RISK FACTORS AND BURDEN OF HOSPITAL ACQUIRED URINARY TRACT INFECTIONS AMONG CATHETERIZED PATIENTS AT KENYATTA NATIONAL HOSPITAL'S CRITICAL CARE UNIT

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Risk Factors and Burden of Hospital Acquired Urinary Tract Infections among Catheterized Patients at Kenyatta National Hospital's Critical Care Unit

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DECLARATION

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

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DEDICATION

This study is dedicated to my family: my mother Rebecca Wanjiru for always believing in me and encouraging me throughout my study. It is also dedicated to my wife Edith Njoki Githinji and our wonderful children Judebec, Margaret and Mary, for their understanding and sacrifice in the course of preparation of this work.

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ABBREVIATIONS/ ACRONYMS

CAUTI	Catheter Associated Urinary Tract Infection
CCU	Critical Care Unit
CDC	Center for Disease Control
DF	Degree of Freedom
ICU	Intensive Care Unit
KNH	Kenyatta National Hospital
RR	Relative Risk
US	United States of America
UTI	Urinary Tract Infection
UoN	University of Nairobi
WHO:	World Health Organization

OPERATIONAL DEFINITIONS

Burden of Disease the impact of a health problem as measured by financial cost, mortality, and morbidity

Catheter associated urinary tract infection A urinary tract infection (UTI) involving any part of the urinary system, including urethra, bladder, ureters, and kidney in a patient with a urinary catheter

Facility level factors factors associated with the health facility to include, catheter insertion procedure, care of the urinary catheter, type of the catheter, urine emptying procedure etc.

Incidence the rate or range of occurrence of a disease

Nosocomial infection is an infection whose development is favored by a hospital environment, such as one acquired by a patient during a hospital visit or one developing among hospital staff.

Patient level factors this include patient's age, gender, diagnosis, type of antibiotics they are on etc.

Period prevalence proportion of people in a population who have a disease or attribute at any time during the interval

ABSTRACT

Intensive Care Unit Acquired Urinary tract infection is a complication which is common in critical illness and has been associated with increased patient morbidity. Urinary tract infections are the most common type of nosocomial infections in the world. Indwelling catheter device contribute 80% of the UTIs. Urinary tract infections are said to complicate the critically ill patients' clinical course and at the same time create substantial economic and human cost. There is relatively few researches on nosocomial urinary tract infection specifically acquired in the intensive care unit and more studies need to be done to explain more on the epidemiology and management of the said infections. The study was aimed at establishing the Risk factors and burden of hospital acquired urinary tract infections among catheterized patients at Kenyatta National Hospital's Critical Care Unit. The study was done at the Kenyatta National Hospital Critical Care Unit. A prospective cohort study design was used in this study. The study population was all patients admitted in the unit and were put on urinary catheter. The duration of the study was one year. The patients were recruited consecutively for the period of the study. The patients were followed up until they were out of the unit. The unit admits approximately 50 patients per month (approximately 600 per year). The researcher used census to recruit the study participants. 238 participants were recruited.1st, 2nd, 3rd and 4th Urine specimens were collected within the first 12 hours, then second sample at 72 hours, third sample at the 7th day and the fourth sample at the 14th day of patient's admission. The analysis of the urine samples were done in the microbiology laboratory for the growth of microorganism to determine the incidence rate of nosocomial urinary tract infections and causative organisms. The temporal treads were determined by assessing the sequence on the micro-organisms grown. The time taken to acquire the infection was analyzed using survival analysis. The relationship between causative organisms, patients' comorbidities and characteristics were established by calculating the relative ratios. Cox-regression model was used to test association between the factors and the time to infection. Data was analyzed using SPSS version 23.0. The incidence density of hospital acquired catheter associated urinary tract infection was 32 per 1000 Catheter-days in the critical care unit. The cumulative incidence was 28.7%. Patients with comorbidities had a higher risk to acquire catheter associated urinary tract infection; risk ratio of 1.669 (95% CI: 1.01 to 2.75). Failure to observe aseptic techniques during emptying of the urine bag had a higher risk to acquire catheter associated urinary tract infection; risk ratio of 3.4 (95% CI:2.0 to 5.9). Failure to secure the urinary catheter on the patient's thigh had a higher risk to acquire catheter associated urinary tract infection; risk ratio of 1.84 (95% CI: 1.1 to 3.0). The most common micro-organisms cultured were; *Enterococcus faecalis* (25%) and *Escherichia coli* (20%).The gram-negative micro-organisms were more common during the warmest month of the year. Time to CAUTI increased non-linearly for each additional day of catheterization. The factors that increased the risk of UTI also reduced the time to CAUTI. The incidence of infection was high as compared to other studies. There is need to emphasize strict adherence to infection prevention and control measures in caring for the patients admitted in the CCU set-up.

CHAPTER ONE

INTRODUCTION

1.1 Background

World Health Organization (WHO) (2016); defines 'Nosocomial' or 'healthcare associated infections' (HCAI) as infections appearing in a patient undergoing medical care in the hospital or other health care facility and the infection was not present on admission. WHO (2016) states that the infections can occur during the time the patient is receiving healthcare for other diseases and even after the patient is discharged from the health facility. They comprise infections among the medical staff acquired while delivering health care. According to CDC (2016), these infections are associated to devices that are invasive, example; catheters and respiratory ventilators employed in modern health care.

Urinary Tract Infection (UTI) is defined as an infection that affects any part of the urinary system (urethra, bladder or kidneys). UTI is said to be the most common nosocomial infection; the majority of the infections (eighty percent (80%) are associated with the utilization of indwelling catheter device in the health facilities to drain urine (Nicolle 2014). The UTI is attributed to the use of an indwelling urinary catheter among patients in health care facilities. Biofilm develops on these devices; duration of catheterization is the major determinant for development of bacteriuria. According to Nicolle (2014), Catheter-acquired urinary tract infection (CAUTI), contributes about twenty percent (20%) of health-care acquired bacteremia events in acute care facilities, and over fifty percent (50%) of the episodes in the long term care facilities. Hooton et al (2010), established that CAUTI was the most common healthcare associated infection in the world due to the widespread use of urinary catheters. This was associated with increased cost of care due to personnel time and expenditure by healthcare institutions to reduce the infection rates.

CAUTI is the most common healthcare associated infection in United States of America. Approximately 93000 cases of CAUTI were admitted in the acute care hospitals in the US, in the year 2011(Magill et al 2014). Hollenbeak and Schilling

(2018) estimates the inpatient cost to Medicare for patients admitted in American ICUs to US $ 10,197. According Letica-Kriegel et al (2019), CAUTIs significantly increase the burden on patients, in terms of morbidity and mortality. The risk factors associated with CAUTI in America were, female gender, patients with mobility issues, the length of time the patient was on the catheter, Age (below 50 years) and presence of comorbidities.

According to European Center for Disease Prevention and Control (2018), 32 per 1000 patients staying in the ICU for more than two days were reported to have acquired CAUTI in 2008 to 2012 in Europe. It was estimated that CAUTI contributed to 1.06 million days of excess ICU stay each year in the European hospitals. Patients with UTI had no higher mortality in matched cohort analysis.

A study done in South Africa established the incidence density of CAUTI in Pediatric Critical Care Unit (PICU) was high (16 per 1000 catheter days). The infections were significally associated with PICU stay (odds ratio: 1.9). It was also established that the infections increased the cost of health-care (Dramowski et al. 2016).

A study conducted among patients with indwelling urinary catheters in Kabale regional referral hospital in Uganda, noted that the incidence of CAUTI was 15.3%. The most common organisms identified in this study were; *E. Coli* and *K. Pneumoniae.* The bacteria were resistant to most commonly used antibiotics (Musinguzi et al. 2019). There is paucity of research in this area in Kenya. The main objective of this study is to describe the Risk factors and burden of intensive care unit acquired urinary tract infections among catheterized patients at Kenyatta National Hospital's Critical Care Unit.

1.2 Problem Statement

The Kenyatta National Hospital (KNH) Critical Care Unit (CCU) is the largest in the whole country admitting approximately fifty to sixty (50-60) patients every month. It

is a twenty one (21) bed multidisciplinary unit admitting patients of all ages. Majority of the patients admitted in this unit have urinary catheters fixed to assist in monitoring for urinary output. The most common nosocomial infection is Urinary tract infection with urinary catheters being associated with the complication. Healthcare-associated UTIs contribute approximately 40% of infections in hospitals and 23% of intensive care unit infections (Chenoweth & Saint, 2013). A large number of the UTIs are associated to indwelling urinary catheters; close to 70% of UTIs develop in patients with urinary catheters with 95% occurring in ICUs (Burton et al 2011). Nosocomial infections increase the length of stay in a health facility and also the cost due to the need of strong antibiotics to treat the infections. The major reason for admission in the KNH CCU is severe head injuries mainly result from road traffic accidents and assault.

According to Gomila et al (2019), UTI is a major worldwide healthcare issue. It is the most common hospital-acquired infection and its major risk factor is insertion of urinary catheter (Trautner, 2010). More than one million cases of catheter-associated urinary tract infections (CA-UTI) per year are recorded in the United States (Flores-Mireles et al 2015). CA-UTI are responsible for over 80% of UTI's found in the healthcare facilities and the most common cause of bacteremia in long-term care facilities (Nicolle 2012; Chenoweth & Saint, 2013). It is estimated that 20% of patients that are hospitalized have a urinary catheter on admission, with the risk of developing CA-UTI rising by 3 – 7% per day (Saint et al 2018; Tominaga et al 2014).

1.3 Study Justification

Hospital-acquired infections are major causes of illness and death in hospitalized patients throughout the world. CAUTI is the most common Hospital acquired infection among patients with indwelling catheters. Kenyatta National Hospital is the largest specialized hospital south of Sahara and north of Limpopo. Majority of critical care specialists in Kenya are trained at KNH CCU hence having good healthcare practices in prevention of CAUTI will go further to improve the practices in other health institutions in the country. Approximately 95% of patients admitted in

KNH CCU have indwelling catheters inserted to aid in monitoring urinary output. Majority of patients admitted in the unit are due to trauma. This type of patients have an increased length of stay due to their neurological status as the majority of them has severe head injuries. The longer the patients stay in the critical care unit the longer they have an indwelling catheter. This predispose them to CAUTI. UTI complicate the critically ill patients' clinical course & increase substantial economic and human cost. Majority of the patients admitted in the unit are put on empirical treatment (third and fourth generation of cephalosporin) which are resistant to the micro-organisms responsible for the UTI. Avoiding overuse of anti-biotics reduces the antimicrobial resistance. Urine Culture and sensitivity aids in identifying the most common microorganisms causing UTI and thus assisting in the issue of stocking the most sensitive drugs so that morbidity and mortality can be reduced. Reducing the length of stay caused by the UTI will reduce the economic burden on both the patient and the hospital. There is need to identify the factors associated with CAUTI to assist in development of policies to reduce the infections. It is also important to establish the average time a catheterized patients takes to develop CAUTI to aid in development of standard operating procedures on change and removal of the urinary catheter in the KNH critical care setting.

1.4 Study Objectives

1.4.1 Broad Objective

To determine the Risk factors and burden of hospital acquired urinary tract infections among catheterized patients at Kenyatta National Hospitals Critical Care Unit.

1.4.2 Specific Objectives

1. To determine the burden of hospital acquired catheter associated urinary tract infection among patients admitted at KNH CCU
2. To determine the common causative organisms for catheter associated urinary tract infection at KNH CCU
3. To determine the patient level factors associated with hospital acquired catheter associated urinary tract infection

4. To determine the facility level factors associated with hospital acquired catheter associated urinary tract infections
5. To determine the temporal trends of microbial growth among catheterized patients admitted at KNH CCU
6. To determine the time-to development of urinary tract infection among catheterized patients admitted in the Kenyatta National Hospital Critical Care Unit.

1.5 Research Questions

(i). What is the burden of hospital acquired catheter associated urinary tract infection among patients admitted at KNH CCU?

(ii). What are the common causative organisms for catheter associated urinary tract infection at KNH CCU?

(iii). What are the patient level factors associated with hospital acquired catheter associated urinary tract infection?

(iv). What are the facility level factors associated with hospital acquired catheter associated urinary tract infections?

(v). What are the temporal trends of microbial growth among catheterized patients admitted at KNH CCU?

(vi). What is the time to development of urinary tract infection among catheterized patients admitted in the Kenyatta National Hospital Critical Care Unit.?

1.6 Conceptual Framework

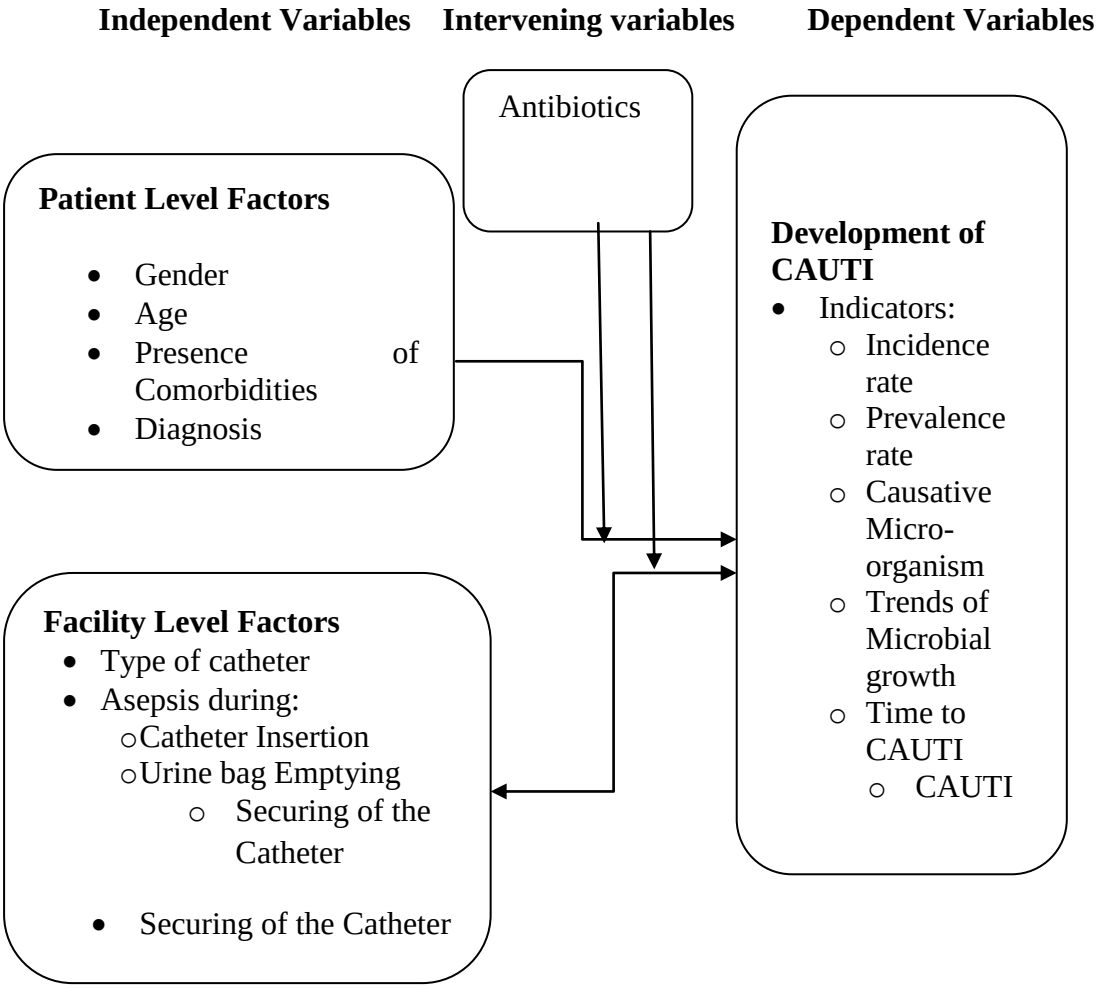

Figure 1.1: Conceptual Framework

Note: Exposed included: Gender – female; Age – 50 years and above; presence of comorbidities; Asepsis not observed during catheter insertion, asepsis not observed during urine bag emptying and failure to secure the urine catheter on patient's thigh.

Unexposed included: Male gender; Age- below 50 years; absence of comorbidities; asepsis observed during catheter insertion, asepsis observed during urine bag emptying and securing the catheter on the patient's thigh.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter presents a review of available literature that is pertinent to the study. The review is divided into five main sections. The first section presents literature on the burden of hospital acquired catheter associated urinary tract infection. The second section reviews literature and studies on causative organisms for catheter associated urinary tract infection. The third section appraises studies on risk factors associated with nosocomial catheter associated urinary tract infection. The fourth section presents literature on trends of microbes associated with catheter associated urinary tract infection. The fifth section presents literature on time to hospital acquired catheter associated urinary tract infection.

2.2 Burden of Hospital Acquired Catheter Associated Urinary Tract Infection

CDC (2013) defines urinary tract infection (UTI) as an infection involving any part of the urinary system (urethra, bladder, ureters, and kidney). Urinary tract infection was reported to the National Healthcare Safety Network (NHSN) as the most common type of healthcare-associated infection. Approximately seventy five percent (75%) of the hospital acquired UTIs are associated with a urinary catheter. Among hospitalized patients, fifteen (15) to twenty five (25) percent receives urinary catheters during their hospital stay.

According to Gomila *et al* (2019), UTI is a major worldwide healthcare issue. It is the most common hospital-acquired infection and its major risk factor is insertion of urinary catheter (Trautner, 2010). More than one million cases of catheter-associated urinary tract infections (CA-UTI) per year are recorded in the United States (Flores-Mireles *et al* 2015). CA-UTI are responsible for over 80% of UTI's found in the healthcare facilities and the most common cause of bacteremia in long-term care facilities (Nicolle 2012; Chenoweth & Saint, 2013). It is estimated that 20% of patients that are hospitalized have a urinary catheter on admission, with the risk of

developing CA-UTI rising by 3 – 7% per day (Saint et al 2018; Tominaga *et al* 2014). There has been a lot of efforts to reduce the incidence of CA-UTI but the rates continue increasing. The US Centers for Disease Control and prevention reported a 6% increase between the year 2009 and 2013 (Centers for Disease Control and Prevention 2015).

Healthcare-associated UTIs contribute approximately 40% of infections in hospitals and 23% of intensive care unit infections (Chenoweth & Saint, 2013). A large number of the UTIs are associated to indwelling urinary catheters; close to 70% of UTIs develop in patients with urinary catheters with 95% occurring in ICUs (Burton *et al* 2011). The Centers for Disease Control and Prevention (CDC) estimated that in 2007, 139,000 CAUTIs occurred in US hospitals. The infection is said to be the most frequent hospital acquired infection. The incidence density for Intensive Care Unit acquired UTIs was 9.6-11.3 per 1000 ICU days (Laupland, *et al* 2005).

In surveillance cohort study by Laupland *et al* (2005) on adult patients admitted to multi-system and cardiovascular surgery ICUs in the Calgary Health Region, the incidence density of Intensive Care Unit-acquired urinary tract infections was 9.6 per 1000 ICU days.

CAUTI lead to significant economic and clinical consequences. Catheter associated bacteriuria may be associated with increased mortality with a case fatality of 32.8% (Shuman & Chenoweth, 2010; Chang *et al* 2011). Each CAUTI episode costs approximately $600 while blood stream infections related UTIs costs approximately $2800 (Chenoweth & Saint, 2013).

In a large retrospective study, 12.7% mortality rate was attributed to bacteremia urinary tract infections. The crude fatality rate was approximated to exceed thirty percent (30%). An estimated number of 4500 deaths occurring in the USA were said to be caused by nosocomial UTIs even though most of these deaths may occur in patients who have serious underlying disease process (Burke &Yeo, 2004).

Recent prevalence studies report a urinary indwelling catheter as the most commonly used indwelling device. European hospitals reported 17.5% of patients admitted in

sixty six (66) of their hospitals in twenty three (23) countries having a catheter (Zarb *et al*, 2012) and 23.6% in one hundred and eighty three (183) United States of America hospitals (Magill *et al* 2014). In the National Healthcare Safety Network (NHSN) 2011 surveillance report, forty five (45) to seventy nine (79) percent of patients admitted in adult critical care units had an indwelling catheter, seventeen (17) percent of those on medical wards, twenty three (23) percent on surgical wards, and nine (9) percent on rehabilitation units (CDC 2013). This reveals that the use of indwelling urethral catheter is very common in many health care facilities making prevention of hospital acquired infections attributable to these devices be an important goal of health-care infection prevention programs.

A study done in an intensive Care Unit in Bahrain established an overall rate of 5.8 per 1000 catheter days (Alkhawaja, e*t al.* 2017). Another study conducted at a tertiary care University hospital concluded that the rate of infection of CAUTI was 11.5±3.1 (Huang et al. 2015). Health Safety Network (NHSN) in 2010 reported a CAUTI rate of 1.3 infections per 1000 catheter-days in medical/surgical ICUs (Dudeck et al. 2011).

In the United States of America, skills nursing facilities, assisted living facilities and nursing homes, are named as Long-term care facilities (LTFCs). CAUTI is also among the most common infections in these facilities (Saint et al 2008). Sen et al (2016) identified twenty five (25) CAUTIs over 24 months in a University hospital. Most of these (88%) were found in the intensive care units. During the time this study was done, ICU CAUTIs' incidence went down ($P = 0.04$).

According to Mohamed et al (2015), hospital acquired urinary tract infection (UTI) increases the cost of hospitalization and morbidity. They used a cohort study design to study all the post –operative pediatric patients who were admitted in the Pediatric Cardiac Intensive Care Unit (PCICU) in 2012. The patients were divided into two groups: those with UTI (UTI group) and those without UTI (control group). Both groups were compared for multiple peri-operative risk factors. The study population was made up of four hundred and thirteen (413) children. Twenty nine (29) children (7%) had UTIs following cardiac surgery (UTI group), and three hundred and eighty

four (384) a proportion of ninety three (93) percent were UTIs free (control group). All the twenty nine children had UTI which was catheter-associated (CAUTIs). In the study a total of one thousand, five hundred and seventy eight (1578) urinary catheter days were evaluated, with the results showing CAUTI density rate of eighteen per thousand (18 /1000) catheter days. Uçkay *et al* (2013), established a high prevalence of urinary tract infections among patients admitted in hospitals: a cross-sectional study of symptomatic UTI among fourty nine (49) Swiss hospitals done in 2004, detected 3.7% prevalence of UTI among those catheterized for at least twenty four (24) hours of their hospital stay, and 0.9% of those who had not been catheterized. Uçkay, et al. (2013) established a high prevalence (3.7%) of catheter acquired urinary tract infections among patients admitted in 49 Swiss hospitals. The cumulative incidence rate of catheter acquired urinary tract infection at Kenyatta National Hospital in the year 2011 was 17.8% (Inyama et al 2011). Chant et al (2011), in their study concluded that CAUTI is associated with significant increase in mortality and length of stay. In the case of mortality the odds ratio [OR], was 1.99; (95% confidence interval [CI], 1.72-2.31; $p < .00001$; $I2 = 54\%$; eight studies; 62,063 patients) and length of stay in the intensive care unit showed a weighted mean difference of + 12 days; 95% CI, 9-15; $p < .00001$; $I2 = 96\%$; seven studies; 13,011 patients).

2.3 Causative Organisms for Cauti

A study done in Salmaniya medical center in Bahrain by Elkhawana et al (2017) showed that, *E. coli* was the most isolated micro-organism (28.8%) followed by *Klebsiella species* (26.9%), *candida albicans* (25%), and *pseudomonas species* (11.6%) and *Proteus mirabilis species* (7.7%). Another study conducted in Turkey by Inan et al. (2006), showed that, the most frequently isolated causative agents were *Candida spp.* in 37.1% of the UTIs, *E.coli* in 21.1% of the UTIs and *Pseudomonas spp.* in 16.5% of the UTIs. In another study done in an ICU at a university hospital in Turkey by Keten at al. (2014) *candida species* were the most prevalent organisms at 34.7%, followed by *E. coli* at 20.6%, *pseudomonas species* at 14%, *Klebsiella species* at 9.9% and *Acinetobacter species* at 8.2%.

According to Murugan *et al* (2016), contamination of urinary catheters and other indwelling medical devices play an important role in hospital acquired infections. The main contaminants are self-reproducing microbial biofilm community. Murugan et al (2016), in their study on Catheter Associated Urinary Tract Infection isolated *Pseudomonas aeruginosa, staphylococcus aureus,* and *Enterobacter faecalis*. Among the organism isolated from fifty (50 culture positive urinary catheters were; *S. aureus (24%), P. aeruginosa (18%), E. faecalis (14%) and others (44%). After the identified E. faecalis esp, S. aureus ica,* and *P. aeruginosa* cup A gene sequencing and phylogenetic analysis was done, their close branching and genetic relationship was demonstrated. The degree of CAUTI isolates biofilm formation was shown to be an environmentally sensitive process by the analyzed pH, sugar, salt, and temperature.

In the study by Mohamed et al (2015), they isolated Gram negative bacteria accounting for 63% of the CAUTI. The leading causes of CA-UTI were *Escherichia coli* (21%). Candida (24%) Klebsiella (27%), and Resistant organisms caused 34% of CAUTI. Mladenović et al (2015) in their study at an Intensive Care Unit (surgical), in a Medical Academy ran by the military in Belgrade, Serbia isolated seventy one (71) pathogens from cultured urine samples of sixty four (64) patients diagnosed with CAUTIs. The most frequently isolated organisms were; Klebsiella spp. (15.5%), *Pseudomonas aeruginosa* (18.3%) and *Candida spp*. (28.2%).

Cardwell *et al* (2016) in their study identified a total of 216 pathogens. The most commonly identified pathogen was *Pseudomonas aeruginosa*, extended-spectrum beta lactamase (ESBL)-producing organism and *Escherichia coli.*

2.3.1 Microbial Sensitivity

Elkhawana *et al*. (2017), established that the gram-negative micro-organism were sensitive to Aminoglycosides and Meropenem as a mono therapy. Keten *et al* (2014) study showed that *Acinetobacter baumaunnii* was sensitive to Meropenem at 30%. *Candida Albicans* were sensitive to Fluconazole and Voriconazole (60%), Amphotericin B (40%), Fencitocine (40%), Caspofugine (40%), and Micafugin (40%). The results were consistent with keten et al (2014) study.

2.4 Risk Factors Associated with Hospital Acquired Catheter Associated Urinary Tract Infection

Prolonged use of indwelling urinary catheter is a high risk factor for developing a catheter-associated UTI (CAUTI). Catheters should therefore be used only where well indicated and must be removed as soon as the indication is resolved (CDC, 2013). Urethral catheter can bypass certain defense mechanisms that are known to minimize or prevent bacteria–epithelial cell interactions. During insertion of the catheter the bacteria can gain access to the urinary tract. This becomes a common feature in patients having their perineum and distal urethra inadequately cleansed before introduction of the catheter. Introduction of organisms in hospitalized patients at the time of introduction of the catheter could be critical. Approximately twenty (20) percent of patients will be colonized immediately after catheterization (Tenke et al 2008).

According to Saint et al, (2008) an estimate of more than 100,000 patients in Long-Term Care Facilities (LTFCs) have urethral catheter at any given time and close to all of those patients having indwelling catheters for a longer period are bacteriuric.

Bagshaw and Laupland (2006) found out that, several countries reported, that nosocomial UTI complicates intensive care unit patients' course in many instances. Almost all patients developing an intensive care unit-acquired UTI had indwelling urinary catheters. Female gender, length of stay in the intensive care unit, patient having a catheter in situ for a longer duration and preceding systemic antimicrobial therapy were other factors which were associated with the development of these infections. Despite the acquisition of an intensive care unit-acquired urinary tract infection being associated with an increased length of stay in the ICU, higher cost, and a higher crude case fatality rate, they were not independently increasing the risk for death.

In surveillance cohort study by Laupland *et al* (2005), women were at a higher risk of developing an ICU-acquired UTI (RR-1.58; 95% CI 1.43–1.75; $P < 0.0001$) and in medical (9%) compared with non-cardiac surgical (6%), and cardiac surgical patients (2%). The study done in Calgary Health region reported a risk ratio of 1.58 (95% CI

1.43 -1.75; P value <0.0001). Chenoweth & Saint, (2013) study indicated that women are at a higher risk of developing an ICU-acquired UTI. Another study in Bahrain showed that the male were at a higher risk than the female (Male: Female relative risk [RR] 2.9; (95%CI] 1.4016 to 6.2461; P = 0.011)) (Alkhawaja et al 2017). Chenoweth, and Saint, (2013) indicate that age greater than 50 years is a risk factor. Comorbidities like Diabetes Mellitus and Serum creatinine level greater than 2 mg/dL were identified as risk factors (Chenoweth, & Saint, 2013). Alkhawaja *et al* (2017) in their Bahrain study established that patients with medical cases had higher risk of acquiring UTI than those with surgical cases.

Adherence to aseptic catheter care is a known factor that reduce the risk of acquiring CAUTI (Chenoweth, & Saint, 2013). Other factors were catheter insertion after the sixth day of hospitalization and Catheter insertion outside the operating room (Chenoweth, & Saint, 2013).The CDC CAUTI prevention Bundle recommends asepsis during insertion, sample removal and bag emptying (CDC, 2016). CDC recommends securing of the urinary catheter on the patients thigh (CDC, 2016).

Mohamed *et al* (2015), concluded that an increased length of time of the urinary catheter ($p < 0.001$), the patients having congenital abnormalities of kidney and urinary tract ($p < 0.0041$), and those diagnosed with syndromes (Down, William, and Noonan) ($p < 0.02$) were also main risk factors for CAUTI.

Mladenović *et al* (2015) identified the duration on an indwelling catheter (Odds Ratio=1.014; 95% CI 1.005-1.024; p = 0.003); and being female (Odds Ratio=2.38; 95% CI1.28 – 4.42; p=0.006), as the two risk factors that were independently associated to CAUTIs.

2.5 Trends of Microbial Growth

The variations of the incidences of hospital infections have been reported severally with Gram-negative bacteria being the most common (Richet 2012). Results from a study done at the University of Maryland Center showed significant increase in the incidences of infections caused by Gram-negative pathogens (*Acinetobacter baumannii*, *P. aeruginosa*, *Enterobacter cloacae*, and *Escherichia coli)* during

summer (Perencevich et al 2008). Another study conducted on inpatients one hundred and thirty two (132) hospitals in the US, indicated there were seasonal variations. There were increased cases during in the warmer months of the year. The micro-organisms isolated were; *Acinetobacter spp*, *E. coli*, and *P. aeruginosa* nosocomial infections (Eber *et al*, 2011). There was another study which described seasonal variations in Blood Stream Infections (BSI) caused by *Klebsiella pneumonia*. The results of the study showed an increase of forty one (41) to forty nine (49) percent of the of infection rates during years' warmest months (Anderson, *et al* 2008).

2.6 Time Taken to Acquire UTI Post Urinary Catheter Insertion

Nicolle (2014) connects duration of catheterization to development of bacteriuria, as biofilm ultimately develops on the catheters. Nicolle (2014) continues to say that the increased indwelling catheter use frequency could be attributed to UTI even though the proportion of bacteriuric subjects developing symptomatic infection was low. Interventions like limiting the use of catheter and discontinuing the catheter as soon as clinically feasible are of most importance to prevent bacteriuria and infection. Duration of the catheterization is the most important determinant of bacteriuria (Hooton *et al* (2010). Indwelling catheter being in situ is associated with a daily risk of acquisition of bacteruria at 3-7%. The bacteriuria happens when a catheter remains in situ for several weeks.

Al-Hazmi, (2015), in a study conducted in a nine hundred and twenty (920) bed capacity university teaching hospital in Riyadh, Saudi Arabia identified an association between the UTI rate and the number days the patient was on the catheter. The association was statistically significant. Fifteen percent (15%) acquired infection at three (3) days of catheterization, while sixty eight (68%) had the infection at eight (8) days of catheterization (the median was eight (8) days among infected patients against three (3) days in patients who were not infected; ***P***-value <0.05), eight (8) percent at ten days Length of stay, while (85.7%) at eighteen days. As the duration of stay increases the rate of infection also increases. Length of stay for each patient (median 18 days for patients who were infected versus 10 days for

patients who were not infected; ***P***-value <0.05), and one hundred (100) patients out of two hundred and fifty (250) patients with indwelling catheters had hospital-acquired catheter related UTI, ***P***=0.04).

A meta-analysis of 502 studies concluded that there was no relevance differences among the various types of catheter material with respect to development of CAUTI (Kranz *et al*., 2020).A study by Elkbuli et al., (2018), concluded that using CAUTI bundle to manage patients reduced the CAUTI infection rate by 80%. Henandez et al., (2019) stated that catheter management practices impact on CAUTI prevention efforts when performed consistently as a bundle of care across all four components outlined in the checklist.

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Site

The study was carried out at Kenyatta National Hospital (KNH) Main Critical Care Unit in Nairobi County, Kenya. KNH is the largest Teaching and Referral Hospital in East and Central Africa and the main referral hospital in Kenya with a bed capacity of 1800. The hospital was established in the year 1901 and became a corporate in 1987. It is located in Dagoretti constituency, Nairobi County which is also the capital city of Kenya, Upper Hill area, 3 kilometers from the Nairobi central business district along Hospital road off Ngong' road. It borders Mbagathi way in the south and Nairobi hospital in the west. The hospital serves as a research, teaching and main referral center in Kenya. It is also the teaching hospital for University of Nairobi and Kenya Medical Training College. It offers quality medical and surgical services, obstetrics and gynecology services and specialized intensive care services. The Main critical care Unit is situated on the first floor of the old hospital wing. The CCU is situated at the first floor of the old hospital neighboring the renal unit, burns unit, cardiology unit, and the main theatres. The CCU is the largest in the country with a 21-bed capacity. The Unit is multidisciplinary and admits patients of all ages irrespective of gender. The average monthly admission is 50 to 60 patients.

3.2 Study Design

The study design used was prospective cohort design. This design was chosen because it is the best design to study incidence rates as patients are followed up until they develop the outcome of interest (CAUTI) when exposed or not exposed. Patient level factors and institutional level factors were treated as exposures. Example; a Patients whose catheter was not secured on the thigh was said to be exposed and those whose catheter was secured on the thigh was said to be unexposed. The patients were followed up from admission until they exit the unit through discharge or death. The study period was one year (January 2019 to January 2020).

3.3 Study Population

The study population was all the patients who were admitted to the critical care unit and had indwelling urinary catheters fixed.

3.4 Sampling

Census was adopted whereby 238 participants who met the inclusion criteria were recruited consecutively over a period of one year. This is because the whole population was accessible.

3.4.1 Sample Size

Sample size was determined using Fleiss (1981) formulae:

$$N = \frac{r+1}{r} \times \left(\frac{Z_{1-\alpha/2} + Z_{1-\beta}}{p_1 - p_2} \right)^2 \times \bar{p} \times (1 - \bar{p})$$

$$= \frac{1+1}{1} \times \left(\frac{1.96 + 0.84}{0.75 - 0.25} \right)^2 \times 0.5 \times (1 - 0.5)$$

$$= 28.88$$

$$approxmately = 29\, patients$$

N= $$total = 58\, patients$$

Exposed group = 29 patients and unexposed group = 29 patients.

The sample size was taken as the minimum sample. Census was adopted whereby 238 participants who met the inclusion criteria were recruited consecutively over a period of one year.

3.4.2 Inclusion Criteria

For a patient to be included in the study they had to be free from UTI on admission to the CCU, have an indwelling urinary catheter fixed, a Glasgow Coma Scale of 15 to enable them give consent or have a next of kin consent on their behalf if the Glasgow Coma Scale (GCS) was below 15.

3.4.3 Exclusion Criteria

Patients who were admitted being unknown persons were not recruited. Patients who were discharged before the third day (before the second urine sample was collected) were removed from the study. Patients whose GCS was below 15 and had no next of kin to give consent were excluded from the study.

3.5 Data Collection Procedure

After consent was obtained, a patient was assessed via history taking and physical examination. Data was collected using data collection forms, lab records and an observational checklist for recording information on each of the subjects. Urine samples were collected following the prescribed procedure to avoid contamination and to ensure whatever organism cultured were not a contaminant. The results were entered in a form. The first urine specimen was collected within the first twelve (12) hours, second urine specimens at 72 hours, third specimen at 7 days and the fourth specimen at 14 days of a patient's admission.

3.5.1 Urine Collection Procedure

The equipment (sterile gloves, Alcohol swabs, twenty milliliter syringe, Urinalysis indicator strip, blunt cannula (G21), Catheter clamp, a sterilized specimen jar, Patient label, lab request form, plastic biohazard bag and a sterilized trolley) were prepared before the procedure. Informed consent was obtained from the patient if conscious and if not from the next of kin (this is after the procedure and rationale is explained). The investigator checked to make sure that the indwelling catheter possess a rubber port for specimen collection. The equipment was organized and patient screened for privacy. The investigator washed his hands (Moment 1), clamped the catheter below the rubber and allowed at least twenty (20) minutes for urine to collect. Then he

washed his hands again (Moment 2) and put on a gown and sterile gloves. He put together a syringe and a sterile needle, then cleans the catheter tubing with alcohol swab and allow thirty seconds for it to dry.

The investigator would insert the needle carefully into the port and withdraw twenty (20) milliliters of urine, he transferred most of the urine into sterile specimen jar (taking care not to contaminate jar), transfer the remaining urine onto the urinalysis indicator strip and put the sharps in the sharps container for disposal. He then removed the clamp to release the catheter and appropriately dispose of other equipment. He ungloved and hand washed (Moment 3), attached patient address label to specimen jar and indicate time, date and specimen. The specimen was placed in biohazard bag (sealed plastic bag) and the request form sent to the laboratory without delay. Testing was done within two hours of collection. Chemical preservatives (boric acid used for culture and sensitivity) was used in the instance the specimen was not be processed within 2 hours of collection. This type of specimens was refrigerated at 2-8°C.

3.5.2 Urine Culture And Sensitivity

The cultures were identified by standard microbiology techniques. Urine specimens were processed as per KNH Microbiology procedure for urine culture and antimicrobial susceptibility testing was done.

3.6 Inoculation and Isolation Techniques

CLED/MacConkey agar plate was labeled with laboratory identification number. A sterile calibrated loop of 1µl was dipped vertically into a well-mixed specimen. One loopful was streaked down the center of a CLED/ MacConkey agar plate. Without flaming, cross-streaks at a 90 degree angle were made perpendicular to the original streak. Inoculated plates were incubated inverted at 35°C for 18 hours.

3.7 Bacterial Identification Aand Interpretation of Cultures

The plates were read for growth and determined the colony count. If confluent/ heavy growth of pure culture was obtained report > 10^5 per ml, it was considered significant. More than two colonies were considered as contaminants and repeat sample was requested. In children below five (5) years, all colony counts were reported regardless of pyuria. In antenatal women, all colony counts were reported.

3.8 Identification and Antimicrobial Susceptibility

Isolates of potential pathogens present in significant numbers were identified according to KNH microbiology identification using Vitek equipment.

3.9 Principle of Equipment

The VITEK 2 Compact is an automated system for microbial identification. It provides highly accurate and consistent results utilizing growth-based technology. The system fits in colorimetric reagent cards (GN, GP, and YST) that are incubated and interpreted automatically. It also provides an option of automatic pipetting and dilution for antimicrobial susceptibility testing (AST cards).

Table 3.1: Recommended specimens-- Pure culture organisms and Quality Control organisms (QC)

Equipment	Supplies	Reagents
-Vitek 2 Compact	-75 × 12 mm polystyrene tubes (single use only)	-Supplemental Media
DensiCHEKplus meter	- DensiCHEKplus standard kit	-Gram's stain reagents
	-0.45% saline solution	-V2C test kits (ID/ AST cards)
-Adjustable volume dispenser	-Bar-coded 10 well cassette card holders	
	-Internal carousel for card holder	
- 145 µl pipette	- Sterile cotton swabs	
-280 µl pipette	-Pipette tips	

3.10 Environmental and Safety Controls

1. The investigator donned the appropriate protective equipment (gloves, Lab coats or aprons, eyewear or masks) when handling infectious material.
2. The investigator performed the normal precautions required for handling infectious material.
3. The investigator disposed of all waste materials in accordance with local infection prevention and control guideline.

3.11 Calibration

1. The lab technologist ensured the V2C instrument was serviced annually as per the preventative maintenance agreement.
2. Verification of the DensiCHEKplus following the calibration standards were done every month. DensiCHEKplus instrument verification results were within the established range of standards used for the verification (see Table below).

Table 3.2: Standard Acceptable Range

STANDARD McF	ACCEPTABLE RANGES
0.0	0.00 - 0.00
0.5	0.44 - 0.56
2.0	1.85 - 2.15
3.0	2.79 - 3.21

3. Used the DensiCHEKplus meter with the calibration standards

The lab technologists did not vortex DensiCHEKplus standards, inverted tube to re-suspend.

Occasionally the instrument could freeze. To reboot, the lab technologist removed and then replaced the batteries.

NOTE: the tubes were rotated during reading.

Pressing the POWER button.

1. Pressed the MENU button.
2. Pressed the green READ button to move the upper flashing triangle to "GLASS".
3. Pressed the MENU button to save the setting.
4. To set the "blank" value, inserted and turned the DensiCHEKplus Standards kit 0.0 McF standard one full rotation. If the reading did not occur, the READ button was pressed to initiate reading and again turned the 0.0 McF standard one full rotation during reading. If the reading was not zero, the "ZERO" key was pressed and rotated the 0.0 McF standard again during reading.
5. DensiCHEKplus Standards kit 0.0 McF was Removed and reinserted , turning the tube one full rotation to check that it was zeroed correctly.
6. To set 0.5 McFarland value, the 0.5 McFarland standard was cleaned and inverted 6 times to re-suspend. The 0.5 McFarland standard was Inserted and turned one full rotation. (Rotated the tube slowly; a full rotation shwasould be

completed before the reading was displayed). In the event the reading failed to occur, the READ button was pressed to initiate reading and again turn the 0.5 McFarland standard one full rotation during reading. Acceptable reading range (refer to table 1)

7. To set 2.0 and 3.0 McFarland value, steps 1-6 were repeated.
8. If calibration failed, the reader could not be used and was returned to Biomerieux for repair.

Setting zero reading for plastic tubes

1. Pressed the MENU button.
2. Pressed the READ button to move the upper flashing triangle to plastic
3. Pressed the MENU button to save the setting.
4. Inserted and turned the blank plastic saline tube one full rotation. If the reading failed to occur, the READ button was pressed to initiate reading and again rotated the blank saline tube during reading. If the reading was not zero, the "ZERO" key was pressed and rotated the blank saline tube again during reading.
5. If calibration failed, the reader could not be used and was returned to Biomerieux for repair.

Gram Staining Procedure

Gram stain was performed using an isolated colony from a pure culture. Gram stain- is used to differentiates two large groups of bacteria based on their different cell wall constituent determine the Gram reaction of organisms and assist in selection of the panel of reagent kit to be used in identification and antimicrobial susceptibility testing. Briefly, the smear of the material or culture label was made and allowed to dry in room temperature, the dried smear was fixed by passing the slide through a flame once or twice or 95% Methanol (until the alcohol evaporates). The stain was then washed with clean water. Tipped off the water, and covered the smear with grams iodine for 1 minute. The iodine was washed off with clean water. Acetone was used to decolorize rapidly (few seconds) then washed immediately with clean water.

The smear was covered with neutral red for 1 minute. The stain was then washed off with clean water and air dried.

Preparation of Inoculum

(i). For ID cards:

- Aseptically transferred 3 ml of 0.45% saline into 12x75 mm clear plastic (polystyrene) tube.
- Using a swab, selected well-isolate colonies and emulsify into the saline.
- Checked the optical density with the DensiCHEKplus. (refer table 2)
- Placed the ID card and the saline tube into the cassette

Table 3.3: Suspension Turbidities Used for Card Inoculation.

CARD	McF RANGE
GN	0.5 - 0.63
GP	0.5 - 0.63
YST	1.8 - 2.20

(ii).For AST cards:

- Created the ID suspension as described above (this was necessary even if an ID card was not needed for testing)
- Aseptically transferred 3 ml of 0.45% saline into 12x75 mm clear plastic (polystyrene) tube.
- Transferred the following volumes from the ID suspension tube:
- 145 µl for gram negative AST testing
- 280 µl for gram positive or yeast AST testing
- Placed the ID card and the saline tube into the cassette
- Discarded the ID suspension if it was not needed for testing.

NOTE 2: The age of the suspension was not allowed to exceed 30 minutes before inoculating the cards.

f. Proceeded to data entry.

Filling and loading cards into the V2c

Virtual Cassette Method

1. From the main screen of the V2c software, the lab technologist selected the View and Maintained the Cassette Icon
2. The Cassette View window would open, clicked on the Maintain Virtual Cassette Icon
3. Next, selected the Create New Virtual Cassette Icon
4. Entered the information pertaining to the Cassette:
   - Cassette ID from the drop-down list
   - Barcode- Scan the barcode of the card for the appropriate slot in the Cassette
   - Accession number
   - Organism if known
5. If two cards belonged to the same accession and isolate number (for example, ID and AST card from the same colony), an isolate pair was created by highlighting both slots of the cassette and clicking on the Define Isolate Pair Icon. The lab technologist was allowed to enter specimen information for all the cards; V2C software treated this information as a single result.
6. The lab technologist loaded the cassette into V2C and closed the filler door. At the instrument user interface, ensured the Filler is idle and instrument Status was OK, and then pressed the Start Fill button. The V2C fill cycle took about 70 seconds.
7. After filling was complete, the lab technologist visually checked the cards to ensure they were filled properly, then transferred the cassette to the load station of the instrument. (The instrument displayed **Transfer)**
8. After loading was complete, the lab technologist removed the cassette from the load station and discarded the suspension tube and straws. (The instrument displayed **Remove**)

Load and go method

1. The lab-technologist printed a Cassette Worksheet to write down the barcode number and accession number for each card in the cassette.
2. The lab technologist placed the cassette into the Filler station of the instrument and initiated the fill cycle.
3. When the Fill cycle was complete, the lab technologist transfered the cassette to the load station of the V2C. (The instrument displayed **Transfer)**
4. After loading was complete, the lab technologist removed the cassette from the load station and discarded the suspension tube and straws. (The instrument displayed **Remove**)
5. After the cassette was processed by the instrument, the lab technologist accessed the cassette information at the workstation.
6. Clicked the Manage Cassette View Icon from the main screen; Load and Go cassettes would present as red cassettes.
7. Using the information from the cassette worksheet, the lab technologist entered the accession information for the cards in the cassette.

Entering patient information

To enter Patient information from the main screen of the software:

1. The lab technologist Selected the Enter Patient View Icon; Clicked on the Add New Patient icon to create a new patient in the V2C software.
2. The lab technologist Entered:
    - Patient ID
    - Patient name
    - Lab ID (also known as “Accession Number” in other parts of the software)
    - Type (the specimen being tested)

Managing patient results

Results were concurrently printed and the data sent to the Results View folder on the left side of the screen also called the Navigation Tree where the information was

archived. A red cassette in the Navigation Tree wss indicative of an error. If an error occurred during processing, the lab technologist referred to the Software User.

Viewed results printout and file as follows:

1. Clicked on the Enter Isolate View icon from the main screen.
2. The isolates in the system would appear in the navigation tree and would be preceded by an icon:

 Qualified results. Necessary information missing

 Preliminary results, Results not finished

 Results needs to be reviewed

 Results needs to be approved

 Final results will be sent to LIS

1. Isolates that were qualified but were missing essential information such as Patient information, Organism name or Offline test would remain in the active workspace until resolved by the User.
2. Isolates requiring Review or Approval would vary depending on the configuration settings and bioART rules.

Patient reports

There were four types of generated reports:

(i).Lab Report

(ii).Chart report

(iii).Card detail report

AES detail report (for isolates with AST cards)

NB: The lab Report contained additional information such as a card Lot number and expiration date.

(i).To access and print patient reports, the lab technologist selected the isolate from the navigation tree.

(ii).Clicked on the print icon in the tool bar. (a window would open)

(iii).Chose the type of report the he wished to preview and print.

Quality control procedure

Quality control materials

1. *E. coli* -ATCC25922
2. **Procedure:** Followed as test procedure.
3. **Managing QC results:** Viewed QC results by clicking on the QC icon on the main screen.
4. **NB:** QC report included the expected and actual test results; deviations were highlighted in yellow for both ID and AST cards.
5. **Quality control reports**
6. To create a cumulative report of the QC isolates:

    I. The lab technologist entered the QC program of the software by clicking on the QC icon on the main screen.

    II. At the "Filter By" field selected the custom…..option (a cumulative QC search criteria window would open)

    III. Entered the criteria of choice for the report for example date range.

NB: The filter criteria for the search performed appeared at the top of the workspace area. When printed QC cumulative report consolidated QC results and sorted them by testing date and lot number into a single cumulative report.

Quality control results

1. Reviewed QC results like patient results and investigated any unacceptable results.
2. Investigated and initiated corrective and preventive action if Quality Control yielded unexpected results.
3. Documented all corrective and preventive action in the corrective action form, review and close.
4. Referred unexplained discrepancies in control results to the Quality Manager or Designee immediately. If quality control results did not meet specifications, patient results were invalid. The lab technologist Identified and corrected the root cause, and repeated the patient samples.

Interferences

Improper sub culturing and filling of VITEK cards could result in inconsistent or erroneous biopatterns. The interferences were avoided.

3.12 Research Assistants

The investigator was assisted by two research assistants. A Kenya registered critical care nurse and a Kenya registered Community Health Nurse working in the main CCU. At the time of the study the research assistant had a working experience of eight years in the unit. He was the clinical instructor in the unit. He was taken through a training on the data collection tools and urine collection procedure. He was conversant with the standard operative procedures in the unit. The other research assistant was lab technologist working in the microbiology lab. He is a holder of Masters of Science degree in mycology and was the in-charge of the microbiology labs. He was competent with standard operation procedures in the lab. He ensured the standard procedure for urinalysis, urine culture and sensitivity was followed.

3.13 Study Instruments / Tools

A questionnaire was used to collect patient information that assisted in identifying patients' characteristics. The information was collecting using history taking and

physical examination. Three observation checklists were used to observe the aseptic technique during insertion and removal of the indwelling catheter on each gender (male & female) and emptying of the urinary bag. The checklist were developed using the CDC CAUTI bundle. Asepsis was said to have been achieved if the guidelines for the aseptic technique were adhered up to a score of 80%. A score of below 80% was entered as non-adherence hence asepsis not observed. According to Haynes (1976), models of adherence to therapeutic regiments guidelines are dichotomized with a cutoff of 80%. Asepsis not observed was termed as exposure and where asepsis was observed was termed as unexposed.

3.14 Validity and Reliability

3.14.1 Pre Testing of the Study Tools

The data collection tools were pretested at the Emergency Ward at KNH. The ward has similar environment like the CCU and it was also used as an ICU. In most of the cases the patients were admitted in this unit awaiting availability of a bed in the main CCU. After the pretesting of the tools it was realized that the tools were able to collect the required information.

3.14.2 Expert Review

The study tools were reviewed by three experts to determine their validity. The experts were; one consultant intensivist/ anesthesiologist, one critical care nurse specialist and an infection control nurse specialist. The tools in appendix II (checklist for steps in male catheterization), appendix III (checklist for steps in female catheterization), and appendix IV (checklist for emptying urinary bag procedure) were developed using the CDC CAUTI bundle. The bundle is recommended in care of catheterized patients to prevent development of CAUTI among catheterized patients.

3.15 Study Variables

3.15.1 Independent Variables

Independent variables included, patient level factors and facility level factors. The patient level factors assessed were, patient's gender (male -unexposed or female - exposed), patient's age in years (50yrs and above-exposed, below 50yrs- unexposed), Patient's diagnosis and presence or absence of comorbidities (presence of comorbidities-exposed; absence of comorbidities- unexposed). The facility level factors assessed were observance of aseptic technique during insertion of the indwelling catheter for both male and female patients (observance of asepsis – unexposed, Non- observance of asepsis- exposed), securing of the urinary catheter on the patient's thigh (unsecured- exposed, secured- unexposed), type of the urinary catheter and observance of the aseptic technique during emptying of the urinary bag (observance of asepsis – unexposed, Non- observance of asepsis- exposed).

3.15.2 Dependent Variables

The dependent variable was the development of Catheter associated urinary tract infections. Time to development of CAUTI was a dependent variable for survival analysis. Indicators for the infections were the type of organisms cultured and the seasonal trends of cultured micro-organisms.

3.16 Data Processing and Analysis

After data collection, data cleaning and coding was done and then prepared for analysis. Statistical analysis was done using Statistical Package for Social Sciences (SPSS) version 23.0. The incidence density of intensive care unit- catheter acquired UTI was calculated as the number of patients with new UTI episodes per total number of days the patients were catheterized and admitted in the ICU during the study period. Cumulative incidence was calculated as the new UTI episodes per the total number of patients who were recruited in the study and the patient that had undergone not less than two sample tests. Normally distributed variables were reported using means and standard deviations, and variables which are not normally

distributed reported using medians. To assess the differences in proportions between categorical data, the researcher utilized the $\chi 2$. Risk ratios were calculated to identify the risk factors associated with the infection. Logistic regression model was developed to identify relationship between patient characteristics, comorbidities and the microbial growth obtained. Survival statistics were used to analyze the time it took to get urinary tract infection among the catheterized patients in the ICU. Cox regression model was used to determine relationship/ association between independent variables and the time to infection. Incompletely observed events were censored. Kaplan-Meier estimator was used for estimating survival functions.

3.17 Dissemination of Results

The study results were disseminated to ITROMID KEMRI and Kenyatta National Hospital research and programs department and the Critical Care Unit. Two publications were done East African Medical journal and African Journal of Health Sciences.

3.18 Ethical Considerations

The proposal was submitted to UoN/KNH Ethical Review Committee where approval was granted. Approval to collect data was sought from the management of Kenyatta National Hospital specialized Unit department and the research department. The Management gave the approval. Patient's consent was sought before recruitment to the study and where not possible due to patient's level unconsciousness, the next of kin gave the consent. For patients aged below 18 years parents/guardian were requested to give consent. Accent was sought from those aged below 18years. Confidentiality of responses was emphasized. The respondents were informed about the risks they were exposed to and the expected benefits of the study. The study findings were made available to the Unit.

CHAPTER FOUR

RESULTS

4.1 Response Rate

The response rate was 100% since all the patients who met the inclusion criteria were recruited in the study.

4.2 Baseline Information

A total of 238 patients were recruited into the study. Thirty four patients (34) had UTI as indicated by the first sample. A total of 174 patients had two or more samples collected and analyzed. Men were 162, making a proportion 68%. Majority (157; 66%) were on Foley's catheter. Those on silicon catheter were 26 (10.9%, while those on silicon coated catheters were 55 (23.1%). Of the 238 patients, 180 (75.6%) were aged below 50 years while those aged 50 years and above were 58 (24.4%). Central Nervous System conditions contributed a total of 144 (60.5%) patients. Other systemic conditions were; musculoskeletal conditions 26 (10.9%), gastrointestinal illnesses 22 (9.2%), cardiovascular conditions; 11 (4.6%), Multisystem; 10 (4.2%), gynecological conditions; 10 (4.2%), Respiratory conditions; 7 (2.9%), endocrine; 4 (1.7%), Ear Nose and Throat 2 (0.8%), and genital urinary tract 2 (0.8%). Approximately 25% (60) had comorbid conditions. Patients with comorbidities were those with underlying condition other than the diagnosis on admission. (Table 4.1 below) displays the baseline data.

Table 4.1: Baseline Information

		Frequency	Percent	95% Confidence Interval	
				Lower	Upper
Patient's Gender	Female	76	31.9	26.1	37.4
	Male	162	68.1	62.6	73.9
Type of catheter	Silicon	26	10.9	7.1	15.1
	Silicon coated	55	23.1	17.7	28.2
	Foley's Catheter	157	66	60.1	71.8
Age group	below 50 years	180	75.6	69.7	81.1
	50 years & above	58	24.4	18.9	30.3
Systemic diagnosis	Cardiovascular	11	4.6	2.1	7.6
	Respiratory	7	2.9	0.8	5
	Neural	144	60.5	54.6	66.4
	Musculoskeletal	26	10.9	6.7	15.1
	Gastro-intestinal	22	9.2	5.9	13
	Genital urinary	2	0.8	0	2.1
	Multisystem	10	4.2	1.7	6.7
	Endocrine	4	1.7	0.4	3.4
	ENT	2	0.8	0	2.1
	Gynae/obstetric	10	4.2	1.7	7.1
Comorbidity	Present	60	25.2	19.7	30.7
	Absent	178	74.8	69.3	80.3

4.2 Burden of Hospital Acquired Catheter Associated Urinary Tract Infection

4.2.1 Incidence of Intensive Care Unit- Acquired Urinary Tract Infection

A total of fifty (50) patients who did not have UTI on admission developed CAUTI in 1576 person-days @risk hence the incidence density of 32 per 1000 catheter-days (95% CI 24/1000 to 42/1000 catheter days). The 50 patients were free from CAUTI on admission.

The cumulative incidence was calculated using the 50 new cases over the 174 patients who had two or more sample collected and analyzed hence 28.7% (287 per 1000 patients (95%CI 21.1% to 36.1%).

4.2.2 Prevalence of Intensive Care Unit- Acquired Urinary Tract Infection

Among the two hundred and thirty eight patients recruited in the study, eighty seven (87) patients had Catheter associated urinary tract infection. The prevalence of CAUTI was 36.6% (95% CI 30.4% to 43.0%).

4.2.3 Relationship Between CAUTI and Mortality

There was a statistically significant association between catheter acquired infection and mortality. A patient who died was 1.8 times more likely to have had CAUTI as compared to a patient who was discharged (Chi-square value 4.693, d.f-1, p-value 0.03). Table 4.2 illustrates the relationship.

Table 4.2: Relationship between CAUTI and mortality

Patient's outcome	CAUTI		95% Confidence interval			Chi-square Value	df	p-value
	Absent	Present	OR	Lower	Upper			
Death	58	46						
			1.799	1.235	2.119	4.693	1	0.03
Discharged	93	41						
Total	151	87						

4.2.4 Relationship Between CAUTI and The Length Of Stay

Patients who acquired CAUTI were likely to have a longer period of hospital stay. Model equation= Y= 7.609+8.057X. CAUTI increased the length of stay by eight days (<0.001). The average cost of CCU admission per day in Kenyatta National Hospital is estimated at Kenya shillings 15,000. A patient developing CAUTI will pay an extra cost of Ksh.120, 000.

Table 4.3: Simple linear regression for Relationship between CAUTI and the length of stay

Coefficients Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	7.609	1.235		6.159	<0.001
	Prevailing infection	8.057	2.043	0.249	3.943	<0.001

a Dependent Variable: number of days in ICU

4.3 Causative Organisms for CAUTI

4.3.1 Identified Micro-Organisms

The most common micro-organisms (60%) causing catheter associated urinary tract infections in ICU are gram-negative. *Escherichia coli* was identified in 17 samples (20%; (95% CI 12% -29%), *Klebsiella species* were also common as they were isolated in 9 urine samples. *Klebsiella pneumoniae* was cultured in 7 urine samples (8%; 95%CI 3%-16%) and *Klebsiella oxytoca* 2 samples (2%; 95%CI 0.3%-8%). *Acinobacter baumaunnii* was isolated in 7 samples (8%; 95%CI 3%-16%), *Pseudomonas aeruginosa* was identified in 5 samples (6%; 95%CI 2% -13%), *Serratia Species* also contributed to CAUTI in the ICU by infecting 8 patients with *Serratia fonticola* and *Serratia Marcescens* being cultured 3 times each (each at 3%; 95% CI 1% -10%) and *Serratia Liquefaciens* twice (2%; 95%CI 0% -8%). Other gram negative organisms cultured were *Pantoea agglomerans* (3%; 95% CI 1% -10%), *Raoultella planticola* (2%; 95% CI 0%-8%), *Citrobacter freundii* (1%; 95% CI 0% -6%) and *Morganella morganii* (1%; 0% -6%).

Gram positive organisms were isolated at a proportion of 33%. Among the Gram-positive organisms isolated, *Enterococcus species* were the most common micro-organisms cultured from the urine samples collected from the ICU patients having indwelling catheters. In 27 cultures, *Enterococcus faecalis* was the most prevalent as it infected 22 patients (25%; 95% CI 17%-36%) and *Enterococcus gallinarum* 5

patients (6%; 95%CI 2%-13%). *Staphylococcus haemolyticus* was cultured twice (2%; 95%CI 0% -8%).

Candida albicans was isolated in 5 cases (6%; 95%CI 2% -13%).

Table 4.4: Proportions of Identified Micro-Organisms

	POSITIVES (k)	**SAMPLE SIZE (n)**	**Prop**	**95% CONFIDENCE INTERVAL**	
				Lower Limit	Upper Limit
Enterococcus faecalis	22	87	0.25	0.17	0.36
Escherichia coli	17	87	0.20	0.12	0.29
Klebsiella pneumoniae	7	87	0.08	0.03	0.16
Enterococcus gallinarum	5	87	0.06	0.02	0.13
Acinetobacter baumaunnii	7	87	0.08	0.03	0.16
Candida albicans	5	87	0.06	0.02	0.13
Serratia fonticola	3	87	0.03	0.01	0.10
Pantoea agglomerans	3	87	0.03	0.01	0.10
Citrobacter freundii	1	87	0.01	0.00	0.06
Pseudomonas aeruginosa	5	87	0.06	0.02	0.13
Staphylococcus haemolyticus	2	87	0.02	0.00	0.08
Raoultella planticola	2	87	0.02	0.00	0.08
Morganella morganii	1	87	0.01	0.00	0.06
Klebsiella oxytoca	2	87	0.02	0.00	0.08
Serratia Liquefaciens	2	87	0.02	0.00	0.08
Serratia Marcescens	3	87	0.03	0.00	0.10

4.3.2 Anti-Microbial Sensitivity

Gram-positive organisms; *Enterococcus species*: *Enterococcus faecalis* were 100% sensitive to Vancomycin, Linezolid, and Teicoplanin. They were also sensitive to Nitrofurantoin and Ampicillin at 73%. The micro-organisms were 100% resistant to gentamycin, vancomycin 100%, streptomycin, levofloxacin and Benzyl penicillin. They were 73% resistant to Tigecycline. *Enterococcus gallinarum* were 100% sensitive to Vancomycin, Linezolid, Teicoplanin. They were also 80% sensitive to Nitrofurantoin, and Ampicillin. The organisms were resistant to Tigecycline, 80%, gentamycin 100%, vancomycin 100%, streptomycin 100%, levofloxacin 100% and Benzyl penicillin 100%. *Staphylococcus haemolyticus* were also 100% sensitive to Vancomycin, Linezolid, Tingecycline, Teicoplanin and Tetracycline.

Gram negative micro-organisms; *Escherichia coli* was sensitive to Amikacin (76.5%), Meropenem (70.6%) and Nitrofurantoin (53%). They were resistant to gentamycin (76.5%), Amoxicillin/Clavulanic acid (82.4%), Piperacillin/Tazobactam (82.4%), Ciprofloxacin (82.4%), and Ampicillin/ Sulbactam (94.1%). The organisms were 100% resistant to Ceftriaxone, Cefepime, Cefuroxime, Cefazolin and Ceftazidime. *Serratia species: Serratia fonticola* were sensitive to nitrofurantoin at 66.7%, Amoxicillin/Clavulanic acid (33.3%), Cefotaxime (33.3%), Ceftazidime (33.3%), Ceftriaxone (33.3%), Trimethoprim/Sulfamethoxazole (33.3%), Amikacin (33.3%), and Meropenem (33.3%). *Serratia Liquefaciens* were sensitive to Nitrofurantoin (100%), Amoxicillin/Clavulanic Acid (100%), Ampicillin/Sulbactam (100%), Peperacillin/Tazobactam (100%), and Cefazolin (100%). *Serratia Marcescens* were sensitive to Amikacin (33.3%). *Pantoea agglomerans* was 66.7% sensitive to Amikacin (66.7%), Tigecycline (33.3%) and levofloxacin (33.3%). *Klebsiella species* were sensitive to Amikacin and Meropenem. *Klebsiella oxytoca:* was sensitive to Amikacin (100%), Meropenem (50%), and Nitrofurantoin (50%). *Klebsiella pneumoniae*: Amikacin (71.4%), Meropenem (42.9%), Gentamycin (28.6%), Cefoxitin (28.6%), Nitrofurantoin (28.6%), and Ciprofloxacin (28.6%). *Acinetobacter baumaunnii* was 100% resistant to Amikacin Meropenem, Amoxicillin/Clavulanic acid, Piperacillin/Tazobactam, Ampicillin/ Sulbactam and ampicillin. They were only sensitive to Ciprofloxacin (42.9%), and Gentamycin (42.9%). *Raoultella planticola* were resistant 100% resistant to Amikacin Meropenem, Amoxicillin/Clavulanic acid, Piperacillin/Tazobactam, Ampicillin/ Sulbactam and ampicillin. They were sensitive to cefuroxime (50%). *Pseudomonas aeruginosa* was sensitive to amikacin, Meropenem and nitrofurantoin at 60%. *Citrobacter freundii* was sensitive to Trimethoprim/Sulfamethoxazole only.

Candida albicans were sensitive to Fluconazole and Voriconazole (60%). They were also sensitive to Amphotericin B (40%), Fencitocine (40%), Caspofugine (40%), and Micafugin (40%).

Table 4.5: Anti-microbial sensitivity (Gram-positive Micro-organisms)

Micro-organism	Enterococcus faecalis		Enterococcus gallinarum		Staphylococcus haemolyticus	
Sensitivity	Sensitive	Resistant	Sensitive	Resistant	Sensitive	Resistant
Vancomycin	100%	0	100%	0	100%	0
Linezolid	100%	0	100%	0	100%	0
Teicoplanin	100%	0	100%	0	100%	0
Nitrofurantoin	73%	27%	80%	20%	0	100%
Ampicillin	73%	27%	80%	20%	0	100%
Tigecycline	27%	73%	20%	80%	100%	0
Gentamycin	0	100%	0	100%	0	100%
Clindamycin	0	100%	0	0	0	100%
Streptomycin	0	100%	0	100%	0	100%
Levofloxacin	0	100%	0	100%	0	100%
Benzyl penicillin	0	100%	0	100%	0	100%
Tetracycline	0	100%	0	100%	100%	0

Table 4.6: Anti-microbial sensitivity (Gram-negative Micro-organisms)

Micro-organism	Escherichia coli		Klebsiella oxytoca		Klebsiella pneumoniae		Raoultella planticola	
Sensitivity	Resista	Sensitiv	Resist	Sensi-	Resista	Sensiti	Resistan	S
Amikacin	23.5%	76.5%	0	100	28.6%	71.4%	100%	0
Meropenem	29.4%	70.6%	50%	50%	57.1%	42.9%	100%	0
Nitrofurantoin	47%	53%	50%	50%	71.4%	28.6%	100%	0
Gentamycin	76.5%	23.5%	100%	0	71.4%	28.6%	100%	0
Amoxicillin/	82.4%	17.6%	100%	0	100%	0	100%	0
Piperacillin/	82.4%	17.6%	100%	0	100%	0	100%	0
Tazobactam Ciprofloxacin	82.4%	17.6%	100%	0	71.4%	28.6%	100%	0
Ampicillin/ Sulbactam	94.1%	5.9%	100%	0	100%	0	100%	0
Trimethoprim/	100%	0	100%	0	100%	0	100%	0
Sulfamethoxazol-								
ampicillin	100%	0	100%	0	100%	0	100%	0
Cefoxitin	100%	0	100%	0	100%	0	100%	0
Cefazolin	100%	0	100%	0	100%	0	100%	0
cefuroxime	100%	0	100%	0	100%	0	50%	50
Ceftazidime	100%	0	100%	0	100%	0	100%	0

Table 4.7: Anti-microbial sensitivity (gram-negative micro-organism)

Micro-Sensitivity	*Pseudomonas*		*Serratia Marcescens*		*Serratia fonticola*		*Citrobacter freundii*	
	Resistant	Sensitiv	Resistan	Sensitiv	Resistant	Sensitiv	Resistan	Sensitiv
Amikacin	40%	60%	66.7%	33.3%	66.7%	33.3%	100%	0
Meropenem	40%	60%	100%	0	66.7%	33.3%	100%	0
Nitrofurantoi	40%	60%	100%	0	33.3%	66.7%	100%	0
Gentamycin	100%	0	100%	0	100%	0	100%	0
Amoxicillin/	100%	0	100%	0	66.7%	33.3%	100%	0
Piperacillin/	100%	0	100%	0	100%	0	100%	0
Ciprofloxacin	100%	0	100%	0	100%	0	100%	0
Ampicillin/	100%	0	100%	0	100%	0	100%	0
Trimethopri m/ ampicillin	100%	0	100%	0	94.1%	5.9%	0	100%
Cefoxitin	80%	20%	100%	0	100%	0	100%	0
Cefepine	80%	20%	100%	0	100%	0	100%	0
cefuroxime	100%	0	100%	0	66.7%	33.3%	100%	0
Ceftazidime	80%	20%	100%	0	66.7%	33.3%	100%	0

Table 4.8: Anti-microbial sensitivity (gram-negative micro-organism)

Pantoea		*Serratia*		*Morganella*		*Acinetobacter*		Micro-organism
Resista	Sensiti	Resistant	Sensiti	Resista	Sensiti	Resista	Sensiti	Sensitivity
33.3%	66.7%	100%	0	0	100%	100%	0	Amikacin
100%	0	100%	0	0	100%	100%	0	Meropenem
100%	0	0	100%	100%	0	100%	0	Nitrofurantoin
100%	0	100%	0	100%	0	25%	75%	Gentamycin
100%	0	0	100%	100%	0	100%	0	Amoxicillin/
100%	0	0	100%	100%	0	100%	0	Piperacillin/
66.7%	33.3%	100%	0	100%	0	100%	0	Tigecycline
100%	0	100%	0	100%	0	25%	75%	Ciprofloxacin
100%	0	0	100%	100%	0	100%	0	Ampicillin/
100%	0	100%	0	100%	0	100%	0	Trimethoprim/
100%	0	0	100%	100%	0	100%	0	Cefazolin
66.7%	33.3%	100%	0	100%	0	100%	0	Levofloxacin
100%	0	100%	0	100%	0	100%	0	Cefepine
100%	0	100%	0	100%	0	100%	0	cefuroxime
100%	0	100%	0	100%	0	100%	0	Ceftazidime

Table 4.9: Anti-microbial sensitivity (fungal)

Micro-organism	Sensitivity	Fluconazole	Voriconazole	Caspofungin	Micafungin	Amphotericin B	Flucytocin	Fencitocine
Candida albicans	Sensitive	60%	60%	40%	40%	40%	0	40%
	Resistant	40%	40%	60%	60%	60%	100%	60%

4.4 Risk Factors Associated with CAUTI

4.4.1 Patient Level Factors

4.4.1.1 Gender

The risk ratio of female to male was 1.098 (95% CI 0.654 to 1.843) p-value 0.724 hence not statistically significant. Therefore gender was not associated to the development of CAUTI. The risk of the male patients getting CAUTI was not different from those of the female patients.

4.4.1.2 Age

Age was divided into two groups; those aged below 50 years and those aged 50 years and above. The Risk Ratio for the age was 1.207 (95% CI 0.702, 2.075) p-value 0.5. Hence not statistically significant. Therefore difference in age was not associated

with to development of CAUTI. The risk of getting CAUTI when a patient was below 50 years was not different from those aged 50 years and above.

4.4.1.3 Comorbidity

Patients with comorbid conditions were at a higher risk of developing CAUTI. The Risk Ratio was 1.669 (95% CI 1.014, 2.745) p-value 0.04. Table 4.10 shows the patient level factors associated with CAUTI

Table 4.10: Patient Level Factors and Risk Ratio

Risk Factor		**Developed UTI (Positive)**	**UTI Absent (Negative)**	**Total Number of patients**	**RR**	**95% Confidence Interval**	
						Lower Limit	Upper Limit
Gender	Female	17	59	76	1.098	0.654	1.843
	Male	33	129	162			
	Total	50	188	238			
Age	Above 50 years	14	44	58	1.207	0.702	2.075
	Below 50 years	36	144	180			
	Total	50	188	238			
Comorbidity	Present	18	42	60	**1.669**	**1.014**	**2.745**
	Absent	32	146	178			
	Total	50	188	238			

4.4.2 Facility Level Factors

4.4.2.1 Adherence to Aseptic Technique While Emptying the Urine Bag

Urine bag emptying procedure was monitored continuously on each patient. The CAUTI buddle protocol by CDC was used to create an observational checklist to observe the urine bag emptying procedure. A cut off point of 80% on the score on following the guidelines as stipulated on the observational checklist was used to

determine whether asepsis was observed or not. Those who scored 80% and above were said to have observed asepsis while those who scored below 80% were said to have not observed aseptic technique. The aseptic technique was observed among 141 patients (59.2%) and not observed in 97 (40.8%) cases. The Risk Ratio for cases where asepsis was not observed during urine bag emptying to those where asepsis was observed was 3.392 (95% CI 1.963, 5.86). Meaning the risk of the patients where asepsis was not observed during urine bag emptying was 3.4 times that of the patients where asepsis was observed. Table 4.11 illustrates the RR.

4.4.2.2 Securing the Catheter on the Patient's Thigh

CDC recommends that the urinary catheter should secured on the patients thigh. One hundred and thirty one (131, 55%) patients had their catheters secured on their thighs throughout the study period. One hundred and seven (107, 45%) patients had their catheters not secured on their thighs. The risk ratio for not securing the catheter to securing the catheter was 1.836 (95% CI 1.108, 3.043). Meaning that the risk for patients whose catheters were not secured were 1.84 times that of those whose catheters were secured. Table 4.11 below illustrates the risk ratio.

4.4.2.3 Adherence to Aseptic Technique During insertion of the Urinary catheter

Aseptic technique during insertion of the catheter was observed in 221 cases (93%), not observed in 2 cases (0.8%) and 15 patients came with the catheters fixed hence insertion not observed. This shows that observance of the aseptic technique during insertion of the catheter on both genders was well embraced in the unit.

Table 4.11: Facility Level Factors

Risk Factor		Developed UTI (Positive)	UTI Absent (Negative)	Total	RR	95% Confidence Interval	
						Lower Limit	Upper Limit
Asepsis during Urine Bag Emptying	Not Observed	35	62	97			
	Observed	15	126	141	**3.392**	**1.963**	**5.86**
	Total	50	188	238			
Securing the Urinary Catheter	Not secured	30	77	107			
	Secured	20	111	131			
	Total	50	188	238	**1.836**	**1.108**	**3.043**

Table 4.12: Adherence to Aseptic Technique during insertion of the Urinary catheter

	Frequency	Percent
NO	2	0.8
YES	221	92.9
Catheter in-situ	15	6.3
Total	238	100

4.5 The Temporal Trends of Microbial Growth among Catheterized Patients Admitted at KNH CCU

According to the data collected from the Kenya metrological department, March was the warmest month with a minimum temperatures of 15.4 ^{0}C and a Maximum temperature of 28.3^{0}C. The mean temperature was 21.9 ^{0}C. This was the month with the highest prevalence of CAUTI. A total of seventeen (17) infections were recorded. The most prevalent micro-organisms cultured during the month of March were the gram-negative (70.6%: 95% CI 44% to 89.7%). With Escherichia Coli forming the majority (29.4%; 95% CI 10.3% to 56%). Other gram negative organisms cultured in the month of March were *Acinobacter Baumanni, Psedomonas. Aeruginosa, Proteous Agglomerans, Klebsiella pneumoniae,and Serratia fonticolla*. The gram-

positive Micro-organisms cultured in March made a proportion of 23.5% (95% CI 6.9% to 49.9%). The *Enterococcus faecalis* (23.5%) was the gram positive organism cultured. The month of July was the coldest month of the year with temperature ranging from 12.9 ^{0}C to 22.8 ^{0}C and a mean temperature of 17.9 ^{0}C. During July the prevalence of Gram negative micro-organisms was 62.5%. *Escherichia Coli* made a proportion 6.25%. This indicate a reduction in the number of *Escherichia Coli* in the coldest month of the year. The prevalence of gram-positive micro-organisms was 37.5% (95% CI 15.2% to 64.6%) during the month of July. The gram-positive micro-organisms cultured during the month of July were *Enterococcus faecalis* (25%), *Enterococcus gallinarum (6.25%) and Staphylococcus Hemolyticus (6.25%)*

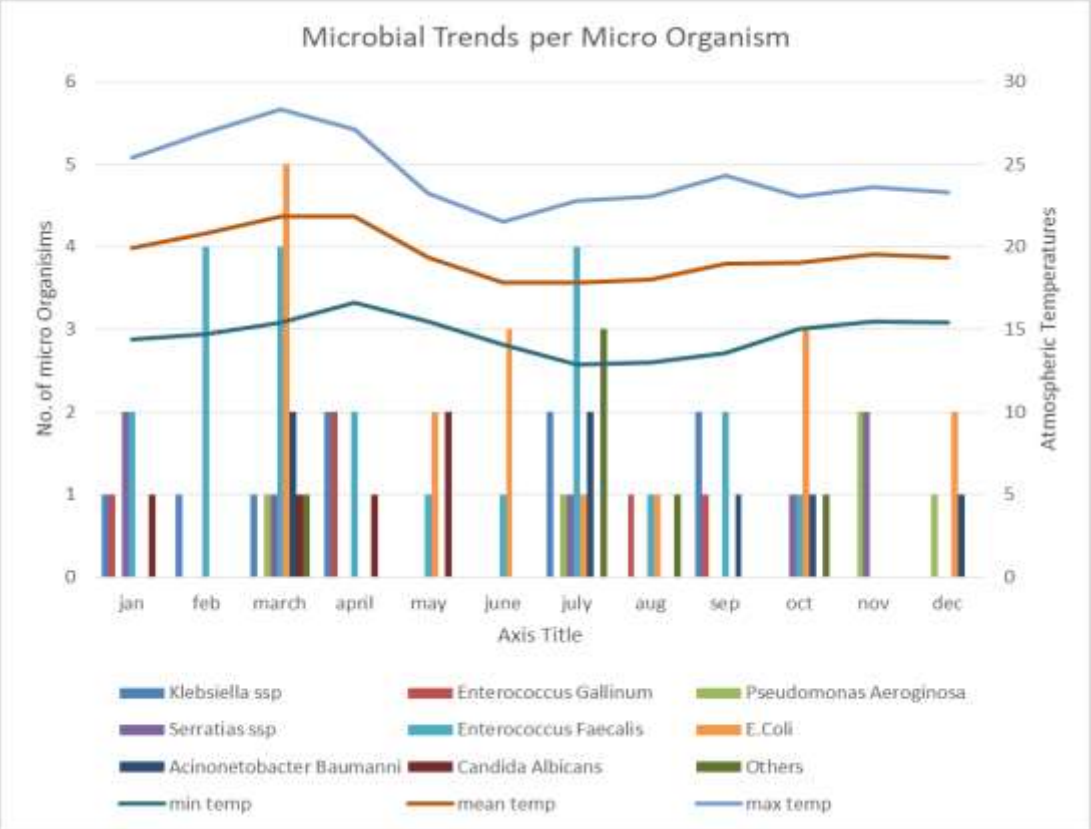

Figure 4.1: Microbial growth per micro-organism per month

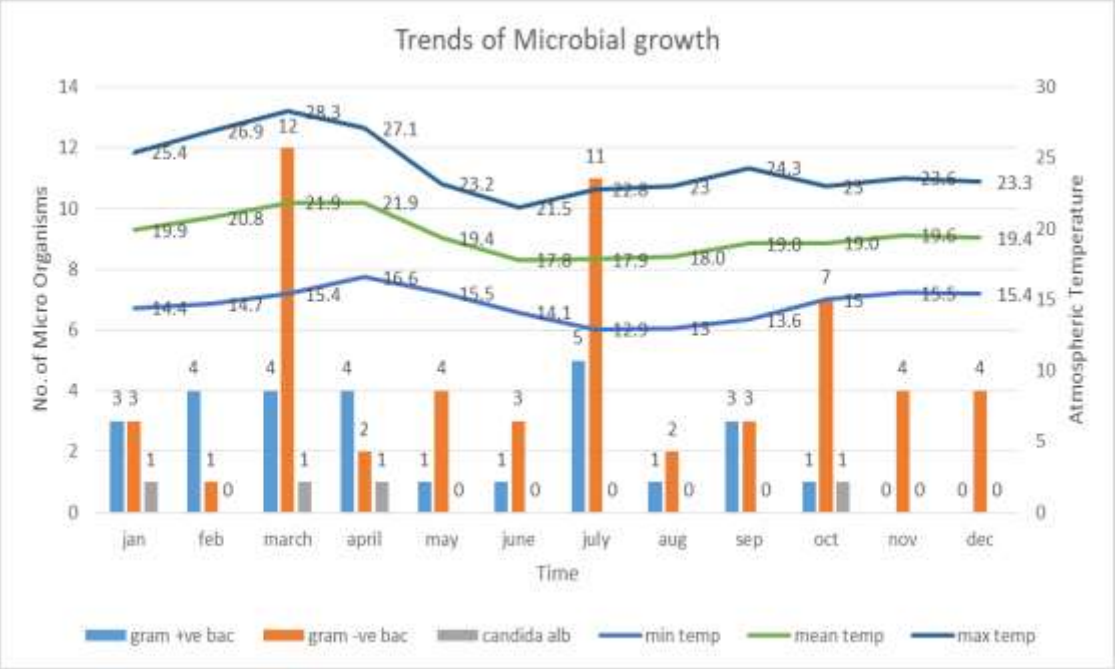

Figure 4.2: Trends of Microbial growth

4.6 Time To Development of Health Outcomes among Catheterized Patients Admitted in the Kenyatta National Hospital Critical Care Unit

4.6.1 Type of a Catheter

There were three types of urinary catheter used in the unit. Twenty six patients were put on silicon catheters, (10.9%; 95% CI 7.1% to 15.1%). Fifty five patients (23.1%; 95%CI 17.7% to 28.2%) had silicon coated catheters in-situ. The majority of patients (157) (66% 95% CI 60.1% to 71.8%) were on Foley's Catheter. The mean time for a patient on a silicon catheter to acquire CAUTI was 11.5 days (95% CI 9.6 to 13.4 days). The mean time for a patient on a silicon coated catheter was 11.0 days (95% CI 9.4 to 12.65 days). The mean time for a patient on a Foley's catheter was 12.1 days (95% CI 11.0 to 13.2 days). By the third day approximately 8%, 10 % and 15% of the patients on silicon, silicon coated and Foley's catheters respectively had acquired CAUTI. By the seventh day a cumulative percent of 30%, 32% and 38% of the patients on silicon, silicon coated and Foley's catheters respectively had acquired CAUTI. By the fourteenth day, approximately 50% of the patients on Foleys'

catheter had acquired the infection while those on silicon catheter remained at 30%. For Silicon coated catheter, 60% had been infected with CAUTI by fourteenth day.

There was no statistically significant difference in time to infection between the three types of catheter as the log-rank test showed a p-value of 0.669 thus failing to reject the null hypotheses that the time to infection for the three types of catheters is equal.

Table 4.13: Types of Urinary Catheters

Type of catheter	**Frequency**	**Percent**	**Valid Percent**	**Cumulative Percent**	**95% Confidence Interval**	
					Lower	**Upper**
Silicon	26	10.9	10.9	10.9	7.1	15.1
Silicon coated	55	23.1	23.1	34	17.7	28.2
Foleys' Catheter	157	66	66	100	60.1	71.8
Total	**238**	**100**	**100**		**100**	**100**

Table 4.14: Mean and Median Survival Times for the Type of Catheters

Means and Medians for Survival Time								
Type of catheter	**Means**				**Median**			
	Estimate	Std. Error	95% Confidence Interval		Estimate	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound			Lower Bound	Upper Bound
Silicon	11.479	0.957	9.604	13.355	.	.	.	.
Silicon coated	11.049	0.817	9.449	12.65	14	4.167	5.833	22.167
Foleys' Catheter	12.113	0.554	11.027	13.199	14	.	.	.
Overall	12.173	0.445	11.301	13.045	.	.	.	.

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

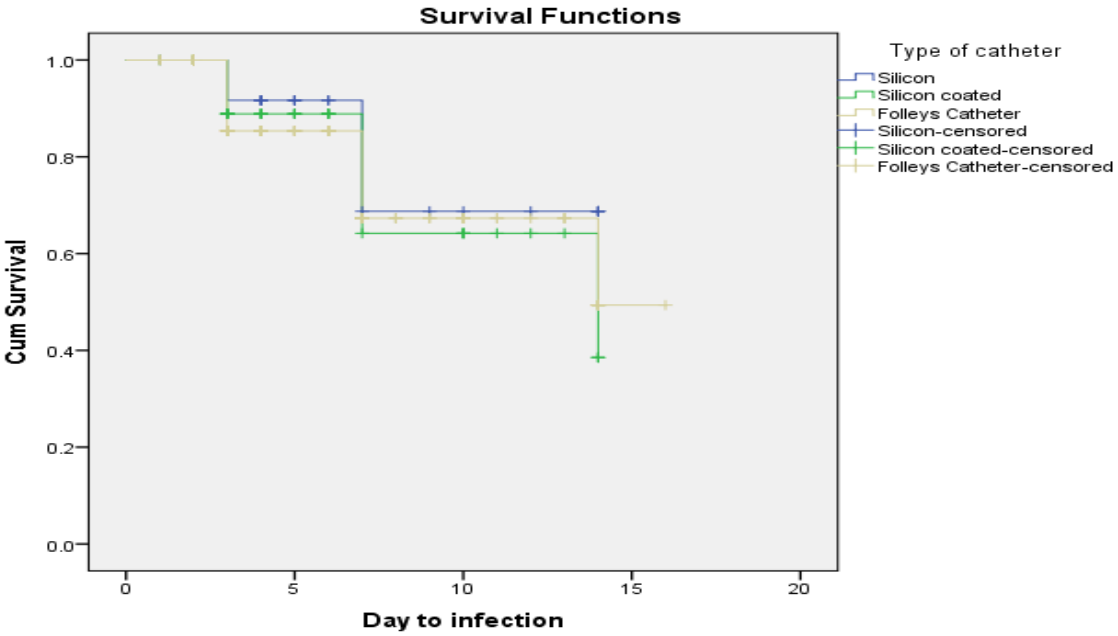

Figure 4.3: Kaplan Meier survival functions for the types of Catheters

4.6.2 Gender

The gender of a patient did not influence the time to acquiring CAUTI. The mean time for a female to acquire CAUTI was 11.1 days (95% CI 9.79 to 12.42days). A male patients was taking a mean of 12.26 days (95%CI 11.2 to 13.3 days) to acquire CAUTI. By the third day 20% of the female had acquired the infection while only 10% of the Male patients got the infection. By the seventh day, 30% of the female patients had gotten infected while the proportion of the male patients increased to 35%. There was no statistically significant difference between the two genders when it comes to time to acquire CAUTI as the p-value from log-rank test was 0.414.

Table 4.15: Mean and Medians for gender

Means and Medians for Survival Time								
patient Gender	Means				Median			
	Estimate	Std. Error	95% Confidence Interval		Estimate	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound			Lower Bound	Upper Bound
Female	11.101	0.672	9.785	12.418	14	.	.	.
Male	12.262	0.532	11.22	13.305	.	.	.	.
Overall	12.173	0.445	11.301	13.045	.	.	.	.

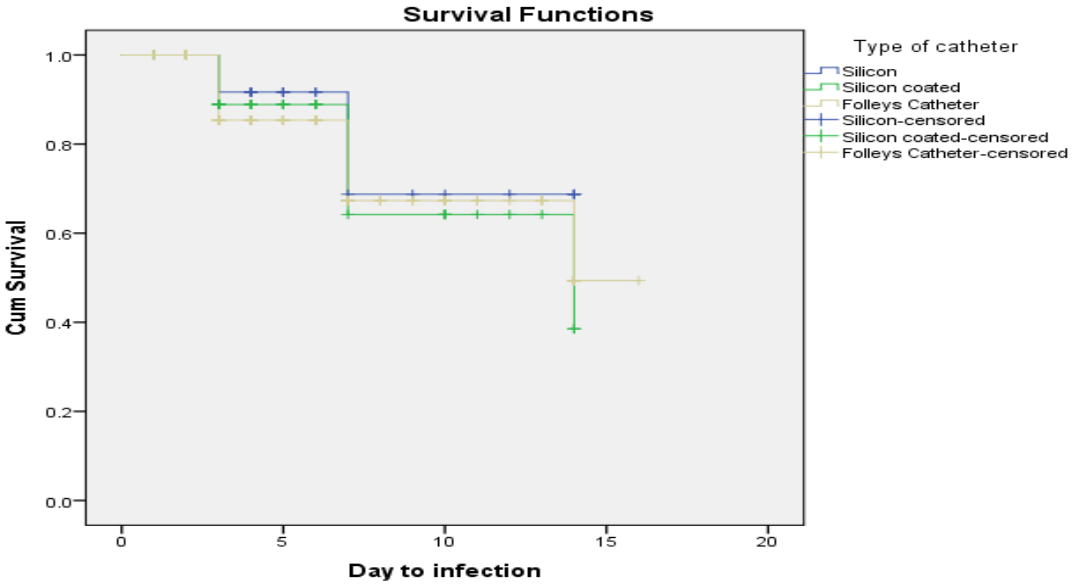

Figure 4.4: Kaplan Meier survival functions for Gender

4.6.3 Comorbidity

Patients having underlying conditions were acquiring CAUTI earlier than those without. The mean time to infection was 9.9 days (95% CI 8.5 to 11.4 days) and 12.6 days (11.7 to 13.6 days) survived for those with comorbidities and those without respectively. 90% of the patients without comorbidities survived the infection (did not acquire the infection) by the third day while about 75% of those with comorbidities survived without getting the infection in the first three days. About

56% of patients with comorbidities survived without getting the infection within the first seven days while the cumulative percent of those without comorbidities was 72%. The difference between the two samples was statistically significant (P-value 0.032) at 95% confidence interval. This means that a patient with comorbidity was acquiring CAUTI earlier than those without.

Table 4.16: Mean Survival time for Comorbidities p- Value 0.032

Means and Medians for Survival Time								
Presence of Comorbidity	**Means**				**Median**			
	Estimate	**Std. Error**	**95% Confidence Interval**		**Estimate**	**Std. Error**	**95% Confidence Interval**	
			Lower Bound	Upper Bound			Lower Bound	Upper Bound
Present	9.938	0.753	8.462	11.413	.	.	.	.
Absent	12.642	0.499	11.664	13.619	.	.	.	.
Overall	12.173	0.445	11.301	13.045	.	.	.	.

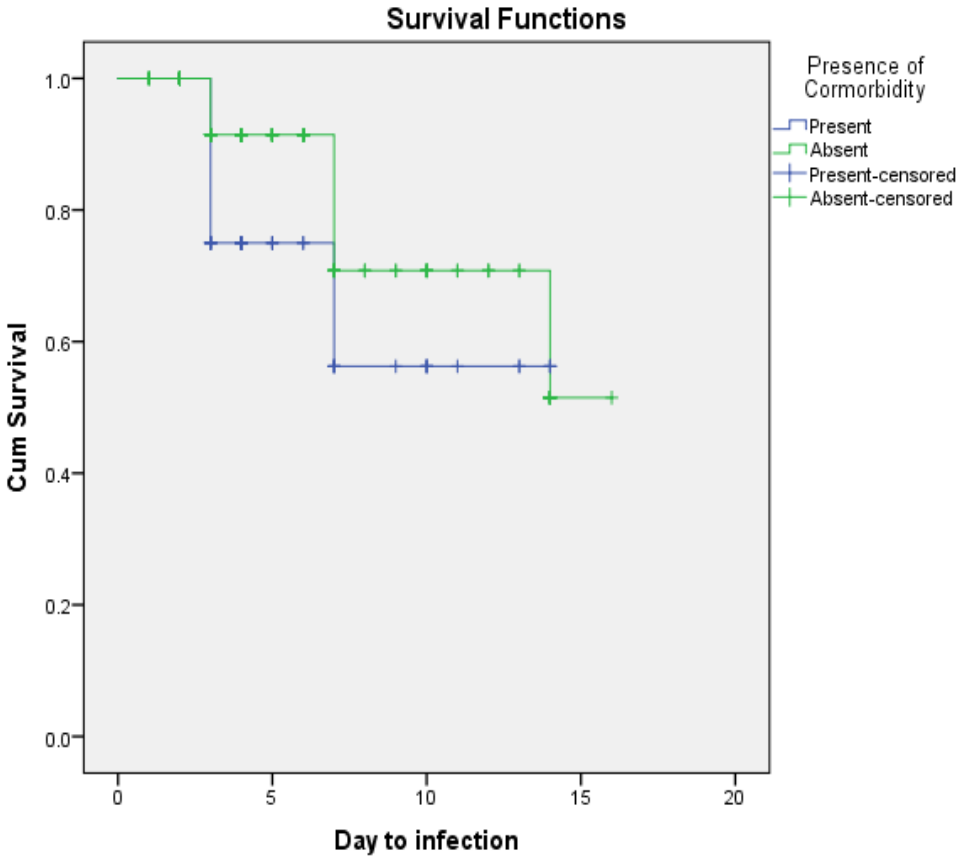

Figure 4.5: Kaplan Meier survival functions for Comorbidities

4.6.4 Observing Asepsis During Urine Bag Emptying

The mean survival time for patients whose urine bags were emptied aseptically was 14 days (95% CI 13.4 to 15.2 days). In the cases where the urine bags was emptied without observing the aseptic technique, the survival time was 9.1 days (95% CI 7.92 to 13 days). Approximately 95% of patients whose urine bags were emptied while observing aseptic technique survived without acquiring the infection in the first three days while only 76% of the cases where aseptic technique was not observed survived without acquiring CAUTI. Approximately 88% of the patients whose urine bags were emptied aseptically survived without the infection in the first seven days. Only 45% of the patients where aseptic technique was not observed while emptying the urine bag survived without acquiring the infection within the first seven days. The median of acquiring infection when asepsis technique is not observed was 7 days

(95%CI 5.3 to 8.7 days). The difference between the two samples was statistically significant (P-Value < 0.001).

Table 4.17: Means and Medians for urine bag emptying P- Value <0.001

Means and Medians for Survival Time								
Urine emptying	Means							
	Estimate	**Std. Error**	**95% Confidence Interval**		**Estimate**	**Std. Error**	**95% Confidence Interval**	
			Lower Bound	Upper Bound			Lower Bound	Upper Bound
asepsis observed	14.285	0.443	13.418	15.152	.	.	.	.
asepsis not observed	9.072	0.59	7.916	10.228	7	0.848	5.339	8.661
Overall	12.173	0.445	11.301	13.045	.	.	.	.

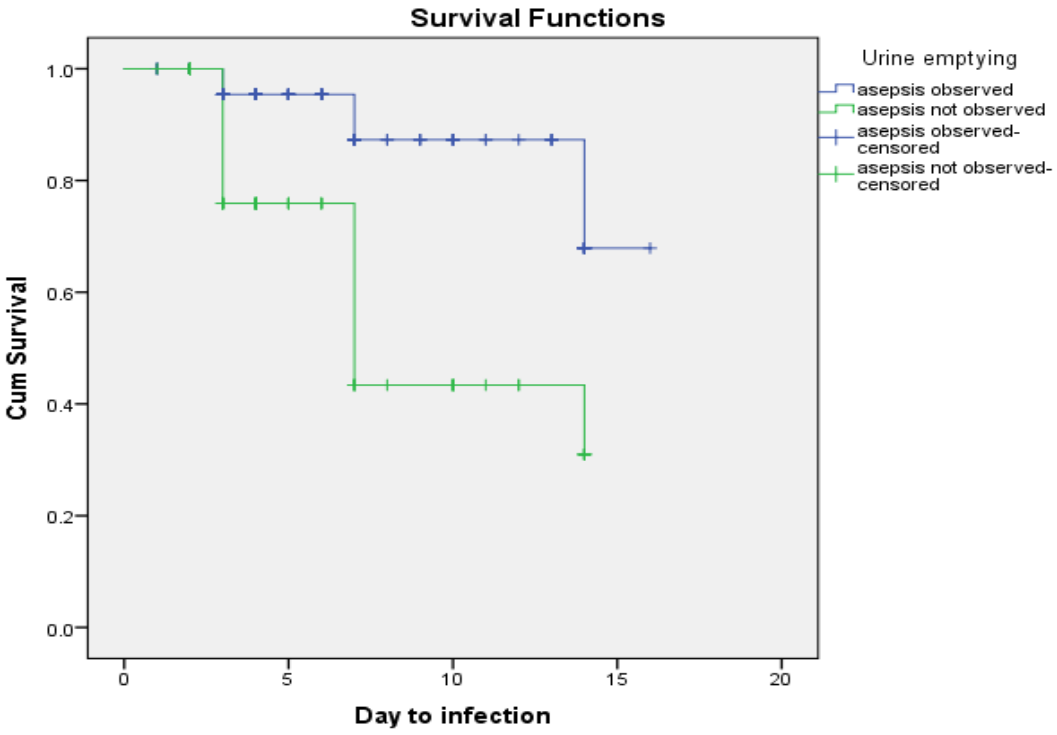

Figure 4.6: Survival functions for urine bag emptying

4.6.5 Model

The cox regression model showed that a patient whose catheter was secured on the thigh was 1.87 times (95% CI 1.025 to 3.419) more likely to acquire CAUTI as compared to the one whose catheter was secured at the thigh (P-value 0.041).

Table 4.18: Cox regression Model

Variables in the Equation

	B	**SE**	**Wald**	**df**	**Sig.**	**Exp(B)**	**95.0% CI for Exp(B)**	
							Lower	**Upper**
patient Gender	0.136	0.344	0.158	1	0.691	1.146	0.584	2.249
Type of catheter			0.254	2	0.881			
Type of catheter(1)	-0.251	0.501	0.251	1	0.616	0.778	0.292	2.076
Type of catheter(2)	-0.048	0.34	0.02	1	0.889	0.953	0.49	1.857
Age group	-0.151	0.336	0.202	1	0.653	0.86	0.445	1.662
Presence of Comorbidity	-0.457	0.343	1.773	1	0.183	0.633	0.323	1.241
number of days on catheter	0.003	0.048	0.004	1	0.952	1.003	0.913	1.101
number of days in ICU	0.006	0.008	0.543	1	0.461	1.006	0.991	1.021
Catheter secured to the leg	0.627	0.307	4.169	1	0.041	1.872	1.025	3.419

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

5.1.1 The Burden of CAUTI

5.1.1.1 Incidence of Intensive Care Unit- Acquired Urinary Tract Infection

The study showed the incidence density of Intensive Care Unit-acquired urinary tract infection at the Kenyatta National Hospital Critical Care Unit was 32 per 1000 catheter days. This was noted to be high as compared to similar studies done in other jurisdictions. The incidence density was six times that of a study done in an intensive Care Unit in Bahrain established an overall rate of 5.8 per 1000 catheter days (Alkhawaja,et al. 2017). It was also three times of a study conducted at a tertiary care University hospital concluded that the rate of infection of CAUTI was 11.5±3.1 (Huang et al. 2015). Health Safety Network (NHSN) in 2010 reported a CAUTI rate of 1.3 infections per 1000 catheter-days in medical/surgical ICUs (Dudeck et al. 2011). The incidence density was 25 times the one from the NHSN 2010 report. The incidence density was similar to European Center for Disease Prevention and Control (2018) study where, 32 per 1000 patients staying in the ICU for more than two days were reported to have acquired CAUTI in 2008 to 2012 in Europe. A study conducted on adult patients admitted to multisystem and cardiovascular surgery ICUs in Calgary Health Region concluded that the incidence density for CAUTI was 9.6 per 1000 ICU days (Laupland *et al*. 2005). A study done in South Africa established the incidence density of CAUTI in Pediatric Critical Care Unit (PICU) was high (16 per 1000 catheter days) (Dramowski et al. 2016). This is to mean that the incidence density in KNH CCU was twice the one of South Africa. A study conducted among patients with indwelling urinary catheters in Kabale regional referral hospital in Uganda, noted that the incidence of CAUTI was 15.3% (Musinguzi et al. 2019). The two studies done in Africa indicate that the rates in sub-Saharan Africa are high. The cumulative incidence of CAUTI was established to be

28.7%. This was an increase from 17.8% as noted in a study done in 2011 in the same unit (Inyama et al 2011). This increase shows the need for studying the factors associated with the high incidence rate. The hospital established specialized ICUs in the departments, where the some of the experienced nurses were posted and new nurses recruited to the main CCU to replace them. The new nurses are also specialized in critical care.

5.1.1.2 Prevalence of Intensive Care Unit- Acquired Urinary Tract Infection

The prevalence of CAUTI at KNH CCU was 36.6% (95% CI 30.4% to 43.0%). This was very high compared to a study by Uçkay, et al. (2013) that established a high prevalence (3.7%) of catheter acquired urinary tract infections among patients admitted in 49 Swiss hospitals.

5.1.1.3 Relationship between the CAUTI and Mortality

The study established that a patient who died was 1.8 times more likely to have CAUTI as compared to a patient who was discharged (Chi-square value 4.693, d.f-1, p-value 0.03). This shows there was an association between CAUTI and mortality. Chant et al (2011) in their study concluded that CAUTI is associated with significant mortality (odds ratio [OR], 1.99; 95% confidence interval [CI], 1.72-2.31; $p < .00001$; $I2 = 54\%$; eight studies; 62,063 patients). The results of the study agreed with our study results. According to a study done in Bangkok neuro-surgical wards, the mortality of CAUTI was 14.9% (Danchairvijitr *et al*., 2015). Nuvials *et al*. (2015) found that patients admitted to ICU with Healthcare associated infections had higher mortality as compared to those without the healthcare associated infection. The Nuvials study was in agreement with the results of this study. According Letica-Kriegel et al (2019), CAUTIs significantly increase the burden on patients, in terms of morbidity and mortality.

5.1.1.4 Relationship between CAUTI and Length of Stay

The study established that catheter acquired urinary tract infection was increasing the length of stay by 8 days (P-value <0.001). Model equation= Y= 7.609+8.057X. The

increase in the length of stay affects the patients and their family economically. The approximate cost being fifteen thousand per day, it means the eight extra days will increase the cost by Ksh. 120, 000. The longer the length of stay the higher the risk of acquiring health-care associated infections hence increase in cost due to added antibiotics and issues of morbidity and mortality. According to European Center for Disease Prevention and Control (2018), it was estimated that CAUTI contributed to 1.06 million days of excess ICU stay each year in the European hospitals. Patients with UTI had no higher mortality in matched cohort analysis. The results of the study showed a similarity with a study by Chant *et al* 2011, where CAUTI was associated with increase of length of stay in the intensive care unit. In the Chant et al. (2011) study, the weighted mean difference was + 12 days (p-value <0.0001). The study results agreed with Nuvials et al., (2015) who noted that patients admitted to ICU with Health care associated infections have an increased length of stay in the ward and are more severely ill than those without the Healthcare associated infections.

5.1.2 Causative Organisms for CAUTI

5.1.2.1 Identified Micro-Organisms

In this study, it was realized that gram negative micro-organisms are the most common pathogens in CAUTI (60%). *Escherichia coli* was the most prevalent gram negative micro-organism (20%). *Klebsiella species* were the second most prevalent at 10% followed by *Acinetobacter baumaunnii* and *Serratia species* at 8% each. *Pseudomonas aeruginosa* had a prevalence of 5.9%. Other gram negative organisms cultured were *Pantoea agglomerans* (3%), *Raoultella planticola* (2%), *Citrobacter freundii* (1%) *and Morganella morganii* (1%).

The gram-positive organism contributed 33% of the pathogens. *Enterococcus species* were the most common gram positive micro-organisms (31%). *Enterococcus faecalis* had a proportion of 25% while *Enterococcus gallinarum* (6%). *Staphylococcus haemolyticus* was cultured twice (2%). *Candida albicans* formed a proportion of 6%. The results showed some similarity to a study done in Salmaniya medical center in Bahrain by Elkhawana et al (2017) that showed *E. coli* was the most isolated micro-organism (28.8%) followed by *Klebsiella species* (26.9%), *candida albicans* (25%),

and *pseudomonas species* (11.6%) and *Proteus mirabilis species* (7.7%). A study conducted in Turkey by Inan et al. (2006), showed that, the most frequently isolated causative agents were *Candida spp.* in 37.1% of the UTIs, *E.coli* in 21.1% of the UTIs and *Pseudomonas spp.* in 16.5% of the UTIs. The prevalence of *E. coli* in the Inan et al (2006) study was almost similar to this study. In another study done in ICU at a university hospital in Turkey by Keten at al. (2014) *candida species* were the most prevalent organisms at 34.7%, followed by *E. coli* at 20.6%, *pseudomonas species* at 14%, *Klebsiella species* at 9.9% and *Acinetobacter species* at 8.2%. The micro-organisms cultured in the Keten et al (2014) study were similar to those cultured in this study safe for the proportion of candida species which was less prevalent here. The prevalence of *E. coli* in all these other studies are consistent with the finding of this study. The Ugandan study, noted that the most common organisms identified in this study were; *E. Coli* and *K. Pneumoniae* (Musinguzi et al. 2019). *Enterococcus faecalis, Escherichia coli, Klebsiella pneumoniae* and *enterococcus gallinarum* were more common than any other micro-organism in the study at 59%. This micro-organisms are normally found in the human intestines/ human stool. Comparing with other studies it seems that *Enterococcus faecalis* (25%) is not as common as it is in the study site. Use of diapers is very common in the unit. The increase could be associated with the hygiene while caring for a patient. The question which arises is how often is the diaper changed? When this diapers are changed at regular intervals and not when necessary may lead to fecal matter contaminating the catheter.

5.1.2.2 Anti-Microbial Sensitivity

Escherichia coli was sensitive to Amikacin (76.5%), Meropenem (70.6%) and Nitrofurantoin (53%) and resistant to gentamycin (76.5%), Amoxicillin/Clavulanic acid (82.4%), Piperacillin/Tazobactam (82.4%), Ciprofloxacin (82.4%), and Ampicillin/ Sulbactam (94.1%). The organisms were 100% resistant to Ceftriaxone, Cefepime, Cefuroxime, Cefazolin and Ceftazidime. This is inconsistent with the study by Keten et al. (2014) that showed *E. coli* was sensitive to third and fourth generation cephalosporin. In the Elkhawana et al. (2017) study, the gram negative organisms were sensitive to Aminoglycosides and Meropenem as a mono therapy.

This was consistent with our study. *Klebsiella Pneumoniae* was sensitive Amikacin (71.4%) and Meropenem (42.9%). *Pseudomonas aeruginosa* was sensitive to amikacin, Meropenem and nitrofurantoin at 60%. *Acinetobacter baumaunnii* was 100% resistant to Amikacin Meropenem, Amoxicillin/Clavulanic acid, Piperacillin/Tazobactam, Ampicillin/ Sulbactam and ampicillin. They were only sensitive to Ciprofloxacin (42.9%), and Gentamycin (42.9%). This was inconsistent with Keten et al (2014) study that showed that Acinetobacter baumaunnii was sensitive to Meropenem at 30%. *Candida Albicans* were sensitive to Fluconazole and Voriconazole (60%), Amphotericin B (40%), Fencitocine (40%), Caspofugine (40%), and Micafugin (40%). The results were consistent with keten et al (2014) study. The most common organisms identified in the Kabale hospital study were; *E. Coli* and *K. Pneumoniae.* The bacteria were resistant to most commonly used antibiotics (Musinguzi et al. 2019). This study agrees with the Kabale hospital study as this organisms were resistant to empirical treatment prescribed on admission of the patients to the unit.

5.1.3 Patient Level Factors Associated with CAUTI

In the case of patient level factors; the study established infections among the female were not significantly different from the male gender (RR: 1.098 (95%CI 0.654, to 1.843). Other studies shows that women are at a higher risk of developing an ICU-acquired UTI (Laupland et al, 2005; Chenoweth & Saint, 2013). The study done in Calgary Health region reported a risk ratio of 1.58 (95% CI 1.43 -1.75; P value <0.0001). Another study in Bahrain showed that the male were at a higher risk than the female (Male: Female relative risk [RR] 2.9; (95%CI] 1.4016 to 6.2461; P = 0.011)) (Alkhawaja et al 2017). The results of the study suggested that patients aged 50 years and above were at a higher risk than those aged below 50 years were not statistically significant [1.207 (95% CI 0.702, 2.075) p-value 0.5]. Other studies indicate that age greater than 50 years is a risk factor (Chenoweth, & Saint, 2013). Presence of comorbidities was established to be a risk factor in this study [RR: 1.669 (95%CI 1.014 to 2.745)]. The comorbidities studied were, Diabetes mellitus, retro viral disease, cardiac disease and renal diseases. This agrees with other studies; Diabetes Mellitus and Serum creatinine level greater than 2 mg/dL (Chenoweth, &

Saint, 2013) ; the Bahrain study showed that medical cases had higher risk than surgical cases (Alkhawaja et al 2017). Comorbid illnesses are associated altered adaptive immune response, this could explain the risk of having CAUTI being more in patients with underlying illnesses as compared to those without underlying illnesses.

5.1.4 Facility Level Factors Associated with CAUTI

In the case of facility level factors; the study established that failure to observe aseptic technique during emptying the urine bag was increasing the risk of acquiring CAUTI [RR: 3.392 (95%CI 1.963 to 5.86)]. Adherence to aseptic catheter care is a known factor reducing the risk of acquiring CAUTI (Chenoweth, & Saint, 2013). Catheter insertion on both female and female gender was aseptically done and was not associated with CAUTI. The results were not congruent with other studies. Catheter insertion after the sixth day of hospitalization and Catheter insertion outside the operating room (Chenoweth, & Saint, 2013).The CDC CAUTI prevention Bundle recommends asepsis during insertion, sample removal and bag emptying (CDC, 2016). CDC recommends securing of the urinary catheter on the patients thigh (CDC, 2016).The study looked into this issue by calculating the risk ratio of patients who had their catheters secured on the thigh to those whose catheters were not secured. The results indicated that patients whose catheters were not secured at the thigh had an increased risk of developing UTI [RR: 1.836 (95%CI 1.108 to 3.043)]. This suggest that securing the urinary catheter is very important as it will reduce the risk of acquiring CAUTI. A non-secured catheter may predispose the patient to trauma to the urethra hence increasing the risk to infection. There was no standard operating procedure for emptying the urine bag and securing of the catheter in the unit.

5.1.5 The Temporal Trends of Microbial Growth among Catheterized Patients

The gram negative micro-organisms were the most commonly cultured during the warm months of the year. The results were consistent with a study by Richet (2012) that showed variations of incidences of hospital infections with gram negative bacteria being the most common. A study done at the University of Maryland Centre

showed significant increase in the incidences of infections caused by Gram-negative Pathogens during summer (Perencevich et al 2008). Another study conducted on patients in 132 hospitals in the US indicated there were seasonal variations (Eber et al 2011). Infection cases increased in the warmer months of the year. The micro-organisms isolated in the study were; *Acinebacter spp., E. coli and P. aeruginosa*. Anderson et al (2008), found an increase of 41 to 49% of infection rates by *Klebsiella pneumonia* during the warmest month of the year. Critical Care Unit environment is supposed to be regulated. Air conditioning equipment are normally maintained in an ICU to maintain a conducive environment. The air conditioning equipment in the KNH CCU was not functional during the study period. The environment was not well regulated aiding the growth of the gram-negative pathogens during the warm months of the year.

5.1.6 Time to CAUTI

5.1.6.1 Type of the Catheter and Time TO CAUTI

Three types of urinary catheters were in use in the unit; Silicon, silicon coated and Foleys catheter. The results of the study showed there was no statistically significant difference in time to infection between the three types of catheter. This results agree with Kranz et al (2020), in a meta-analysis of 502 studies that concluded there was no relevant differences among the various types of catheter material with respect to CAUTI. Silicon and silicon coated catheters are more expensive than the Foley's catheter. Their combined mean time to infection was between 11 and 13 days. The median time to infection for all types of catheters was 14 days. The study results were in agreement with Gomila *et al.*, (2019) who established that the time from catheter insertion to CAUTI diagnosis was less than 2 weeks in 44.6% of cases. In this situation, it is wise to go for the cheaper option to reduce the economic burden. According to Letica-kriegel (2019), CAUTI rates increase non-linearly for each additional day of catheterization; CAUTI-free survival was 97.3% (CI: 97.1 to 97.6) at 10 days, 88.2% (CI: 86.9 to 89.5) at 30 days and 71.8% (CI: 66.3 to 77.8) at 60 days. This translated to an instantaneous HR of. 49%–1.65% in the 10–60 day time range. The results of our study also shows CAUTI rates increasing non-linearly.

5.1.6.2 Gender and Time to CAUTI

According to the study, the gender of the patient did not influence the time to acquiring CAUTI. The medium time to CAUTI was 14 days for both male and female. This contradict other studies that female are at a higher risk of getting CAUTI due to their short urethra (Laupland et al, 2005; Chenoweth & Saint, 2013).

5.1.6.3 Comorbidity and Time to CAUTI

Patients with comorbidities were acquiring CAUTI earlier than those without. The results were consisted with other studies which showed patients with underlying conditions had a higher risk to infection as compared to those without (Chenoweth, & Saint, 2013; Alkhawaja et al 2017). Comorbid illnesses are associated altered adaptive immune response, this could explain the risk of having CAUTI earlier being more in patients with underlying illnesses as compared to those without underlying illnesses

5.1.6.4 Asepsis and Time to CAUTI

The study results indicated that, survival time to CAUTI was 14 days where asepsis was observed during the emptying of the urine bag. The survival time reduced to 9 days when asepsis was not observed. Approximately 88% of the patients whose urine bags were emptied aseptically survived the infection in the first seven days. Only 45% of patients whose urine bags were emptied without observing asepsis survived the infection in the first seven days. The median of acquiring infection where asepsis was not observed was 7 days. This shows that failure to observe asepsis during emptying of the urine bag was a major contributor to patients acquiring CAUTI earlier. CDC provides guidelines on infection prevention and control for CAUTI through the CAUTI bundle. A study by Elkbuli *et al.,* (2018), indicated that using CAUTI bundle to manage patients reduced the CAUTI infection rate by 80%. The tools used for data collection were developed using this guidelines. The results indicated that the guidelines were not followed strictly during the emptying of the urine bag. In most of the cases the failure was observed when the health-workers

were allocated more than one patient in the unit. The recommended Nurse patient ration in an ideal ICU is 1:1.

5.1.6.5 Securing the Urinary Catheter and Time to CAUTI

The risk for patients whose catheters were not secured on the thigh as recommended by CDC was 1.9 times those whose catheters were secured. When a catheter is not secured, it causes friction in the urethra when manipulating the patient during nursing procedures. The friction causes trauma hence reducing the time to acquiring CAUTI. CAUTI prevention bundle by CDC recommends securing of the catheter on the patients thigh to reduce the rate of infection. The results of the study are consistent with Henandez *et al.,* (2019), who stated that catheter management practices impact on CAUTI prevention efforts when performed consistently as a bundle of care across all four components outlined in the checklist.

5.2 Conclusion

5.2.1 The Burden of CAUTI

The incidence and the prevalence of Intensive Care Unit-Acquired urinary tract infection at the hospital's Main Critical Care Unit is higher than in other studies conducted in other jurisdictions. CAUTI is associated with increased mortality and length of stay at the critical care unit. CAUTI increases the length of stay in the hospital thus raising the hospital's and patients economic cost to an average of Ksh.120, 000 per patient. The increased length of stay also predisposes the patient to morbidity and mortality.

5.2.2 Common Causative Organisms of CAUTI

Gram negative micro-organisms were the commonest at a proportion of 60%, *with Eschirichia coli* (20%), *Klebsiella ssp.* (8%), and *Accinetobacter bauminnii* (8%). The most common gram-positive micro-organisms were *Enterococcus faecalis* (25%), and *Enterococcus gallinarum* (8%). All this organism are resident in the human intestines. This organisms were resistant to the empirical treatment administered to the patients. Candida albicans contributed to 6% of the CAUTI.

Third and fourth generation cephalosporin should not be used for empirical treatment because of the high resistance among *E.coli* and *Klebsiella* isolates. Amikacin, and Meropenem seem to be sensitive to majority of the gram-negative micro-organisms. *Acinetobacter baumaunnii* was resistant to majority of the drugs available. Gram positive micro-organism were sensitive to Vancomycin, Linezolid, and Teicoplanin. Fluconazole and Voriconazole therapy seems to be the most appropriate choice for the treatment of CAUTIs caused by *C. albicans*.

5.2.3 Patient Level Factors Associated with CAUTI

Patients' comorbid conditions (Diabetes Mellitus, Retroviral Disease, cardiac and renal disease) are associated with the incidence of CAUTI.

5.2.4 Facility Level Factors Associated with CAUTI

Facility level factors that were associated with the high incidence of CAUTI were; failure to observe aseptic technique during urine bag emptying (CDC CAUTI bundle protocol guidelines were not observed) and failure to secure the urinary catheter on the patient's thigh. The Nurse patient ratio was noted to be affecting the observance of the aseptic technique.

5.2.5 Temporal Trends of Microbial Growth

The incidence Gram-negative Micro-organisms is higher during the warmest months of the year. This could be associated with the unregulated temperatures in the unit. The Air conditioner in the unit was not functional.

5.2.6 Time to Development of CAUTI

CAUTI rates increase non-linearly for each additional day of catheterization. The factors that reduced the time acquiring CAUTI were; Failure to observe aseptic technique during emptying of the urine bag. Presence of comorbidity and failure to Secure of the urinary catheter on the patient's thigh.

5.3 Recommendations

1 To reduce the burden of infection, the researcher recommends instituting evidence based protocols as they are known to reduce prevalence and incidence of CAUTI. A standard Operation Procedure to be prepared using the CDC's CAUTI Prevention bundle/ current evidence. This will enhance strict observance of the aseptic technique.

2 The commonest causative organisms cultured are normally found in the human gastro intestinal tract. The researcher recommends the changing of patient diapers to be done when necessary (after every motion) and hygiene to be maintained to reduce the infections caused by the fecal related micro-organisms. There should be judicious use of antimicrobials in the management of CAUTI to prevent multidrug resistant UTIs. The unit administration should consider avoiding third and fourth generation cephalosporin as empirical treatment because of high prevalence of extended spectrum beta-lactamase production among E.coli and Klebsiella isolates and the culture and sensitivity results to treat the patients. Only drugs that are sensitive to the cultured micro-organism to be administered.

3 Since comorbidity was identified as the patient level factor that was associated with increased incidence of CAUTI, the unit administration should consider protective isolation (reverse barrier Nursing) (Patients with comorbid conditions to be isolated).

4 The facility level factors that were associated with high incidence rate could be eliminated by training the staff on observance of the CAUTI bundle as recommended by CDC. The administration of the unit to consider mentoring the new staff on the issues pertaining infection control and prevention. The Health-care staff to have regular refresher course on Infection prevention and control. This is to ensure the staff are updated on the current evidence on infection prevention and control. In most of the cases the observance of the infection prevention and control guidelines were observed when the Nurse patient ratio was 1:1. The Hospital administration to consider improving the staffing ratio to 1:1 in all the shifts.

5 The hospital administration should consider regulating the CCU environment by installing a functional air conditioner. This will reduce the prevalence of the gram negative pathogens which are known to be common during warm seasons.

6 The medium time to development of the CAUTI was less 14 days regardless of the type of the catheter used. The hospital administration to consider changing/ removal of the urinary catheter on the seventh day (one week), to reduce the incidence of CAUTI.

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APPENDICES

Appendix I: Patients' Detail Checklist

Serial No.	Patient IP No.	Date of Insertion	Catheter type	Patient's age	Gender	Diagnosis	Comorbidity	Date of removal	Asepsis observed	1st culture	2nd culture	3rd culture	Catheter secured to the leg	Bag lower than the bladder
1.														
2.														
3.														
4.														
5.														
6.														
7. .														
-														
238														

Appendix II: Checklist for Steps in Male Catheterization

Serial	Step	Yes	No	N/A
1.	Place the patient in the supine position with legs extended and flat on the bed.			
2.	Prepare the catheterization tray and catheter and drape the patient appropriately using the sterile drapes provided. Place a sterile drape under the patient's buttocks and the fenestrated (drape with hole) drape over the penis.			
3.	Apply water-soluble lubricant to the catheter tip.			
4.	With your non-dominant hand, grasp the penis just below the glans and hold upright.			
5.	If the patient is uncircumcised, retract the foreskin. Replace the foreskin at the end of the procedure.			
6.	With your dominant hand, cleanse the glans using chlorhexidine soaked cotton balls. Use each cotton ball for a single circular motion			
7.	Place the drainage basin containing the catheter on or next to the thighs.			
8.	With you non-dominant hand, gently straighten and stretch the penis. Lift it to an angle of 60-90 degrees. At this time you may use the urojet to anesthetize the urinary canal, which will minimize the discomfort.			
9.	With your dominant hand, insert the lubricated tip of the catheter into the urinary meatus.			
10.	Continue to advance the catheter completely to the bifurcation i.e. until only the inflation and drainage ports are exposed and urine flows (this is to ensure proper placement of the catheter in the bladder and prevent urethral injuries and hematuria that result when the foley catheter balloon is inflated in the urethra).			
11.	Note: If resistance is met during advancement of the catheter: Pause for 10-20 seconds. Instruct the patient to breathe deeply and evenly. Apply gentle pressure as the patient exhales			
12.	If you still meet resistance, stop the procedure and repeat above steps.			
13.	Attach the syringe with the sterile water and inflate the balloon. It is recommended to inflate the 5cc balloon with 7-10cc of sterile water, and to inflate the 30cc balloon with 35cc of sterile water. Improperly inflated balloons can cause drainage and leakage difficulties.			
14.	Gently pull back on the catheter until the balloon engages the bladder neck.			

15.	Attach the urinary drainage bag and position it below the bladder level. Secure the catheter to the thigh. Avoid applying tension to the catheter.			
16.	Remove drapes and cover patient. Ensure drainage bag is attached to bed frame. Remove your gloves and wash hands.			
17.	Note: Never inflate a balloon before establishing that the catheter is in the bladder and not just in the urethra. If the patient reports discomfort, withdraw the fluid from the balloon and advance the catheter a little further, then re-inflate the balloon.			

Appendix III: Checklist for Steps in Female Catheterization

Serial	Step	Yes	No	N/A
1.	Place the patient in the supine position with the knees flexed and separated and feet flat on the bed, about 60 cm apart. If this position is uncomfortable, instruct the patient either to flex only one knee and keep the other leg flat on the bed, or to spread her legs as far apart as possible. A lateral position may also be used for elderly or disabled patients.			
2.	With the thumb, middle and index fingers of the non-dominant hand, separate the labia majora and labia minora. Pull slightly upward to locate the urinary meatus. Maintain this position to avoid contamination during the procedure.			
3.	With your dominant hand, cleanse the urinary meatus, using forceps and chlorhexidine soaked cotton balls. Use each cotton ball for a single downward stroke only.			
4.	Place the drainage basin containing the catheter between the patient's thighs.			
5.	Pick up the catheter with your dominant hand			
6.	Insert the lubricated tip of the catheter into the urinary meatus.			
7.	Advance the catheter about 5-5.75 cm, until urine begins to flow then advance the catheter a further 1-2 cm.			
8.	Note: If the catheter slips into the vagina, leave it there to assist as a landmark. With another lubricated sterile catheter, insert into the urinary meatus until you get urine back. Remove the catheter left in the vagina at this time.			
9.	Attach the syringe with the sterile water and inflate the balloon. It is recommended to inflate the 5cc balloon with 7-10cc of sterile water, and to inflate the 30cc balloon with 30-35cc of sterile water.			
10.	Improperly inflated balloons can cause drainage and leakage difficulties.			
11.	Gently pull back on the catheter until the balloon engages the bladder neck.			

Appendix IV: Checklist For Emptying Catheter Bag Procedure

Serial	STEP	YES	NO	N/A
1.	Wear disposable gloves. Remove gloves and wash hands between each patient.			
2.	When emptying catheter bags with gloved hands, avoid interruption and potential contamination of other equipment etc. until task is completed and hands are washed.			
3.	Use a clean jug large enough to avoid spillage eg 2-3 litres			
4.	After emptying the bag, wipe the end of the catheter outlet with an alcohol swab.			
5.	Note the amount and colour of drainage – record prn			
6.	Empty jug carefully down the sluice to avoid splashing			
7.	Place jug straight into sanitiser and store dry			

Appendix V: Consent Information and Consent Forms

Consent Form

Study on Intensive Care Unit Acquired Urinary Tract Infection

Introduction: I Elijah Githinji Mwangi, a PhD student in Epidemiology at Jomo Kenyatta University of Agriculture and Technology, am conducting a study on **intensive care unit acquired urinary tract infection** and would like to recruit you/ your next of kin into the study. Your participation will involve you allowing me to access your/ your next of kin personal information concerning your age as well as diagnosis and collecting urine samples to for culture and sensitivity.

Broad Objective: the aim of the study is to determine the risk factors and burden of hospital acquired urinary tract infections among catheterized patients at Kenyatta National Hospitals Critical Care Unit.

Voluntariness of Participation: Your participation in this study is on a voluntary basis and should you wish to withdraw from the study at any point then you will be at liberty to do so.

Confidentiality: Your / your kin participation in this study will be kept in confidence and your/ your kin's actual name will not be used in the study. Confidentiality of information obtained from you/ from your/your kin's record will be protected through such processes as using code numbers for concealed identity and limiting the number of people with access to the information.

Benefits: The benefits to you for being involved in the study will not be direct. The indirect benefit include identification of early urinary tract infection and early treatment

Risks: There are no risks from you getting involved in this study. The study findings will not be used for any monetary gains.

Right to Withdrawal: Should you decide to withdraw from the study at any point, you will not be subjected to any discriminatory treatment.

Should you require any further information or clarification then the main researcher may be contacted using the contacts on the consent certificate/form

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Participant's Statement

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

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

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

I agree to participate in this research study: Yes No

Participant printed name: _____

Participant / Next of Kin's signature / Thumb stamp _____

Date _____

Researcher's statement

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

Researcher's / Research Assistant's Name: _____ **Signature** _____ **Date**: _____

Fomu ya Idhini

Uchunguzi Kuhusu Ugonjwa Wa Njia Ya Mkonjo Ambao Unapatikana Kwa Wagonjwa Wenye Wamelazwa Katika Chumba Cha Wagonjwa Mahututi Na Wenye Wanatumia kifaa cha Mpira Kupitishia Mkonjo

Utangulizi: Mimi, Elijah Githinji Mwangi anayesomea udaktari wa filosofia kwenye chuo Kikuu cha Jomo Kenyatta kwa ushilikiano na ITROMID Taasisi ya uchunguzi wa afya (KEMRI), ana fuatilia upelelezi kuhusu ugonjwa wa njia ya mkonjo unaopatikana kupitia kifaa cha mpira kinachotumika kutoa mkonjo katika chumba cha wagonjwa mahututi. Usaidizi wako utahusu wewe kunikumbalia kupima mkonjo wako kuweza kujua kama umeambukizwa huu ugonjwa na pia kuangalia faili/tupa yako kujua mambo fulani kama vile, umri wako, na ugonjwa uliofanya wewe kulazwa katika chumba cha wagonjwa mahututi.

Lengo kuu: lengo kuu la uchunguzi huu ni kutaka kujua hatari na mzigo wa ugonjwa wa njia ya mkonjo unaopatikana kupitia kifaa cha mpira kinachotumika kutoa mkonjo katika chumba cha wagonjwa mahututi.

Kujitolea Kuhusishwa: Kuhusishwa kwako katika upelelezi huu ni kulingana na mapendeleo yako na sio lazima, na isitoshe, unaweza kujiondoa kutoka upelelezi huu wakati wowote.

Usiri: Kuhusishwa kwako katika upelelezi huu ni jambo la siri baina yako na mpelelezi, na jina lako halitatumika kwenye upelelezi. Matokeo ya upelelezi huu itakua niya siri kati yako nampelelezi mkuu, na siri hii itawekwa kwa njia tofauti kama vile kutumia nambari za siri badala ya majina yako, pamoja na kuhusisha wasaidizi wachache katika upelelezi huu.

Faida: Fadhili utakazozipata ni kwamba ukiwanjwa utajulikana na kutibiwa mapema.

Hatari: Hakuna hatari au mashaka yanayoweza kutoke kutokana na upelelezi huu. Hakuna faida ya pesa zozote ambazo zitapatikana kutokana na upelelezi huu.

Haki ya kujitoa: uko na haki ya kujitioa kutoka kwa uchunguzi huu wakati wowote ule. Ukijitoa hutapata maafa yoyote

Ukihitaji maelezo zaidi unaweza kushirikiana na mpelelezi mkuu kwa anwani, baruapepe au simu zilizo andikwa hapa chini.

Numbari za simu, anwani na baruapepe za mkaguzi, wasimamizi na Jamii ya walio chaguliwa kugauwa maadili ya upelezi:

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Appendix VI: Publications

Antimicrobial Susceptibility Patterns of Isolates from Catheterized Patients at Kenyatta National Hospital Critical Care Unit

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Summary

BACKGROUND

Intensive care unit acquired urinary tract infection is a complication which is common in critical illness and has been associated with increased patient morbidity and mortality Urinary tract infections are said to complicate the critically ill patients' clinical course and at the same time create substantial economic and human cost. Identification of the type of microorganisms causing the infections and their drug sensitivity profiles is essential in the management of these infections.

OBJECTIVE

The aim of this study was to identify microorganisms causing catheter associated urinary tract infection in the Kenyatta National Hospital critical care unit and their drug sensitivity.

METHODOLOGY

The study was conducted at Kenyatta National Hospital main critical care unit. The study population was two hundred and thirty eight patients admitted in the critical care unit between January 2019 and January 2020 and on urinary catheters. A Prospective cohort design was adopted. Urine culture and sensitivity was done to identify infective microorganisms and their drug sensitivity profiles. Patients were recruited consecutively for the period of the study.

RESULTS

The microorganisms identified were; *Enterococcus* species (32%), *Escherichia coli* (20%), *Klebsiella* species (10.4%), *Acinobacter baumaunnii* (8%), *Pseudomonas aeruginosa* (6%), *Candida albicans* (6%), *Serratia* species (11.7%), *Pantoea agglomerans* (3.5%), and *Raoultella planticola* (2.4%). *Enterococcus* species were 100% sensitive to *Vancomycin, Linezolid* and *Telcoplanin* and 73% to *Nitrofurantoin* and Ampicillin. *Staphylococcus haemolyticus* was also 100% sensitive to *Vancomycin, Linezolid* and *Teicoplanin. Serratia* species was sensitive to Cefazolin, Nitrofurantoin, Amoxicillin/ Clavulanic Acid, Piperacillin/ Tazobactam, and Ampicillin/ Sulbactam. *Pantoea* agglomerans was 66.7% sensitive to Amikacin. *Klebsiella* species were sensitive to Amikacin and Meropenem. Escherichia coli was sensitive to Amikacin, Meropenem and Nitrofurantoin. Acinetobacter baumaunnii and Raoultella planticola were resistant. Candida albicans were highly sensitive to Fluconazole and Voriconazole.

Key words: Catheter-associated urinary tract infections; Critical care unit; Urinary tract infection, Microorganisms, urinary catheter, anti –microbial drugs

East African Medical Journal Vol. 96 No. 7 July 2019
INCIDENCE AND PREDICTORS OF INTENSIVE CARE UNIT-ACQUIRED URINARY TRACT INFECTIONS AMONG CATHETERIZED PATIENTS ADMITTED AT KENYATTA NATIONAL HOSPITAL CRITICAL CARE UNIT

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INCIDENCE AND PREDICTORS OF INTENSIVE CARE UNIT-ACQUIRED URINARY TRACT INFECTIONS AMONG CATHETERIZED PATIENTS ADMITTED AT KENYATTA NATIONAL HOSPITAL CRITICAL CARE UNIT

E. G. Mwangi, S. M. Karanja, P. Wanzala and Z. W. Ngumi

ABSTRACT

Objective: **To determine the incidence and predictors of hospital acquired catheter associated urinary tract infections among catheterized patients admitted at Kenyatta National Hospital Critical Care Unit**

Study Design: **Prospective Cohort Study**

Setting: **Kenyatta National Hospital Critical Care Unit**

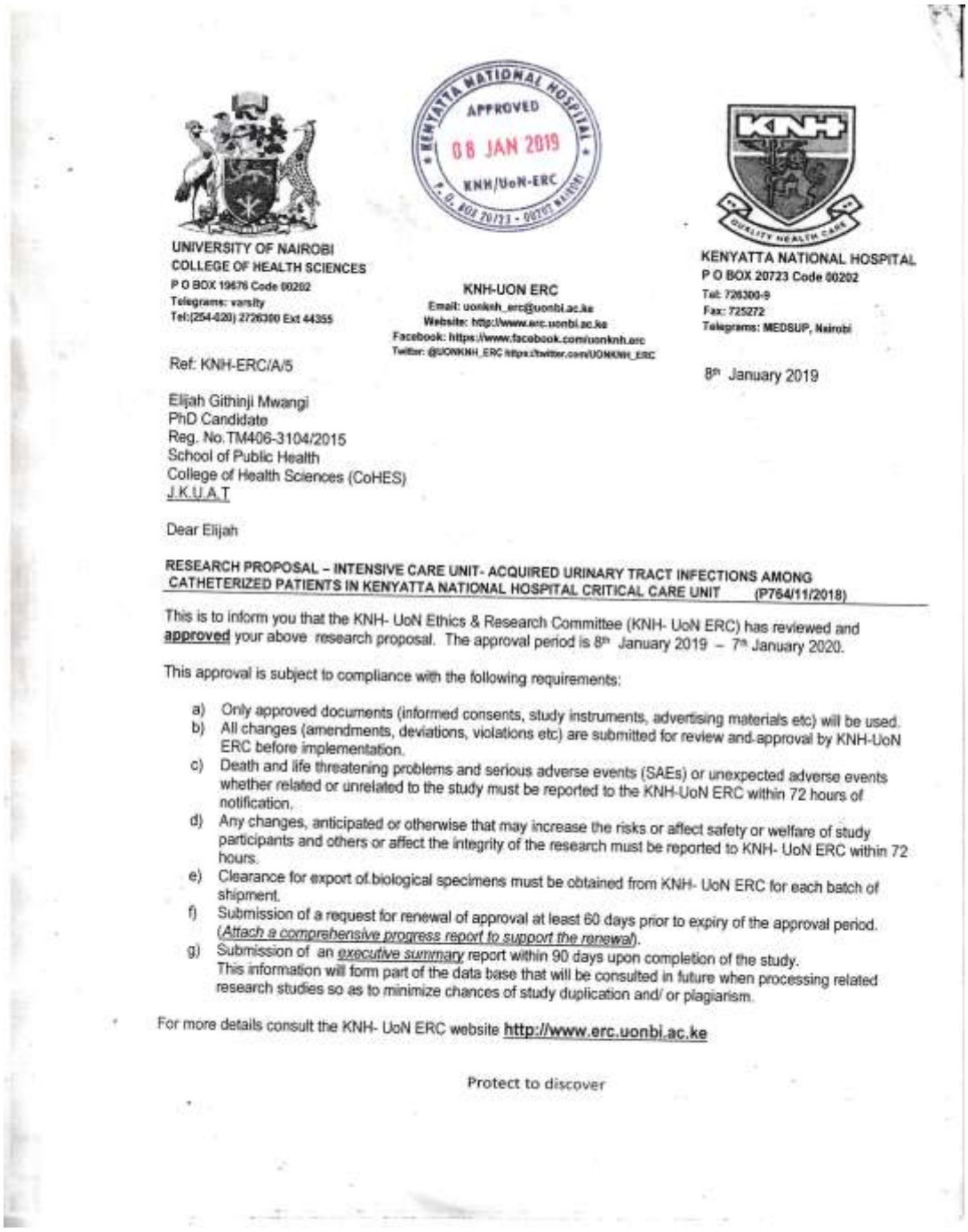
Subjects: **the study population was two hundred and thirty-eight patients admitted in the critical care unit between January 2019 and January 2020 and were put on urinary catheter**

Main Outcome Measures: **Incidence of hospital acquired urinary tract infection, patient level and hospital level risk factors associated with catheter associated urinary tract infections.**

Results: **the incidence density of hospital acquired catheter associated urinary tract infection was 32 per 1000 Catheter-days in the critical care unit. The cumulative incidence was 28.7%. Patients having other comorbidities had a higher risk to acquire catheter associated urinary tract infection; risk ratio of 1.669. Failure to observe aseptic techniques during emptying of the urine bag had a higher risk to acquire catheter associated urinary tract infection; risk ratio of 3.392. Failure to secure the urinary catheter on the patient's thigh had a higher risk to acquire catheter associated urinary tract infection; risk ratio of 1.836.**

Conclusion: **the incidence of intensive care acquired catheter associated urinary tract infection at the critical care unit is relatively high compared to other jurisdictions. The risk factors associated with the high incidence of the urinary tract infection are comorbidities, failure to observe aseptic techniques**

Appendix VII: KNH/UoN-ERC Letter of Approval



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8th January 2019

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J.K.U.A.T

Dear Elijah

RESEARCH PROPOSAL – INTENSIVE CARE UNIT- ACQUIRED URINARY TRACT INFECTIONS AMONG CATHETERIZED PATIENTS IN KENYATTA NATIONAL HOSPITAL CRITICAL CARE UNIT (P764/11/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 8th January 2019 – 7th January 2020.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

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

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Yours sincerely,

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

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Appendix VIII: Originality Report