32 with a p-value of 0.041; showing that post-emergency surgery increased the likelihood of development of HCAIs. Can be attributed to having more severe pre-existing illnesses increasing their susceptibility to infections due to diminished immune responses and requiring longer ICU stay(50).

c) The median length of stay to the development of HCAI was 6 days. There was a significant association as the odds ratio was 1.01 with a p-value of 0.03; showing that increased length of stay increased the likelihood of development of HCAIs. Alluded to by the WHO report on endemic HCAI shows that length of stay is one of the environmental risk factors for the development of HCAI (5). The study shows similar findings to those done by Haque et al that showed an increased risk of acquiring HCAIs in patients with hospital stays longer than 8 days (9), and Sligl et al that showed the first date of bacteremia was 6.5 days in patients with HCAI(51). This finding is supported further by the Kaplan-Meier curve that shows the probability of the development of HCAIs increases as the patient's length of stay increases in the ICU.

6.0 CONCLUSION

We found that HCAI is still a significant problem in our critically ill patients at Main ICU with an overall incidence of 24%; with the commonest type being SSI accounting for 42%. Followed by VAP, CAUTI, and CLABSI/BSI at 33%, 21%, and 5% respectively.
The commonest organisms causing HCAIs were *Escherichia coli, Pseudomonas aeruginosa, Klebsiella pneumonia, and Staphylococcus aureus* affecting 9%, 8,%, 4%, and 3% of the study participants respectively; with 84% of the organisms isolated being gram-negative.
Those participants whose ages were between 11 and 20 years, were post-emergency surgery and had a longer length of stay were all associated with a higher predisposition to the development of HCAIs in the ICU.
This study has laid the groundwork for the improvement of patient outcomes as prevention of HCAIs demands knowledge of the infection rates and of the sources, the pathogens involved as well as the common risk factors for infection.

6.1 Strength of the study

The strength of this study is that it included all critically ill patients admitted to the ICU; prospectively followed for seven days. There was the implementation of proper surveillance techniques for those suspected of infection and appropriate laboratory identification of causative organisms. Provides a valuable resource to clinicians managing patients with critical illness.

6.2 Study Limitation

- This study was limited to a single ICU in KNH thus the results cannot be generalized as the inferences are limited to Main ICU.
- The sample size was relatively small to conclusively infer risk predictors to the types of HCAIs.
- The full burden of HCAIs could not be captured:
    1. Participants were only followed up for their duration of stay in the unit thus leaving out patients who may have potentially developed HCAI after discharge.
    2. The study was limited to seven days thus leaving out patients who may have potentially developed a HCAI after.

6.3 Recommendations

- Continued surveillance of HCAIs to optimize patient outcomes in the critical care unit; as knowledge of the local epidemiology is crucial for the suggestion of the empirical antimicrobial choice pending microbiological confirmation.
- Continued education on infection prevention strategies such as ensuring antimicrobial prophylaxis has been to patients before surgery and the prompt discharge of patients that no longer require ICU care.
- A larger structured study to get more conclusive risk factors for each type of HCAIs via a bigger sample size and longer duration of follow-up or a case-control study.

6.4 Results Dissemination Plan

- The results were shared and presented to the Department of Anesthesia at the University of Nairobi, Kenyatta National Hospital's Anesthesia Department, the Microbiology Department of KNH and UON, KNH Department of Laboratory Medicine, the UON repository, the KNH/ UON research ethics committee, and health care providers.
- The research paper will be submitted for scientific publication in a peer-reviewed journal and shared with surveillance collaborators and health stakeholders in KNH and Kenya to inform during policy formulation aimed at infection prevention and improved outcomes for critically ill patients.
- To present the results at the annual scientific conference of the Critical Care Society of Kenya and Kenya Society of Anaesthesiologists.

STUDY TIMELINES

	February -August 2022	September 2022	September-January 2023	February – April 2023	May 2023	June 2023	June 2023
Proposal development							
Proposal presentation							
Ethical approval							
Data collection							
Data analysis							
Results presentation							
Dissertation and manuscript submission							

STUDY BUDGET

CONCEPT/ ITEM	QUANTITY	UNIT COST	TOTAL
Stationery, photocopy, and printing of materials			25,000
Statistician		40,000	40,000
Research assistants	3	20,000	60,000
Lockers	1	3,000	3,000
KNH/UON ethics & research submission fee	1	2,000	2,000
Contingency/other expenses			20,000
TOTAL (KSH)			**150,000**

The Principal Investigator financed the study.

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APPENDICES

Appendix I: Consent Form (English)

Study Title: "Patterns of Healthcare-Associated Infections in Patients at Kenyatta National Hospital Main Intensive Care Unit"

Introduction

I am Dr. Elly Thathi, a postgraduate student pursuing a Master of Medicine in Anaesthesia and Critical Care at the University of Nairobi. I am the principal investigator of this study; you are very welcome to participate in this study. 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. When I have answered all your questions to your satisfaction, you may decide to be in the study or not.

May I continue? YES / NO

Study Purpose

HCAIs are a global problem. The study aims to identify the burden, causative organisms, and those at risk of developing a healthcare-associated infection in the intensive care unit. This will improve patient care now and patients' future outcomes at the Kenyatta National Hospital. Hence your participation in this study is very instrumental. This study has been approved by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No…..

Study Description

There will be approximately 163 participants in this study randomly chosen. The study will collect sociodemographic data and clinical characteristics from the inpatient file during their stay in the ICU. For those patients who will be diagnosed with an infection; the sample will be taken from either the surgical wound site, the lower respiratory tract, midstream urine, a sample from an indwelling catheter, or the bloodstream by the principal investigator or trained RA. These collected samples will then be taken to the microbiology laboratory for analysis to identify the causative organism for the infection and treat the condition accordingly.

Study Participation

Your decision to participate in this study is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time; as this will not affect future care or treatment. Standard patient care will be maintained for all participants at all times during the study period. The principal investigator will undertake the costs of the study. No additional costs will be incurred by the patient during the study.

Risks to Participation

The participant shall have minimal exposure to any health risk and every effort will be put in place to minimize the risk. There may be some bleeding, pain, or discomfort associated with sample collection. This will be alleviated by the use of the smallest needle(23G) available for specimen collection the and application of pressure with a ball of cotton wool or gauze after the collection of the blood sample.

Confidentiality

Total confidentiality will be maintained to ensure that the data does not get into the wrong hands. No identifier information will be used in the data collection, analysis, and results in the presentation. All the participants and the corresponding samples will be labeled uniquely using anonymous IDs throughout the study. The data sharing will be in a representative format, only indicating the variables of interest in the study.

Benefits of participation

There will be no direct benefits or allowances given for participating in the study.

The information you provide will help us better understand the burden of HCAIs in our ICU setup and the presence of any change in the local antibiogram. This information is a contribution to science as it will inform a basis for recommendations on the antimicrobial protocol thus optimizing patient outcomes in the critical care unit.

Contacts information

If you have any further questions regarding the study, you may call or send a text message to any of the study staff. Their contacts are provided below.

Principal investigator:

Dr. Elly Thathi **Contact:** 0724777624 **Email:** ekthathi@students.uonbi.ac.ke

Supervisors contact:

Dr. Antony Gatheru **Contact**: 0721654806 **Email:** gatherua@uonbi.ac.ke

Dr. Idris Chikophe **Contact:** 07221436926 **Email:** idris6664@gmail.com

Dr. Moses Masika **Contact**: 0721770306 **Email**: mosmasika@uonbi.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.

Contacts: Tel: 2726300 ext 44102, **Email:** uonknh_erc@uonbi.ac.ke

Consent Form

I…… consent for the voluntary participation in the research study. I have fully comprehended the study's purpose and significance as it has been explained to me in a language that I understand. I also have the right to participate voluntarily and withdraw from the study.

Signature or Thumbprint:……Date:……

OR

I, (Your name)……. fully comprehend the study's purpose and significance to the participant named below and it has been explained in a language that I understand. I freely agree for my child or next of kin to participate in the research and do give consent for:

Patient's name:……..
To be included in the study, by virtue of being critically ill and or underage.

Name:……Date:……..

Signature or Thumbprint:……

Investigator's Declaration:
I, the undersigned, have fully explained the relevant details of this research study to the participant or guardian or next of kin named above and believe that the participant, guardian, or next of kin has understood and has willingly and freely given his/her consent. I have also answered their questions satisfactorily.

Signature……Date…….

Appendix II: Consent Form (Kiswahili)

Fomu ya Ridhaa

Kichwa cha Utafiti: "Mifumo ya maambukizi yanayohusiana na huduma ya afya kwa wagonjwa katika kitengo cha wangonjwa mahututi cha Hospitali ya Kitaifa ya Kenyatta"

Utangulizi

Mimi ni Dkt. Elly Thathi, mwanafunzi wa Shahada ya Uzamili ninayefuata Shahada ya Uzamili ya Dawa ya Anaesthesia na Utunzaji Makini katika Chuo Kikuu cha Nairobi, na mimi ndiye mpelelezi mkuu wa utafiti huu, unakaribishwa kushiriki katika utafiti huu. Madhumuni ya fomu hii ya idhini ni kukupa taarifa utakayohitaji ili kukusaidia kuamua kama kuwa mshiriki au la katika utafiti. Jiskie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti. Wakati nimejibu maswali yako yote kwa kurithika kwako,unaweza kuamua kuwa katika utafiti au la. Naweza kuendelea? Ndio au La

Kusudi la Kusoma

Maambukizi yanayohusiana na huduma ya afya ni tatizo la kimataifa. Utafiti huu unalenga kubainisha mzigo,vijidudu vinavyosababisha, na wale walio kakita hatari ya kupata maambukizi yanayohusiana na afya katika kitengo cha wagonjwa mahututi. Hii itaboresha huduma ya wagonjwa katika Hospitali ya Kitaifa ya Kenyatta. Kwa hivyo ushiriki wako katika utafiti huu ni muhimu sana.Utafiti huu umeidhinishwa na Itifaki ya Kamati ya Maadili na Utafiti ya Hospitali ya Kitaifa ya Kenyatta-Chuo Kikuu cha Nairobi nambari…..

Maelezo ya Utafiti

Kutakuwa na takriban washiriki 163 katika utafiti huu waliochaguliwa bila mpangilio. Utafiti utakusanya data ya demografia na sifa za kiafya kutoka kwa faili ya wagonjwa waliolazwa wakati wa kukaa katika kitengo cha wagonjwa mahututi. Kwa wale wagonjwa ambao watagunduliwa na maambukizi; sampuli itachukuliwa kutoka kwa eneo la jeraha, njia ya chini ya upumuaji,mkojo wa kati, sampuli kutoka katheta inayokaa ndani, au mkondo wa damu na mpelelezi mkuu au msaidizi aliyefunzwa. Sampuli hizi zilizokusanywa zitapelekwa kwenye maabara ya biolojia kwa uchambuzi ili kubaini kisababishi cha maambukizo na kutibu hali ipasavyo.

Ushiriki Katika Utafiti

Uamuzi wako wa kushiriki katika utafiti huu ni wa hiari. Uko huru kukataa kushiriki katika utafiti na unaweza kujiondoa kwenye utafiti wakati wowote; kwani hii haitaathiri utunzaji au matibabu ya baadaye ya siku zijazo. Utunzaji wa kawaida wa mgonjwa utadumishwa kwa washiriki wote wakati wote wa kipindi cha utafiti. Mpelelezi mkuu atachukua gharama za utafiti. Hakuna gharama za ziada zitakazotumiwa na mgonjwa wakati wa utafiti.

Athari za Ushiriki

Mshiriki atakuwa na mfiduo mdogo kwa hatari yoyote ya kiafya na kila juhudi itawekwa ili kupunguza hatari. Kunaweza kuwa na kutokwa na damu, maumivu, au usumbufu unaohusishwa na mkusanyiko wa sampuli. Hii itapunguzwa kwa matumizi ya sindano ndogo zaidi (23G) inayopatikana kwa ukusanyanji wa sampuli na uwekaji wa shinikizo kwa mpira wa pamba au chachi baada ya kukusanya sampuli ya damu.

Usiri Wa Ushiriki Katika Utafiti

Usiri kamili utadumishwa ili kuhakikisha kuwa takwimu haingii mikononi mwa watu wasio sahihi. Hakuna maelezo ya kitambulisho yatatumika katika ukusanyaji wa takwimu, uchambuzi na uwasilishaji wa matokeo. Washiriki wote na sampuli zinazolingana zitawekwa lebo ya kipekee kwa kutumia vitambulisho visivyojulikana wakati wote wa utafiti. Ushirikiano wa takwimu utakuwa katika umbizo wakilishi,ikionyesha tu vigeu vya manufaa katika utafiti.

Faida za Ushiriki Katika Utafiti

Hakutakuwa na manufaa ya moja kwa moja au posho zitakazotolewa kwa kushiriki katika utafiti. Maelezo unayotoa yatatusaidia kuelewa vyema mzigo wa maambukizi yanayohusiana na afya katika usanidi wetu wa kitengo cha wagonjwa mahututi na kuwepo kwa mabadiliko yoyote katika antibiogram ya ndani. Habari hii ni mchango kwa sayansi kwani itaarifu msingi wa mapendekezo juu ya itifaki ya antimicrobial hivyo kuboresha matokeo ya mgonjwa katika kitengo cha utunzaji muhimu.

Maelezo ya Mawasiliano

Ikiwa una maswali yoyote kuhusu utafiti huu, unaweza kupiga simu au kutuma ujumbe mfupi wa maaandishi kwa mfanyakazi yeyote wa utafiti. Anwani zao zimetolewa hapa chini.

Mchunguzi mkuu:

Dr. Elly Thathi Nambari ya Simu: 0724777624 **Barua pepe:** ekthathi@students.uonbi.ac.ke

Mawasiliano ya Wasimamizi:

Dr. Antony Gatheru Nambari ya Simu: 0721654806 **Barua pepe:** gatherua@uonbi.ac.ke

Dr. Idris Chikophe Nambari ya Simu: 07221436926 **Baruapepe:** idris6664@gmail.com

Dr. Moses Masika Nambari ya Simu: 0721770306 **Baruapepe:** mosmasika@uonbi.ac.ke

Kwa maelezo zaidi kuhusu haki zako kama mshiriki wa utafiti, unaweza kuwasiliana na Katibu/ Mwenyekiti, Hospitali ya Kitaifa ya Kenyatta- Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi.

Nambari ya Simu: 2726300 ext 44102 **Barua pepe:** uonknh_erc@uonbi.ac.ke

Fomu ya Idhini

Mimi…… ninakubali kushiriki kwa hiari yangu katika huu utafiti. Nimeelewa kikamilifu madhumuni na umuhimu wa utafiti kama ulivyofafanuliwa katika lugha ninayoelewa. Ninaeelewa kua nina haki ya kushiriki kwa hiari na kujiondoa kwenye utafiti.

Sahihi/ Alama ya kidole:……Tarehe:……

AU

Mimi, (Jina lako)……kufahamu kikamilifu madhumuni na umuhimu wa utafiti kwa mshiriki aliyetajwa hapa chini na imefafanuliwa katika lugha ninayoelewa. Ninakubali mtoto au jamaa wangu wa karibu kushiriki katika utafiti na kutoa idhini kwa:

Jina la mgonjwa:……..
Kujumuishwa katika utafiti,kwa sababu ya kuwa mgonjwa sana na au umri mdogo.

Jina:……..Tarehe:…….

Sahihi/Alama ya Kidole……..

Taarifa ya Mpelelezi:

Mimi, aliyetia sahihi hapa chini, nimeeleza kikamilifu maelezo muhimu ya utafiti huu kwa mshiriki au mlezi au jamaa aliyetajwa hapo juu. Ninaamini kuwa mshiriki,mlezi,au jamaa wa karibu ameelewa na ametoa ridhaa yake kwa hiari na kwa uhuru. Nimejibu pia maswali yao kwa kuridhisha.

Sahihi……Tarehe……..

Appendix III: Data Collection Tool: English Version

A questionnaire to Investigate the Patterns of Healthcare-Associated Infections in patients at Kenyatta National Hospital Main Intensive Care Unit

DATE OF ADMISSION: …… **SERIAL NO:** ……

1. Please indicate the patient's age in years: ☐
2. The gender of the patient: ☐ Male ☐ Female
3. The admitting diagnosis/diagnoses: ……
   …….
4. Surgical intervention:
   a. Type of surgery: Emergency ☐ Elective ☐
   b. Duration of surgery in hours: ……
5. Antimicrobial prophylaxis given at the start of surgery: Yes ☐ No ☐
6. History of co-morbidities:
   - Hypertension ☐ Diabetes Mellitus ☐ Convulsive disorder ☐
   - Asthma ☐ HIV ☐ Chronic kidney disease ☐
   - Others (specify)…… None ☐
7. The invasive device in situ, day of insertion, and length of duration:

DEVICE	Present at admission	Date of insertion	Duration of stay
Central Venous Catheter			
Urinary Catheter			
Endotracheal Tube			
Tracheostomy Tube			
Nasogastric Tube			
Arterial Line			
Surgical Drain			
Specify specify ……			

Part B: Health-Care Associated Infections Screening Tool: (Tick or fill where appropriate)

1. Record in the table below the various vitals at the hours the patients stayed in the unit:

DATE							
DAY	**0**	**2**	**3**	**4**	**5**	**6**	**7**
VITALS	At **0** hours	At **48** hours	At **72** hours	At **96** hours	At **120** hours	At **144** hours	At **168** hours
Mean Arterial Pressure (mmHg)							
Heart rate*							
Respiratory rate							
Oxygen Saturation (SPO_2)							
Temperature* (^0C)							
Total white cell count ($*10^9/L$)							
Breathing Apparatus (*RA, NP, NRM, V*)							
Fraction of inspired oxygen (FiO_2) (%)							

2. Has the **S.I.R.S. criteria** been met: (**at least two)** for the pediatric population; the value considered for HR and RR is 25% above the baseline for the expected age.

HR>=90// **RR**>=20// **Temp**>38.3 or <36// **WBC**<4 or >12)//

D2……. // D3……. // D4……. // D5……. // D6……. // D7……. //

3. The medications the patient was given during their stay in the unit and duration in days:

MEDICATION	**STATUS (YES/NO)**	**DURATION (Days)**
Stress Ulcer Prophylaxis		
Corticosteroids		
Sedating Agents		

4. **SURGICAL SITE INFECTION** (S.S.I.) diagnosis includes the presence of at least one of the following: ***(X/3)***

   a) Signs of inflammation: localized tenderness, warmth, erythema
   //D2//D3//D4//D5//D6//D7
   b) Purulent discharge at the incision site/wound/drain
   //D2//D3//D4//D5//D6//D7
   c) Abscess identified:
   //D2//D3//D4//D5//D6//D7

   D2……. // D3……. // D4……. // D5……. // D6……. // D7……. //

5. **VENTILATOR-ACQUIRED PNEUMONIA** (VAP) diagnosis includes the presence of at least two of the following: ***(X/3)***

   a. Cough:
      //D2//D3//D4//D5//D6//D7
   b. Purulent sputum:
      //D2//D3//D4//D5//D6//D7
   c. Worsening signs of gas exchange: such as increased oxygen requirements by at least 20% or increased ventilation demand: (Can be a *change* of vent mode ex CPAP to SIMV **OR** *increase* in FiO_2 ex 30-45)
      //D2//D3//D4//D5//D6//D7
   d. A new infiltrate on the chest x-ray not present on admission:
      //D2//D3//D4//D5//D6//D7

   D2……. // D3……. // D4……. // D5…… // D6……. // D7……. //

6. **CATHETER-ASSOCIATED URINARY TRACT INFECTIONS** (CAUTI) diagnosis includes the presence of at least one of the following: ***(X/6)***

    a. Haematuria:
        //D2//D3//D4//D5//D6//D7
    b. Suprapubic/costovertebral angle pain or tenderness:
        //D2//D3//D4//D5//D6//D7
    c. If the catheter is removed: urgency, frequency, and dysuria
        //D2//D3//D4//D5//D6//D7
    d. Sediments along the catheter length:
        //D2//D3//D4//D5//D6//D7
    e. Condition of the urinary catheter insertion site;
        i. Discharge: *//D2//D3//D4//D5//D6//D7*
        ii. Redness: *//D2//D3//D4//D5//D6//D7*
        iii. Leakage: *//D2//D3//D4//D5//D6//D7*

    D2……. // D3……. // D4……. // D5……. // D6……. // D7……. //

7. **BLOODSTREAM INFECTION** (BSI) /**CENTRAL LINE BLOODSTREAM INFECTION** (CLABSI) diagnosis includes the presence of at least one of the following: ***(X/5)***

    a. Chills/rigors:
        //D2//D3//D4//D5//D6//D7

    b. Hypotension:
        //D2//D3//D4//D5//D6//D7

    c. Condition of the central venous catheter insertion site;
        i. Discharge: *//D2//D3//D4//D5//D6//D7*
        ii. Redness: *//D2//D3//D4//D5//D6//D7*
        iii. Leakage: //D2//D3//D4//D5//D6//D7

    d. In the case of infants;
        i. Hypothermia: *//D2//D3//D4//D5//D6//D7*
        ii. Bradycardia <80 beats per minute: *//D2//D3//D4//D5//D6//D7*

    D2……. // D3……. // D4……. // D5……. // D6……. // D7……. //

Part C: Health-Care Associated Infections sample collection and culture results

1. Type of sample taken from the patient for culture and sensitivity:

SAMPLE	DATE
Blood (CVC+PERIPHERAL)	
Tracheal Aspirate/Sputum	
Midstream Urine	
Wound Swab	

2. The culture results from the samples taken from the patient:

   a. Blood: ☐ No growth

   ☐ Isolate grown: ……

   b. Sputum or Tracheal Aspirate: ☐ No growth

   ☐ Isolate grown: ……

   c. Midstream Urine: ☐ No growth

   ☐ Isolate grown: ……

   d. Wound swab: ☐ No growth

   ☐ Isolate grown: ……

Key:

- bpm-beats per minute
- bpm-breath per minute
- ^{0}C- degrees Celsius
- FiO2- a fraction of inspired oxygen = 21% + (4 * oxygen litre flow)

COMMENTS:

……
……
……
……