

THE PREVALENCE OF BACTERIAL INFECTION OF OPEN FOOT INJURIES AND ANTIBIOTIC SUSCEPTIBILITY OF ISOLATES AT THE KENYATTA NATIONAL HOSPITAL.

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A DISSERTATION TO BE SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF DEGREE OF MASTER OF MEDICINE (M.MED) IN ORTHOPAEDIC SURGERY IN THE UNIVERSITY OF NAIROBI

DECLARATION

I hereby declare that this dissertation is my original work and has not been presented as a dissertation at any other university.

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DEDICATION

I dedicate this dissertation to my wife and family for their love, support, and patience.

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LIST OF ABBREVIATIONS

KNH	Kenyatta National Hospital
A&E	Accident and Emergency
P.aeruginosa	Pseudomonas aeruginosa.
S.Aureus	
The U.S.A	The United States of America.
MDR	Multidrug-resistant.
MRSA	Methicillin-Resistant Staphylococcus aureus.
TROAI	Trauma-related Osteoarticular Infections.
E.coli	Escherichia coli
G-CSF	Granulocyte colony-stimulating factor.
K.pneumoniae	Klebsiella pneumoniae
DFU	Diabetic Foot Ulcer
CFU/g	colony forming units per gram
CFU/ml	colony forming units per milliliter.
MIC	minimum inhibitory concentration.
M/C/S	
O&T	Oestern and Tscherne.
ОМ	Osteomyelitis.
STSG	Split thickness skin graft.
CoNS	Coagulase-Negative Staphylococcus aureus.
ESBL	Extended broad spectrum Beta Lactamase
AMP C positive	beta Lactamase positive.
S.marcescens	Serratia marcescens.

P.rettgeri	Providencia rettgeri.
E. fecalis	Enterococcus faecalis.
E. cloacae	Enterobacter cloacae.
P. vulgaris	Proteus vulgaris
A. baumanii	Acinetobacter baumanii.
P.mirabilis	Proteus mirabilis.
SPSS	Statistical Package for The Social Sciences.

ABSTRACT

Background: Open foot injuries are a common occurrence in Kenya mainly following motor vehicle crash incidents and work-place related injuries. These are usually associated with contamination at the site of injury resulting in infection mainly by bacteria. The prevalence and factors associated with foot infections are well-known in hospitalized patients with Diabetic Foot Ulcers; yet, unknown in other trauma patients.

Determining the prevalence of infection in patients with open foot injuries and local antibiotic susceptibilities to causative bacterial pathogens is key to creating treatment algorithms for prudent antibiotic use and therefore aiding in appropriate patient care.

Broad Objective: The study aimed to determine the prevalence of bacterial infection in patients with open foot injuries at KNH and the antibiotic susceptibilities of underlying bacterial agents.

Study Setting: This study was conducted at The Kenyatta National Hospital.

Study Design: A cross-sectional descriptive study. Patients who were 18 years of age and above who met the inclusion criteria were enrolled using convenient sampling till the desired sample size was achieved.

Methodology: This was a prospective cross-sectional descriptive study with convenient sampling of 37 patients over a period of three months. Ethical approval was sought from KNH/ERC and informed consent was obtained from each patient who agreed to be recruited into the study according to the set criteria. Collected data included the patient's demographics, duration before presenting to hospital, type of foot injury, and anatomical region of the foot affected. Outcomes of interest in the study were the presence of infection and antibiotic susceptibilities of underlying bacterial pathogens.

Data processing: Data acquired was coded, entered, and managed in the Microsoft Access database. Statistical Package for Social Sciences-Version 25 was used for data analysis.

Results:

The prevalence of bacterial infection in patients with open foot injuries at KNH was 86.4%. A total of 12 different bacteria were isolated. Growth was obtained in 32 out of the 37 patients with 7 of these having polymicrobial growth. The commonest isolate was *P.aeruginosa* 11(25%) followed by *S.aureus* 7(15.9%) where 5(71.4%) of the isolates were coagulase-negative and 2(28.6%)were MRSA.*P.mirabilis* was the third common isolated organism 6(13.6%) where 4 of them were extended-spectrum Beta-Lactamase (ESBL) negative and 2 were extended Spectrum beta Lactamase(ESBL) positive. Other isolated organisms included *E.coli* 3 (6.8%), *A. baumanii* 2 (4.5%), *P. vulgaris* 2 (4.5%) and *E. cloacae* (Beta-Lactamase positive), *E. fecalis* 1(2.3%), *K.pneumoniae* 1(2.3%), *S.marcescens* 1(2.3%), P.rettgeri (beta lactamase positive) 1(2.3%), and *Bacillus spp* 1(2.3%). No growth was obtained from 5 (11.4%) patients.

Conclusion:

The prevalence of bacterial infection in patients with open foot injuries at KNH was high (86.4%).*Pseudomonas aeruginosa* was the leading isolate accounting for 25% of the cases followed by *S. aureus* from 15.9% with the coagulase-negative *Staphylococcus aureus* strains being more prevalent than MRSA. *P. aeruginosa* isolates showed a 100% susceptibility to all tested antibiotics in this study -cefuroxime, ceftazidime, cefepime, piperacillin-tazobactam, imipenem, meropenem, tobramycin, gentamicin and ciprofloxacin. *S. aureus* isolates exhibited a high degree of resistance to commonly used antibiotics. Resistance to amoxicillin, ampicillin, and amoxicillin-clavulanic acid was 100% while resistance to vancomycin was 71.4%. Only 2(28.6%) *S. aureus* isolates were sensitive to clindamycin. However, all *S. aureus* isolates showed 100% sensitivity to linezolid (100%) and Fusidic acid(100%).

1.0 INTRODUCTION

1.1 BACKGROUND

Injury is a major cause of morbidity and mortality worldwide, involving particularly the young, healthy, and productive population(1). More than 5,000,000 mortalities occur annually from injury with the majority occurring in developing countries(2).

In Kenya and developing countries in general, there has been an increase in incidents of motor vehicle crashes, occasioned by increased ownership and use of motor vehicles and motorcycles, mainly due to factors such as failure to observe road signs, drunken driving, and over speeding(3).

Over the last decade, Kenya has been one of ten priority countries identified by the World Health Organisation for a road safety campaign dubbed Decade of Action for Road Safety which aimed at reducing global road crash injuries and mortality by at least 50%. Kenya was selected by virtue of being one of the ten worst-hit countries which together accounted for about 50% of worldwide road crash fatalities; the other countries being Brazil, Cambodia, China, Egypt, India, Mexico, Russian Federation, Turkey, and Viet Nam. (4).

In Kenya, more than 3,000 people lose their lives due to motor vehicle crash incidents annually, with even more suffering disabilities. Most victims are usually in the prime ages between 15–45. These incidents have an overwhelming cost to the society and economy at large(1,5).

The most susceptible road users in Kenya are pedestrians, cyclists, motorcyclists, motorized threewheeled vehicles, children, and the young and healthy population(6). The cost to the economy from Road Traffic Accidents In Kenya is more than 50 million US Dollars without including the actual loss of life(1).

In a prospective study done by Myers et al at KNH A&E dept in 2017 over 3 months, injuries accounted for about a quarter of all admissions at KNH(7). The burden of orthopedic trauma involving the lower extremity including the foot is on the rise mainly due to motor vehicle crash incidents and causes such as falls other than from vehicles, injuries due to assault, and workplace injuries.

Traumatic injuries to the leg, foot, and lower limb, in general, are regularly seen in accident and emergency departments worldwide. Traumatic foot injuries are typically often associated with significant amounts of skin and soft tissue loss (2), which results in the exposure of muscles, tendons, and bone which often complicates wound care.

The associated loss of this protective barrier coupled with contamination at sites of injury predisposes patients who have sustained these injuries to localized infection that usually complicates definitive orthopedic management. If not kept in check infection stemming from these injuries can result in cellulitis, necrotizing fasciitis ascending infections, potential limb loss, and therefore incapacitation.

The biomechanical complexities of the extremity and the underlying circumstances that cause foot infections contribute to the difficulty in treating these infections. Foot infections either result following contamination by foreign material and/or colonization by bacteria following direct mechanical trauma and loss of tissue(8).

The diagnosis of infection in patients with open foot infection is done primarily on clinical examination. The occurrence of the five cardinal signs of inflammation (edema, erythema, warmth, loss of function, and pain) with the presence of pus or pus discharge should be key to the diagnosis(9,10). Lipsky and Berendt argue that the presence of two or more signs of inflammation or pus should be used as a clinical indication of infection(9,10).

Infection following injuries to the foot may range from superficial cellulitis to deep soft tissue or bone infections that can lead to poor outcomes. The management of such infections has further been complicated by the emergence of antibiotic-resistant strains of bacteria Infection prevention control measures including but not limited to meticulous surgical debridement, are essential to appropriate outcomes. Pseudomonas aeruginosa and methicillin-resistant Staphylococcus aureus have traditionally been considered prevalent pathogens in foot infections. (3)

Obtaining specimen samples from patients with open foot injuries for microbiological culture and susceptibility at KNH may provide valuable information to judicious antibiotic treatment to achieve better outcomes, reduce the length of hospital stay and number of surgical procedures. The understanding of the local prevalence may form a basis for a rationale of initial empiric antibiotic administration in such patients. This study's main objective was to define the prevalence of infection in open foot injuries and related antibiotic susceptibility in a tertiary institution in Kenya, thus availing local data to help develop protocols on the management of infections following such injuries in Kenya.

2.0 LITERATURE REVIEW:

2.1 OVERVIEW OF THE ANATOMY OF THE FOOT:

The foot is an appendage responsible for gait propulsion and locomotion comprising multiple bones, joints, ligaments, tendons, intrinsic and extrinsic muscles.

The inferior of the foot is known as the plantar aspect while the superior aspect is known as the dorsum of the foot. (1)

The foot can be classified into:

The Forefoot – comprising of the metatarsals and phalanges(11).

Midfoot - comprising of the navicular, cuboid, and cuneiform bones; and

Hindfoot – talus and calcaneus(11)

The bones of the foot are also classified into tarsal bones, metatarsals, and phalanges arranged in a complex manner from proximal to distal articulating at various joints. Additionally, the first metatarsal usually has round to oval-shaped bones embedded in the tendon of flexor hallucis brevis known as sesamoid bones(12).

2.2 THE TARSAL BONES:

The foot has a total of seven tarsal bones that articulate with each other forming various joints. The talus articulates with the distal tibia and fibula to form the ankle joint while the heel of the foot is formed by the calcaneus(12).

The calcaneus articulates with the talus superiorly at the subtalar joint and with the cuboid anteriorly forming the calcaneocuboid joint. The talocalcaneonavicular joint forms the articulation between the talus, calcaneus, and navicular bone. The other tarsal bones comprise the medial, intermediate, and lateral cuneiforms(12,13).

2.3 THE METATARSALS:

They are five in number usually counted from the first metatarsal medially with the fifth metatarsal being the most lateral(11,13). Their proximal ends are the metatarsal bases while their distal articular surfaces are known as the metatarsal heads. They articulate proximally with the cuneiform bones to form the Lisfranc joint and with the proximal phalanges at the metatarsophalangeal joints



2.4 PHALANGES:

The phalanges are bones that form the bony skeleton of the toes. The 2nd, 3rd, 4th, and 5th toes all have proximal, middle, and distal phalanges while the great toe only has the distal and proximal phalanges. Every phalanx has a base, a shaft, and a head(11,13).

2.5 FOOT BLOOD SUPPLY AND POTENTIAL ROUTES FOR THE SPREAD OF INFECTION INTO THE DEEP COMPARTMENTS:

A good understanding of foot anatomy is important to understand the route of the spread of infection into the deep fascia and subsequently the deep soft tissue compartments, the bones, and joints of the foot.

The sole is designed mainly for weight-bearing purposes and at the same time offering protection to the underlying structures.

The superficial fascia is made up of dense and fibrous connective tissues. The deep fascia and the plantar aponeurosis have fibrous bands binding them to the skin. The deep plantar space and the superficial plantar space lie deep and superficial to the foot plantar aponeurosis in the sole respectively.

Fig1

The three compartments of the foot comprising the great toe (medial compartment) the small toe (lateral compartment) and the central compartments are formed by vertical septa extending from the aponeurosis. The lateral and medial spaces are of less significance as they rarely get infected.

The foot blood supply is via the anterior tibial and posterior tibial arteries. The dorsalis pedis artery in the dorsum of the foot arises from the anterior tibial artery and terminates as the deep plantar artery. The plantar arch is formed by the deep plantar artery and the arcuate artery, from whence the dorsal digital arteries arise.

Ventrally, the posterior tibial artery divides into a large lateral plantar artery and the smaller medial plantar artery. The common digital arteries arise from the plantar and then divide into 2 plantar digital arteries each. In diabetics, thrombotic obliteration of the plantar digital arteries of the second, third, and fourth toes occurs often. The main nerves of the sole are the lateral and the medial plantar nerves, which are the terminal branches of the tibial nerve. The nerves accompany the respective arteries and veins(14).

2.6 PATHOLOGY:

2.61 TRAUMA:

Foot injuries related to traumatic events such as motor vehicle crash incidents, assaults, workrelated injuries, etc are inherently contaminated. The bacteria that may cause infection vary, depending on the nature, location, and time of the injury. A careful history-taking and physical exam is indispensable in the management of these patients

2.6.2 INFECTION:

There are many definitions of infection. A generally accepted definition of infection is the presence of systemic signs of infection such as fever (temp> 37.5), elevated white blood cells count, purulent discharge, or two or more localized signs and symptoms of inflammation erythema, tenderness, pain, warmth, or induration(9).

The American College of Surgeons [2] defines infection as the product of bacterial invasion into the patient's tissues, with subsequent proliferation, metabolism, and resultant pathophysiological effects.

White et al. [3] described infection as the presence of proliferating bacteria in body tissues, resulting in an inflammatory response and cellular damage caused by microbial toxins or intracellular microbe replication.

FACTORS PREDISPOSING TO INFECTION OF THE FOOT:

OPEN FRACTURES:

Zalavras et al (15) described an open fracture as soft tissue disruption that results in communication of the fracture site with the external environment. Several studies have found that approximately 60 to 70% of open-fracture wounds are contaminated(16–18).

GUSTILO & ANDERSON OPEN FRACTURES CLASSIFICATION:

Type I:

Open fracture with a wound less than 1cm and minimal involvement of the soft tissues without crush component. Is usually a result of an inside to outside injury (the fractured bone punctures the skin from inside). The fracture is usually a short transverse or oblique fracture(15,19).

Type II:

These fractures have wounds 1-10 cm, the soft tissue injury is moderate and the fracture patterns are in general simple with mild comminution, and with adequate bone coverage (15,19).

Type III:

These fractures entail extensive injury of the soft tissue with segmental fracture pattern and comminution is extensive(15,19). They are usually associated with gross contamination. These fractures are further divided into three groups:

Group a) Those with extensive soft tissue injury but bone coverage is sufficient.

Group b) This is marked by exposed bone and periosteal stripping with inadequate bone coverage

Group c) This has an associated vessel injury requiring vascular repair.

Gustillo & Anderson system is still the most commonly utilized as it is uncomplicated, guides management, and predicts outcomes, especially risk for complications. Generally, the greater the score, the more the involvement of soft tissue and bony injury, and the more the risk of poor results, most commonly deep infection. The risk of infection for type I injuries come close to the same

rates as those of closed injuries, the infection rate for type iii fractures can vary from 10% to 50%(18).

OSTEOMYELITIS:

A Common sequel of open fractures is osteomyelitis. Osteomyelitis is an infection of the bone that can involve the periosteum, cortex, and medullary cavity. A variety of bacteria can cause osteomyelitis, with the commonest cause being S.aureus. Bacteria may reach the bone through direct inoculation from an open fracture or via the bloodstream (20). Intravenous antibiotics are usually given for 4–6 weeks for the treatment of osteomyelitis (Waldivogel et al., 1970)

Chian Guan Lee et al defined osteomyelitis as the finding of at least 3 out of 4 of cellulitis, deep tissue positive bacteriologic culture, a positive histological diagnosis, or positive radiological findings. Lee et al also defined osteomyelitis as the presence of at least two out of the following five findings: probing to the bone, bone exposure, a wound diameter greater than 2 cm, presence of cellulitis, and a wound with no cellulitis but a raised ESR of more than 70 mm/hr (20).

SOFT TISSUE INJURIES:

Valderrama-Molina et al did a prospective study to establish interobserver concurrence on Tscherne classification for injuries of the soft tissues and concluded that the O&T classification could be used as a benchmark and to guide management of patients with soft tissue injury and to carry out research work (21).

OESTERN & TSCHERNE CLASSIFICATION:

Oestern and Tscherne categorized soft tissue injuries into four categories based on the size of the wound, fracture pattern, and the degree of contamination.

Grade One: Those with a small puncture injury associated with no muscle contusion and no significant bacterial contamination. Grade one wounds are usually a result of low-energy injuries. (22,23).

Grade Two: There is a small skin laceration, negligible soft-tissue contusion, and associated mild bacterial contamination, with no major vessel or peripheral nerve injury. Grade ii injuries can be a result of several types of mechanisms of injury (21–23).

Grade Three: includes large cut wounds or lacerations that have gross contamination with extensive soft tissues injury. Grade three injuries often have an associated vascular or nerve injury.

Grade four injuries have a partial or total amputation with variable outcomes dependent on the size and type of injury(21–23).

According to the International Society for Reconstructive Surgery Replantation Committee, injuries where all important anatomical structures are involved and with less than a quarter circumference of the remaining limb tissue bridge are categorized as grade four (24).

For this study, both the Gustillo & Anderson equivalent and Oestern and Tscherne classifications will be used for open fractures and soft tissue injuries of the foot respectively.

PUNCTURE WOUNDS OF THE FOOT:

Trauma caused by puncture wounds involves mostly the plantar aspect of the foot. The rates of developing osteomyelitis range from 0.04 to 1.60 percent following such injuries(25). Several complications may arise from these injuries ranging from superficial cellulitis to abscesses. Abscesses may involve bone, tendon, deep fascia, muscles, and joints and in worst-case scenarios may lead to ascending infection, bacteremia, and sepsis. The degree of involvement is an important characteristic that could determine whether the infection will resolve without the need for complex intervention(25).

Patzakis et al demonstrated three zones in the plantar aspect of the foot and the risk for developing osteomyelitis or pyoarthrosis in these zones(26).

Zone One includes the region overlying the heads of the metatarsals extending to the distal aspect of the toes. This region has minimal tissue coverage. This is a key weight-bearing area and bears the greatest risk of developing Osteomyelitis(26).

Zone Two includes the region from the distal calcaneus extending to the metatarsal necks. This area has adequate soft tissues with no involvement in weight-bearing and has minimal risk of being involved in the development of deep tissue infections.

Zone Three is the area overlying the calcaneus. This is a major weight-bearing area and is also at high risk despite having a thick coverage(26).

8

The organisms most commonly involved in puncture wounds are mainly Staphylococcus aureus and beta-haemolytic streptococci with P. aeruginosa being the main isolate in puncture wounds through shoes and other footwear. Osteomyelitis developing from puncture wounds usually involves P. aeruginosa with or without Staph aureus. S.epidermidis, E.coli, and K.pneumoniae. are other gram-negative bacteria that have been implicated(26).

Several authors advocate for radiological imaging in all puncture wounds. In the first ten to fourteen days following injury, radiologic results are usually negative except in cases of ingrained radio-opaque matter. Plain radiographs are less sensitive compared to bone scans and should therefore be used for wounds with infection manifesting four to five days after injury(26).

CELLULITIS:

Cellulitis is defined as a bacterial infection of the skin and subcutaneous tissues (8). It may result from abrasions, puncture wounds, cuts/lacerations, or other such factors that may cause trauma to the foot. The commonest contaminants in cellulitis are S.aureus and Group A streptococci from the normal flora of the skin. Lymph node involvement, lymphangitis, and contiguous spread to adjacent bony structures, deep structures, and tissue planes are common complications of cellulitis (8)

TENDOVAGINITIS:

Anatomically, the tendon is enclosed by a structure known as the paratenon which is further surrounded by a layer of connective tissue known as the tendon sheath. It is thought that bacteria may spread proximally or distally between these two structures and that the tendon movements may enhance this bacterial spread through a "massage effect."(8)

It is thought that the paratenon may have a protective role in tendon infections, and when this anatomical structure is violated, an infection may spread along the length of the tendon fibre. Movement of the tendon precipitate "massaging," which promotes the bacterial spread to other areas of the tendon fibres. Tendon necrosis may involve a single tendon fibre or may involve several tendon fibres(8).

DEGLOVING INJURIES:

These injuries result from a shearing force applied on the skin that results in the undermining and elevation of the skin through a subcutaneous tissue plane. This results in either an intact or a

completely avulsed flap. Degloving injuries are potentially serious injuries that can result in significant infection(8).

The involvement of anaerobic bacteria should be suspected given that these injuries generally occur in contaminated settings such as motor vehicle crash incidents. Replacing an intact tissue flap over the lesion should be done to allow demarcation to take place. After obtaining well-defined margins, debridement of the non-viable tissue is done, with the aim for definitive reconstruction using STSG while others may require flap coverage e.g. a rotational flap(8).

CRUSH INJURIES OF THE FOOT:

These injuries are frequently secondary to trauma to the foot, occurring mostly due to road traffic accidents and work-related circumstances.

These may range from skin lacerations, contusions, fractures, vascular disruption, or traumatic amputations or combinations thereof. When the digits are involved, the nail bed is usually a lacerated nail with an underlying phalanx fracture. These injuries are managed as open fractures(8).

2.7 PREVALENCE OF FOOT INJURIES AND INFECTIONS:

A prospective cohort study done in Uganda by Lekuya et al, on degloving injuries with fractures and those that did not have an underlying fracture in a tertiary hospital in sub-Saharan Africa found that 84% were due to motor vehicle crashes with the lower extremities (56.14%) was the most involved anatomical site of degloving injury.45.1% of these injuries were associated with an underlying fracture. The most performed surgical procedures were a series of debridement (22%) and surgical removal of an avulsed flap (14%). This same group had about 4 times higher risk of poor outcomes, primarily infection after 30 days and a longer duration of hospital stay of 26 +/-31days (27).

Vuhaka et al did a cross-sectional study at Mulago Hospital in Uganda in 2012 on the prevalence of traumatic foot injuries. In that particular study, the prevalence of traumatic foot injuries was found to be 10.8% with 63.3% being open foot injuries (28).

Amin et al did a retrospective study in 2012 on orthopedic trauma involving motorcycle crash incidents seen at an A&E department at a Level I Trauma Centre at The Drexel University College in the US. 71.5% out of 151 patients involved in motorcycle collisions needed an orthopedic

consultation. The average age was 35.0 years, and the male-to-female ratio was 8:1. Motorcycle versus automobile (48) was the commonest mechanism of injury. 206 fractures in 108 patients were identified mostly involving the lower extremities. 57 patients (52.8per cent) had open fractures of various types that needed emergent orthopedic intervention(29).

A study done at KNH in 2020 by Macharia et al reported that P. Aeruginosa was the commonest isolate in patients presenting with open fractures of the appendicular skeleton in 21 patients(34%) followed by S. Aureus(20%) in 12 patients. 14% of these cases were open foot and ankle injuries(54).

In a study done in 2016 in Australia by Lazarinni et al on the point prevalence, and the related independent factors for the overall inpatient foot burden including infections, ulcers, and ischemia in a representative hospitalized population, it was found that 11.8% of all patients had a major foot condition present. 2.3% of these patients had acute foot wounds and 1.9% had new amputation procedures(30).

Wiersema et al did a retrospective study on the incidence of infection and rates of amputation in patients presenting with open calcaneal fractures. 115 open fractures of the calcaneous were identified. 71 of the patients were of the male gender while 56 were of the female gender. The mean age was 39.7 years. 58% of the injuries were due to falls followed by 21% motor-vehicle crash incidents. Classification of open calcaneal fractures was done using the Gustillo-Anderson classification system. Out of the 115 fractures, 27(23.5%)had either an infection or developed wound necrosis (31).

Pollak et al, did a multi-centered prospective cohort study in Texas, The USA in 2010 involving eight level-I trauma facilities for the management of limb-threatening trauma to the lower extremity. The study's main objective was to determine the relationship between the duration before a debridement procedure and the Incidence of Infection following open high-energy trauma to the Lower Extremity. The Inclusion criteria were Type-IIIB, IIIC, and selected IIIA Gustilo tibial, pilon, foot, and ankle fractures that were classified by the surgeon as limb-threatening injuries. The study established that patients who were transported to a trauma centre within three hours following admission to the first hospital had a tendency towards lower infection rates than the ones who were transferred to the trauma treatment centers eleven to twenty-four hours following the injury. The study also established that the differences were not related to the injury

severity, patient characteristics, or the type of treatment. These findings suggested that transfer to an institution for an extensive limb-salvage procedure should be accelerated if this was deemed necessary for the definitive management of an open lower extremity high-energy fracture(32).

A case-control study by Lavery et al in 1995 at The University of health science centre San Antonio on infected penetrating foot injuries showed that non-diabetics had pseudomonas aeruginosa as the commonest involved organism that resulted in osteomyelitis while polymicrobial infections were common in diabetics(33).

Lavery et al did a prospective cohort study in 2009 in which 1666 diabetic patients were followed up at a health care outpatient facility in Texas. 9% (151 patients) developed foot infections. All except one infection occurred due to penetrating injury or in the setting of a wound with most infections involving the soft tissues only.20% of patients had osteomyelitis that was proven from bone culture(34).

McNeil et al did a retrospective study at the Baylor College of Medicine, Houston, in the USA in 2018 on Osteoarticular Infections after open trauma in children. The study identified cases from the inpatient database as seen from January 2011 to December 2016. Trauma-related osteoarticular infections cases were the ones that developed joint infections following a history of an open fracture, penetrating trauma, traumatic amputation, or crush injury. Recurrent infections, chronic osteoarticular infections, 34 met the inclusion criteria. Eleven cases (32.4%) of TROAI were due to penetrating trauma to the foot. The median time from injury to the presentation at a health care facility was 15 days. Septic arthritis of the ankle or metatarsophalangeal joints was present in four patients. The most frequent isolate was S. aureus in 3 out of the 11 cases (27.3%) with one case being MRSA. 18.2% (2) of the cases were polymicrobial with an additional two cases having mycobacteria isolated from pure culture. A single case had Pseudomonas aeruginosa isolated and three cases (27.3%) were culture-negative(35).

A COMPARISON OF ORGANISMS ISOLATED FROM PATIENTS WITH DIABETIC FOOT ULCERS:

Young et al, USA, Colorado University, Denver between July 1, 2012, and December 31, 2013, did a cross-sectional study on diabetic patients presenting with a foot infection to an urban hospital. All of the patients had bone or tissue cultures obtained from bedside debridement or debridement

in the operating room. In this particular study, the most common isolates were streptococcus species and Staph aureus with *Pseudomonas aeruginosa* being isolated in only 4.5% of patients(36).

Kim et al 2020 did a study in the USA at The Maryland University School of Medicine in Baltimore on the local prevalence and potential risk factors of P.aeruginosa, methicillin-resistant Staphylococcus aureus, and other bacteria isolated from diabetic foot ulcers. The study found that methicillin-resistant Staphylococcus aureus was not as prevalent as the 10%–20% literature values while P.aeruginosa was more prevalent (5%–10%). The only risk factor significantly associated with methicillin-resistant Staphylococcus aureus diabetic foot infections was a history of prior methicillin-resistant Staphylococcus aureus-associated infection (37).

Lavery et al, did a retrospective study in the USA in 2014 which looked at the risk factors for Methicillin-Resistant Staph Aureus in diabetic foot ulcers. The prevalence of S.aureus in diabetic foot ulcers was 42.1%. Out of these, 70% were resistant to methicillin; the overall prevalence of methicillin-resistant S.aureus in diabetic foot infections was 29.8%. Nasal colonization by methicillin-resistant Staphylococcus aureus, a history of methicillin-resistant Staphylococcus aureus foot infection, and multidrug-resistant organisms were identified as risk factors for Methicillin-Resistant Staph Aureus diabetic foot infections (38).

A prospective study in India by Sivanmaliappan et al aimed to establish the antimicrobial sensitivity of P. aeruginosa from patients with diabetic foot ulcers attending tertiary care institutions by collecting pus swab specimens for m/c/s from 2006 June to 2007 April. The study conducted sensitivity for 15 dissimilar antibiotics for the isolated 18 strains of P. aeruginosa from 270 diabetic foot infections isolated most of which displayed some degree of resistance to the antibiotics used. MDR was observed among 55.5% of the isolates to 8-11 antibiotics. Disk diffusion technique results showed complete resistance to erythromycin, norfloxacin, cefoperazone, ampicillin, and only cefotaxime and ciprofloxacin, exhibited superior antibiotic activity against P.aeruginosa(39).

Illgner et al did a retrospective study in 2013 in Germany, to determine the duration of hospital stay and the number of surgeries for infection with p.aeruginosa versus infection with other bacteria in patients with Charcot foot arthropathy. The study found that P.aeruginosa infections resulted in a longer duration of hospital stay and more surgical procedures compared to other

bacterial isolates. For instance, MRSA infection rates were15.2% compared to those of P.aeruginosa 17.7%. Patients who had a deep infection due to P.aeruginosa had a significantly longer hospital stay (52 compared to 35 days) and needed considerably more surgical procedures (1.71 operations compared to 1.28)(38).

THE ROLE OF MAGGOT THERAPY AND COLONY-STIMULATING FACTOR:

A Randomized Controlled Trial done in Tehran, Iran by Malekian et al in 2019, on the Efficacy of Maggot Therapy(Lucilia sericata Sterile larvae) on P.aeruginosa and S.aureus in diabetic foot ulcers. The study involved 50 patients. 44 out of 50 diabetic foot ulcers were found to be infected, 18 with S.aureus, and 16 had P.aeruginosa infection. Following maggot therapy, the number of infections due to S.aureus was found to have significantly reduced 48 hours following initiation of maggot therapy while those of P.aeruginosa were found to have significantly reduced after 48 hours(40).

Yonem et al (2001) did a randomized controlled trial at The Gulhan School of Medicine in Turkey on the outcome of Granulocyte-Colony Stimulating Factor (G-CSF) in the management of diabetic foot ulcers involving a group of 30 diabetic foot patients. 15 patients (standard group) were put on standard treatment that consisted of antibiotics and local wound care, and the other 15 patients (G-CSF group) were put on standard treatment and G-CSF. The aim was to evaluate the duration of the resolution of infection, compare the length of hospital stay, the outcome of G-CSF on neutrophil function, and the requirement for an operative procedure. The study established that while G-CSF administration resulted in increased absolute neutrophil numbers and an improved neutrophil function, this improvement was not associated with a decrease in the period of antibiotic administration, length of hospital stay, or necessitation for amputation in patients with diabetic foot ulcers (41).

2.8 DIAGNOSING INFECTION:

Mutonga et al did a study from September 2017 to August 2018 at KNH comparing standard microbiological tests vs polymerase chain reaction (PCR) in isolating S.aureus in diabetic foot ulcers. The study found that over 90% of the diabetic foot ulcers were infected with staph aureus being the most major isolate. However, the study failed to explain the uncharacteristic amplification for MRSA in samples that were both culture and polymerase chain reaction negative for S.aureus(42).

Weiner et al did a study to distinguish between the accuracy of microbiology compared to histology in Identification of osteomyelitis in patients with diabetic foot ulcers. The study found that there was no significant difference in the ability to diagnose Osteomyelitis using either histology or microbiologic tests. Weiner et al argued that a practitioner can sufficiently diagnose Osteomyelitis with histology or microbiology with comparable results(43).

2.8.1 SIGNIFICANCE OF MICROORGANISMS IN WOUNDS:

It has been well-documented that the soft-tissue local defenses in a wound can efficiently eradicate inoculums of as many as 100,000 organisms/g of tissue without developing an infection. The local defenses are, however, overwhelmed when a greater amount of bacteria are present, and this will most likely result in an infection. In 1988, Merritt argued that the level of bacterial contamination determines whether or not a compound fracture progresses to infection(44).

Robson and Heggers, in work spanning more than thirty years, observed that acute or chronic wound infection is present when the microbial load is 100,000 colony forming units per gram of tissue(45).

In addition, Bendy et al. described the clinical significance of the microbial load in prolonged wound healing. Quantification was done using superficial wound swab samples in that particular study. They observed that healing in bed sore ulcers improved only when the bacterial load was 10,000,000 colony forming units /ml of wound fluid.

More recently, Breidenbach and Trager demonstrated that a crucial bacterial load of 10,000 colony-forming units per gram of tissue must be attained to cause infection in complex wounds of the extremities, and that tissue cultures were more effective in predicting the likelihood of developing an infection in wounds than swab cultures.

2.9 STUDY QUESTION:

What is the prevalence of bacterial infection of open foot injuries and the associated antibiotic susceptibility of isolates at the Kenyatta National Hospital?

2.9.1 BROAD OBJECTIVE:

To determine the prevalence of bacterial infection in patients with open foot injuries at The Kenyatta National Hospital.

2.9.2. SECONDARY OBJECTIVE:

To determine the antibiotic susceptibility of isolates from patients with open foot injuries at The Kenyatta national hospital.

2.9.3 STUDY JUSTIFICATION:

Although associated with low mortality, foot injuries are associated with high morbidity and need timely evaluation and management to prevent long-term disability.

The prevalence of infection in open foot injuries in Kenya has not been well documented. There are no local studies in Kenya with regards to the prevalence of infection of open foot injuries and antibacterial susceptibility thus no adequate data on these.

With sufficient data on the prevalence of infection of open foot injuries at the Kenyatta National Hospital and the associated antimicrobial susceptibility, adequate measures can be instituted to minimize infection, and associated morbidity and mortality.

This study aimed to provide information on:

- The prevalence of infection of open foot injuries at the Kenyatta National Hospital,
- The bacteriology of infections,
- The bacterial antibiotic sensitivity.

The above information can then be utilized to inform clinical decisions and help develop protocol, strategies, policy, and treatment algorithms that will help guide the treatment of these patients in a standardized and cost-effective manner.

3.0 STUDY MATERIALS AND METHODS:

3.1 STUDY DESIGN:

A Cross-Sectional descriptive study.

3.2 THE STUDY SETTING:

The study was carried out in the A/E department, Orthopedic wards, clinics, and operating theatres at the Kenyatta National Hospital.

3.3 STUDY DURATION:

1st Feb 2021 to 31st May 2021

3.4 STUDY POPULATION:

All patients with open foot injuries aged 18 years and above and who met the inclusion criteria were included in the study. Informed consent was obtained from each patient or the next of kin for those unable to give consent. Each patient had their demographic data including age, sex, and co-morbidities recorded in the questionnaire designed by the principal investigator.

3.5 INCLUSION CRITERIA:

1. Adults patients aged 18-65 years who had open foot injuries.

3.6 EXCLUSION CRITERIA:

Patients who failed to consent to the study.

Patients already receiving tailored antibiotics based on tailored m/c/s results.

3.7 RECRUITMENT AND SAMPLING STRATEGY:

Approval to carry out the study was sought from the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee (KNH-UoN ERC). Once the relevant approval to carry out the study was obtained, patients who met the eligibility criteria and gave written informed consent were enrolled into the study using convenient sampling until the desired sample size was achieved.

Information regarding patients' demographic data, including age, sex, Nationality, duration of diagnosis, co-morbidities, and details of previous medical and surgical therapies and clinical features such as type of wound, wound size, location of the lesion were collected.

SPECIMEN COLLECTION AND HANDLING PROTOCOLS:

Sterile cotton swabs moistened with sterile Amies transport medium (composed of -3.0gm/l Sodium chloride, 0.2gm/l Potassium chloride, 0.1gm/l Calcium chloride, 0.1gm/l Magnesium chloride, 0.2gm/l Monopotassium phosphate, 1.15gm/l Disodium phosphate, 1.0gm/l Sodium thioglycolate , 10.0gm/l Charcoal, and 4.0 gm/l Agar) that maintained the viability of collected microbes were used for deep pus swab collection.

All culture media were checked visually beforehand for contamination, significant physical imperfections (e.g. uneven distribution of media, colour, gross deformation of the surface on the media), and expiry date. Culture media had an identifiable batch or quality control number and had passed QC tests before use.

Sample collection was done at the point of contact with the patient. The infected wound area was cleaned using sterile gauze soaked in normal saline after donning a pair of sterile gloves and draping the wound area; a deep pus swab and tissue culture samples were collected from the deepest part of the wound avoiding contamination by superficial microflora. The swab was well applied in the centre of the wound while tissue for culture was collected utilizing sterile tissue forceps from a sterile wound care kit. The swab and tissue culture samples were then placed in a specimen collection tube with Amies transport media provided by the lab, sealed in a tight polythene bag. The samples were transported to the microbiology lab within an hour of sample collection. This was due to the fact that the recovery of anaerobes would be compromised if the transport time exceeded 3hrs. They were delivered to Lancet Pathology Labs at Fifth Ngong Avenue and this was facilitated by a dedicated courier service. The samples were received and recorded as per date, time, and number of samples. Serial numbers were assigned and sent for processing. The lab personnel were blinded as to the source of the sample.

The samples were streaked on the culture media immediately they reached the microbiology lab by a trained microbiologist and incubated at 37 degrees Celsius for 24 hours under controlled conditions. Sheep blood agar and MacConkey agar were used. Inspection was done after 24 hours of incubation. Further processing was done in those specimens that had bacterial growth. For those that didn't show bacterial growth, re-incubation was done for an additional 24 hours.

After 48 hours both quantitative and qualitative analysis was done. Isolated organisms were then counted as Y number of colonies per plate.

Antimicrobial SUSCEPTIBILITY was done on samples that had obtained bacterial growth. The Drugs of choice used were the following as is usually the case for common laboratory isolates.

The collected specimen was inoculated into 5% Sheep Blood Agar and Maconkey without CV and incubated at 37 degrees Celsius for 24 hrs.

ANTIBIOTIC DISKS & AMOUNT OF ANTIBIOTIC USED:

AMINOGLYCOSIDES:

AMIKACIN- 30 micrograms

GENTAMICIN - 10 micrograms

TOBRAMYCIN - 10 micrograms

CLINDAMYCIN- 2 micrograms

CEPHALOSPORINS:

CEFUROXIME- 30 micrograms

CEFEPIME- 30 micrograms

CEFTAZIDIME- 30 micrograms

CEFTRIAXONE- 30 micrograms

FLUOROQUINOLONES:

CIPROFLOXACIN- 5 micrograms

PENICILLINS AND MONOBACTAMS:

PIP-TAZOBACTAM- PIPERACILLIN 100 micro grams/TAZOBACTAM - 10 micrograms (PTZ

- 110 micrograms)

CARBAPENEMS:

IMIPENEM - 10 micrograms

MEROPENEM - 10 micrograms

DORIPENEM - 10 micrograms

CARBAPENEM ETEST (MEROPENEM/IMIPENEM MICs)

MICs were done in case of carbapenem resistance.

QUALITY ASSURANCE:

The specimens were delivered to Pathologists Lancet Kenya laboratories at Upper Hill, 5th Ngong Avenue along Ngong Road, Nairobi. To ensure reliability and validity of the tests, the lab did monthly External Quality Control Tests by running lyophilized Quality Control samples for growth, identification, and sensitivity of bacteria.

3.8 SAMPLE SIZE:

Kenyatta National Hospital has 3 orthopedic wards that each with approximately 10-12 patients with orthopedic foot infections. The study envisaged a recruitment period of 12 weeks which was projected to result in a study population of 40-60 patients.

3.9 SAMPLE SIZE DETERMINATION:

Sample size calculation was done using the Cochrane formula;

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

Where,

n = The desired sample size

Z = the value from std normal distribution that corresponds to desired confidence level (Z=1.96 for 95% CI)

P = expected true proportion (estimated at 6.7%, from a study done by Sivanmaliappan T.S. et al., in Coimbatore, India; looking at antimicrobial susceptibility patterns of P. aeruginosa from DFU patients, found 18 of the 270 pus specimens (6.7%) were found to be P. aeruginosa(39).)

d = desired precision (0.05)

$$n_0 = \frac{1.96^2 x \, 0.067(1 - 0.067)}{0.05^2} = 96$$

It was estimated that approximately 60 patients were expected to be seen at the Kenyatta National Hospital with foot injuries within the study period of 3 months. Adjusting the sample size for finite populations less than 10,000

$$\mathrm{nf} = \frac{\mathrm{n_0}}{1 + \frac{\mathrm{n_0} - 1}{\mathrm{N}}} = \frac{96}{1 + \frac{96 - 1}{60}} = 37$$

A Sample size of 37 patients was required for the study.

3.10 PATIENT IDENTIFICATION:

Demographic details of the patients were recorded using a structured questionnaire developed by the principal researcher. The questionnaire was administered to each patient once informed consent had been given. Information acquired during the follow-up days of the study was also recorded in the questionnaire. (Appendix 7.1)

3.11 DATA COLLECTION TOOLS AND ANALYSIS:

Data was coded, entered, and managed in a Microsoft Access database and later exported to SPSS version 25 for analysis.

Demographic and clinical data were analyzed and presented as frequencies and proportions for categorical data and as means with standard deviations for continuous data or as median with an interquartile range where applicable. The prevalence of bacterial infection in patients with open foot injuries was calculated as a proportion of patients with positive growth over the total sample size and reported as a percentage. The antibiotic susceptibility of isolates from patients with open foot injuries was analyzed and presented as frequencies and percentages.

3.12 ETHICAL CONSIDERATIONS AND APPROVAL:

Approval to proceed with the study was sought from the KNH/UoN Ethics and Research Committee.

Patients who met the inclusion criteria and had given a written informed consent were recruited into the study. The principal investigator clarified that involvement in the study was voluntary and not taking part would have no bearing on patient management. The consent form had brief information on the study; explaining the study purpose and the procedure to be followed and the potential risks and gains of participating in the study. It also contained information on safeguarding the participant's privacy and the sharing of the study's findings. The investigator conducted the consent discussion and confirmed that the patient understood the information provided on the consent form.

Any pertinent questions regarding the study from the patient were answered at this point before signing the consent form. Consent obtained was voluntary and free from coercion.

Data was then collected utilizing a questionnaire and physical exam. Deep tissue swab and tissue culture Specimens for m/c/s were then taken from all patients who had given informed consent.

3.13 STUDY LIMITATIONS:

Patients opting out of the study.

3.13.1 STUDY DELIMITATIONS:

Adequate patient education was done before enrolment.

3.14 DISSEMINATION OF THE STUDY FINDINGS:

The findings of the study will be disseminated in a three-tier fashion. One copy of the published dissertation will be kept at the department of orthopaedics, University of Nairobi. Another one will be placed at the university library. The findings will also be shared through publication in a peer-reviewed journal.

4.0 RESULTS:

There were 37 patients in this study out of which 32 (86.5%) were male, and 5 (13.5%) were female patients. The mean age of the patients was 33.8 (SD 8.6) years, and the youngest patient was 21 years while the oldest was 55 years. The most common mode of injury was due to road traffic accidents 31(83.8%). The results are as shown in Table 1.

Gender	Frequency (n=37)	Percentage
Male	32	86.5
Female	5	13.5
Age	Frequency (n=37)	Percentage
21-30	15	40.5
31-40	12	32.4
41-50	9	24.3
51-60	1	2.7
Mode of injury	Frequency (n=37)	Percentage
Falling object	2	5.4
Road traffic accidents (26 involving motorcycles, 5 other not motorcycle-related RTAs).	31	83.8
Workplace injury	4	10.8

Table 1.0: Characteristics of the patients

The mean duration before presentation was 15.1 (9.4) hours, and the minimum duration observed was 6 hours, while the highest being 48 hours. Degloving injuries involving the foot were the commonest injuries 24(64.9%) with the dorsum 26(70.3%) being the commonest involved site.

Duration before presentation (hours)	Frequency (n=37)	Percentage
≤12	20	54.1
13-24	14	37.7
25-48	3	8.1
Type of foot injury	Frequency (n=37)	Percentage
Achilles tendon tear	2	5.4
Crush injury 1 st ,2 nd ,3rd Middle & distal phalanges	1	2.7
Crush injury 3 rd ,4 th Mid & distal phalanges	1	2.7
Deep cut wound with fracture of distal phalanx great toe	2	5.4
Degloving injury foot	24	64.9
Degloving plus 2 nd , 3 rd Metatarsal fracture	1	2.7
Degloving with fracture phalanges	2	5.4
Open fracture phalanx	1	2.7
Open 1 st &2 nd Metatarsal	1	2.7
Traumatic amputation	1	2.7
Traumatic disarticulation	1	2.7

Table 2.0: Characteristics of injury

Table 3.0: Site of injury

	Frequency (n=37)	Percentage
Dorsum	26	70.3
Dorsum and plantar	7	18.9
Heel	2	5.4
Plantar	2	5.4

Table 4.0: O and T classification:

	Frequency (n=37)	Percentage
2	3	8.1
4	4	10.8
N/A	30	81.

Table 5.0: Gustillo equivalent

	Frequency (n=37)	Percentage
1	1	2.7
2	13	35.1
N/A	23	62.2

Only 4 patients had co morbidities. 3(8.1%) patients had hypertension and only 1(2.7%) had diabetes mellitus. This is shown in the table below:

	Frequency (n=37)	Percentage
DM	1	2.7
HTN	3	8.1
None	33	89.2

Table 6.0: Co morbidity
Table 7.0: Substance use

Out of the 37 patients recruited in the study 9(24.3%) were smokers while 28(75.6%) were nonsmokers.11 patients (29.7%) consumed alcohol while 26(75.6%) had no history of alcohol consumption. This is represented in the table below:

Smoking	Frequency (n=37)	Percentage
Yes	9	24.3
No	28	75.7
Alcohol	Frequency (n=37)	Percentage
Yes	11	29.7
No	26	70.3

 Table 8.0: Antibiotic and dosage received before sample collection:

Antibiotic	Frequency (n=37)	Percentage
Cefazolin 1g twice a day for 3 days	7	18.9
Cefazolin 1g twice a day for 48 hrs	2	5.4
Cefazolin 1g twice a day for 5 days	4	10.8
Cefazolin 1g twice a day for 7 Days	1	2.7
Ceftriaxone 1g twice a day for 24 hrs	2	5.4
Ceftriaxone 1g twice a day for 3 days	3	8.1
Ceftriaxone 1g twice a day for 48 hrs	9	24.3
Ceftriaxone 1g twice a day for 5 days	9	24.3

Table 9.0: MCS results:

Bacterial growth was obtained from 32 out of the 37 patient samples. No growth was obtained from 5 patients (11.36%). The prevalence of bacterial infection was thus 86.5%. The commonest isolated organism was P.aeruginosa 11 (25%) followed by S.aureus 7(15.9%) with 5(71.4%) isolates being coagulase-negative and 2(28.6%) being MRSA.P.mirabilis was the 3rd most

common isolated organism 6(13.6%). Other isolated organisms and their frequencies are shown in table 6.0 below.

Bacterial Isolate		Frequency (n=44)	Percentage
P. aeruginosa		11	25.0%
S. aureus		7	15.9%
Coagulase-negative S.aureus	5(71.4%)		
MRSA	2(28.6%)		
P. mirabilis		6	13.6%
ESBL Negative	5(83.3%)		
ESBL Positive	1(16.7%)		
No growth isolated		5	11.4%
E.coli		3	6.8%
A.baumanii		3	6.8%
E. cloacae (Beta-Lactamase positive)		2	4.5%
P.vulagaris		2	4.5%
Providencia. rettgeri Beta-Lactamase p	ositive	1	2.3%
E. fecalis		1	2.3%
Bacillus spp		1	2.3%
Serratia.marcescens		1	2.3%
K. pneumonia		1	2.3%

Table 10.0

Bacterial growth was obtained from 32 out of the 37 patient samples. No growth was present in 5 patients (13.5%). The prevalence of bacterial infection was 86.5%. This is shown below.



Figure 1.0: Prevalence of bacterial infection



Fig 2.0 A bar graph depicting the frequency of isolated bacteria

The highest number of colonies per plate was 66.2 (38.0) cfu/plate, and the minimum number of colonies per plate observed was 24 CFU/plate, while the highest being 210 CFU/plate.

	Frequency (n=44)	Percentage
≤ 50	14	37.8
51-100	19	51.4
>100	4	10.8

Table 11.0: Number of colonies per plate:

Table 12.0: Sensitivity results:

The most prevalent of the isolates was P. Aeruginosa of which the results of the sensitivity tests indicating that all the strains isolated were 100% sensitive to piperacillin-tazobactam, cefepime, ceftazidime, meropenem, imipenem, doripenem, amikacin, gentamicin, tobramycin, and ciprofloxacin. None of the isolated strains showed any resistance to the tested antibiotics. The sensitivity findings are shown in tables 12.0 and 13.0 below.

	N	Vancomycin	Linezolid	Fusidic acid	Cefuroxime	Ceftazidime	Ceftriaxone	Cefepime	Ampi/amoxicillin	Amox-clav	PIP-TAZ	Ertapenem	Doripenem	Imipenem	Meropenem	Amikacin	Gentamicin	Tobramycin	Cipro	Cotrimoxazole	Clindamicin
A. baumanii	2												2	1	2	1					
E. cloacae (AMP C positive)	2											1	1	2	2	1				1	
E. coli	3				1		1	1		1	1	2	3	3	3	3	1	1	1	1	
E. fecalis	1	1	1						1								1				
K. pneumoni ae	1				1		1	1		1	1	1	1	1	1	1	1		1	1	
P. aeruginos a	1 1				1 1	1 1		1 1			1 1		1 1	1 1	1 1	1 1	1 1	1 1	1 1		
P. mirabilis	3				2		2	2	1	2	2	3	3		3	3	2		2	1	
P. mirabilis ESBL negative	2				2		2	2		2	2	2	2		2	2	2		2		
P. mirabilis ESBL positive	1											1	1		1	1					
P. rettgeri AMP C positive	1							1			1	1	1	1	1	1			1		
P. vulgaris	2				2		2	2	1	2	2	2	2		2	2	2		2	2	
S. aureus	2		2	2					2	2							2			2	2
S. aureus coagulase negative	3		3	3													2				
S. aureus MRSA	2	2	2	2																1	
S. marcesce ns	1							1			1	1	1	1	1	1	1		1	1	

Table 12.0: Sensitivity against commonly used antibiotics:

	n	Fusidic acid	Cefuroxime	Ceftazidime	Ceftriaxone	Cefepime	Ampi/amoxicillin	Amox-clav	PIP-TAZ	Ertapenem	Imipenem	Meropenem	Amikacin	Gentamicin	Tobramycin	Cipro	Cotrimoxazole	Clindamicin
A. baumanii	2			1		2			2				1	2	1	2		
A. baumanii (multi-resistant gram negative bacillus)	1			1		1			1		1	1	1	1	1	1		
E. cloacae (AMP C positive)	2		2		2	2	2	2	2					1		1	1	
E. coli	3		2		2	2	3	2	2	1				2		2	2	
K. pneumonia	1						1											
P. mirabilis	3		1		1	1	2	1	1					1		1	2	
P. mirabilis ESBL negative	2						2										2	
P. mirabilis ESBL positive	1		1		1	1	1	1	1					1		1	1	
P. rettgeri AMP C positive	1		1		1		1	1						1			1	
P. vulgaris	2						1											
S. aureus coagulase negative	3						3	3	3					1			2	2
S. aureus MRSA	2						2	2						2				1
S. marcescens	1		1		1		1	1										

Table 13.0: Resistance against commonly used antibiotics

5.1 DISCUSSION:

Traditionally the most prevalent pathogens in foot infections have been P. aeruginosa and *Staphylococcus aureus* (3). Road traffic accidents (RTA) mainly involving motor vehicles and motorcycles are the biggest culprit behind most open foot injuries, and these types of injuries are usually associated with contamination at the site of injury that results in infection mostly by bacteria.

Among the patients who had open foot injuries enrolled in this study, the prevalence of bacterial infection stood at 86.5%. The study noted that most of the patients were of a young and productive age and that most of their injuries were as a result of being involved in an RTA (83.8%). Motor-cycle-related injuries were the highest at 67.7% of the RTAs. This finding is comparable to a retrospective study by Amin et al whose findings revealed that the mean age of the patients was 35.0 years which compares well with this study of which the mean age was 33.8 years. The study by Amin also showed that the ratio of male to female involvement was 8:1 which is more or less comparable to this study of 6.4:1. Also of note was that motorcycle involvement was the commonest mechanism of injury (29), which compares well to this study.

The results of this study show that *P. aeruginosa*, *S. aureus*, *P. mirabilis*, *E.coli*, *A.baumanii*, *E. cloacae*, *P.vulagaris*, *Providencia*. *rettgeri*, *E. fecalis*, *Bacillus spp*, *Serratia.marcescens*, *K. Pneumonia* are found in infected open foot injuries.

Pseudomonas aeruginosa, a common cost of nosocomial infections, was the predominant isolate that was present in 29.7% of the patients, followed by S. aureus that in 18.9% of the patients, while P. mirabilis was the third commonest isolated organism with 16.2% of the patients infected.

In this study, the prevalence rate of polymicrobial infections (17.9%) was lower than that of monomicrobial infections (82.1%). This contrasts to the high prevalence rate of polymicrobial infection in diabetic foot infections (80% - 87.2%) as has been shown in several studies(46,47). This may be attributed to the fact that only 2.7% of the patients in this study had diabetes mellitus as a co-morbidity.

Sensitivity results from this study indicated that P. aeruginosa was sensitive to cefuroxime, ceftazidime, cefepime, piperacillin-tazobactam, imipenem, meropenem, tobramycin, gentamicin and ciprofloxacin and this finding compares well with a previous study done in Kenya by Naomi et al(2014) that looked at antimicrobial susceptibility patterns of bacterial isolates from pus samples from outpatient and inpatient departments at KNH(48). This was also similar to findings from studies done by Bayram et al(49), Kaup et al(50), Naomi et al(48) and Mahmood et al(51) that showed P.aeruginosa was most sensitive to carbapenems, aminoglycosides and quinolones. However, this is in contrast to studies carried out in KNH by Njeri et al (2018) and Aga Khan university Hospital in Kenya with a majority of isolates from ICUs with strains that exhibited highest antibiotic resistance compared to other wards majority of which were mainly attributed to Metallo Beta Lactamase production of which our study differ significantly in terms of drug sensitivity(52).

In this study *,Staphylococcus aureus* was most sensitive to linezolid(100%) and Fusidic acid(100%).Other studies have reported similar findings(48,50). Staphylococcus aureus resistance to vancomycin was high in this study (71.4%) which well compares to a study by Daniel et al (2013) in India(53). Resistance to amoxicillin,ampicillin and amoxicillin-clavulanic acid was 100% in this study which was also in keeping with a similar study done in KNH by Naomi et al in 2014 (48).

The presence of P. aeruginosa being the most prevalent in the orthopedic setting amongst patients with open foot injuries compares well to a study by Lawrence A. et al whose study on infected penetrating foot injuries showed that p. aeruginosa as the commonest involved organism(33).

However, our study slightly differed from a study done in the USA by McNeil et al in 2018 on Osteoarticular Infections after Open Trauma in Children of which 34% of the cases involved the foot. The most frequent isolate in that particular study was S.aureus in 3 out of the 11 cases (27.3%) with one case being MRSA. 18.2% (2) of the cases were polymicrobial with an additional two cases having mycobacteria isolated from pure culture. A single case had P aeruginosa isolated and three cases (27.3%) were culture-negative(35).

5.2 CONCLUSION:

The prevalence of bacterial infection in patients with open foot injuries at KNH was high(86.5%). The commonest isolate was *P.aeruginosa* accounting for 25% of the cases followed by *S.aureus* (15.9%) where 5(71.4%) of the isolates were coagulase negative and 2(28.6%) were MRSA.

P. aeruginosa isolates showed a 100% susceptibility to all tested antibiotics in this study - cefuroxime, ceftazidime, cefepime, piperacillin-tazobactam,imipenem, meropenem, tobramycin, gentamicin and ciprofloxacin. *S. aureus* isolates exhibited a high degree of resistance to commonly used antibiotics. Resistance to amoxicillin, ampicillin and amoxicillin-clavulanic acid was 100% while resistance to vancomycin was 71.4%.Only 2(28.6%) *S. aureus* isolates were sensitive to clindamycin. However, all *S. aureus* isolates showed 100% sensitivity to linezolid(100%).

This understanding may be used as a basis for the formulation of treatment algorithms for prudent antibiotic use and thus aiding in appropriate patient care that will see a reduction in the length of hospital stay and number of surgical procedures.

5.3 RECOMMENDATIONS:

The findings of this study recommend that further research be conducted to determine the source of infections in patients with open foot injuries, and also determine the length of stay and accompanying complications and cost implications that arise with such infections.

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APPENDICES

APPENDIX I: QUESTIONNAIRE

Date	NO	Age	Gender	. Mechanism of
		_		Injury
				Vital signs at first contact;
Date and time o	finiury			Temperature
Date and time o	r injur y			Temperature
•••••		•••••		Blood pressure
Duration before	presenting to			Dulas acts
KNH				Pulse fale
				Respiratory rate
TYPE AND SIT	TE OF FOOT	INJURY:		
i)Degloving Ini	Irv.	Site		O&T classification
	ury	5110.		
ii)Cut wounds/la	aceration:		Site:	O&T classification
		C .,		1 • 1 /
111)Open fractur	es:	Site a	ind Gustillo-A	nderson equivalent
iv)Traumatic an	nputation		Site:	
, ,				
v)Other				
Specify				
speeny.		<u></u> .		
COLODDIDIT	150			
COMORBIDIT	IES		A	Antibiotic received prior to sample
DIABETES			с	collection
			N	No of dosages
1.YES	IF YE	S,	r	eceived
ON INSULIN				
1.YES	2.NO			

HYPERTENSION
1 YES
NO
1.YES 2.NO
HIV
1 YES 2 NO
IF YES,ON MEDICATION,
1.YES2.NO
COCIAL HICTORY.
SUCIAL HISTORY:
SMOKER
1.YES2.NO
IF YES,NO OF CIGARETTE STICKS PER DAY
ALCOHOL CONSUMPTION:
1.YES2.NO
IF YES,QUANTIFY

Specimen Collection:										
Duration from time of injuryhrs/days.										
Take swab and tissue culture sample for MCS	Take swab and tissue culture sample for MCS and label with participants ID									
Specimen ID										
MCS RESULTS:										
BACTERIA:										
SENSITIVITY RESULTS:										
NOTES:										

APPENDIX II: CONSENT FORM: RESEARCH TOPIC:

THE PREVALENCE OF BACTERIAL INFECTION AND ASSOCIATED ANTIBIOTIC SUSCEPTIBILITY IN OPEN FOOT INJURIES AT THE KENYATTA NATIONAL HOSPITAL.

ENGLISH VERSION

This form is to ask for Consent from patients and/or their kin who present to KNH with open foot injuries and would be investigated for the presence of bacterial infection. Antibiotic susceptibility will then be done on samples found to be infected. Principal investigator: DR. YAKUB RUBEY JUMA.

Institution: School of Medicine, Department of Orthopaedic surgery- University of Nairobi

Supervisors: PROF J.E.O ATINGA and DR. VINCENT MUTISO

This informed consent has three parts:

informed consent has three parts:

Information sheet (to share information about the research with you)

Certificate of Consent (for signatures if you agree to take part)

Statement by the researcher

Part I: Study back ground and objective:

My name is Dr. Yakub Rubey Juma, an Orthopaedic Surgery post graduate student at the University of Nairobi, School of Medicine. I am carrying out a study entitled **"THE**

PREVALENCE OF BACTERIAL INFECTION AND ASSOCIATED ANTIBIOTIC SUSCEPTIBILITY IN OPEN FOOT INJURIES AT THE KENYATTA NATIONAL HOSPITAL."

The purpose of this study is to determine the prevalence of bacterial infection in patients with open foot injuries which has not yet been established in Kenya.

The study also aims to establish antimicrobial susceptibility from bacteria isolated from any such infection at the Kenyatta National Hospital.

I am inviting you to willingly take part in this study

Your Obligation:

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

You will be examined by the principal researcher or his trained assistant. This will enable the researcher or his trained assistant determines the type of open foot injury you have. Once you have given informed consent, a swab and tissue culture sample will be taken from the site of infection under sterile conditions and anesthesia in theatre before during the debridement procedure. This will not cause discomfort as you will be under anesthesia. This sample will be taken to the lab for microscopic analysis, culture and sensitivity studies. Your treatment for the injury you have will continue as planned and will not be affected by your participation in the research.

Benefits of the Study:

The results of the study may inform the prevalence of bacterial infection in patients with open foot injuries. It will shed light to information on the types of causative bacterial pathogens in such patients. The study will provide useful information on the antibiotic sensitivity of bacteria isolated from patients with open foot injuries. This information will be essential especially in health facilities which handle these patients and do not have treatment algorithms for same.

Voluntariness of participation:

Please note that your participation in this study is voluntarily and you have a right to decline or withdraw from the study. Your withdrawal of participation will not affect your treatment or management in any way. Furthermore, this study poses no harm to the patient and there will be no extra cost incurred for participating in the study. There will be no financial grant to the participants.

Confidentiality:

All the information gathered will be taken in confidence and no one will see it except my assistant, my supervisors and I, all who are duty-bound to ensure confidentiality.

The patient's name or identity will not appear in any research document. The information about the patient will be identified by a unique research number and only the researchers can relate the number to you/your patient as a person. Other than for (2) above, your information will only be used for this study and will not be shared with anyone else unless authorized by the Kenyatta National Hospital/University of Nairobi - Ethics and Research Committee (KNH/UoN-ERC).

Study Credibility and Legitimacy:

My two supervisors approved this study. It was also appraised and approved by the Chairman of the Department of Orthopaedic Surgery, School of Medicine at the University of Nairobi. It was then submitted to KNH/UoN-ERC, which reviewed and approved it to be done for a duration of three months. KNH/UoN-ERC is the regulatory body in the hospital whose work is to make sure research process is safe for the participants and that you are protected from harm.

Whom to Contact?

You can ask questions or seek clarifications about the study any time you wish to. If need be, you may also talk to anyone you are comfortable with about the research before deciding.

If you have any query about the research you want addressed by another person other than the researchers, please feel free to contact the following who will address your concerns:

Secretary, KNH/UoN-ERC

P.O. Box 20723 -00202

KNH, Nairobi

Tel: +254-020-2726300-9 ext. 44355

Email: KNHplan@Ken.Healthnet.org or uonknh_erc@uonbi.ac.ke

Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

Facebook: https://www.facebook.com/uonknh.erc

Research Supervisors from University of Nairobi

• PROF J.E.O.ATINGA

Professor of Orthopaedics, Department of Orthopaedic Surgery, University of Nairobi E-mail: atinga08@gmail.com

• DR. VINCENT MUOKI MUTISO

CONSULTANT ORTHOPAEDIC SURGEON, SENIOR LECTURER -DEPARTMENT OF ORTHOPAEDICS UNIVERSITY OF NAIROBI

CHAIRMAN, DEPARTMENT OF ORTHOPAEDIC SURGERY,

Email: mutisovm@yahoo.com

Principal Researcher:

DR. YAKUB RUBEY JUMA

Mobile number: 0718887788 E-mail: yakubrubey@gmail.com

Part II: Consent Certificate (confidential once signed) Research Track Number _____

.....freely give consent to take part in the study conducted by Dr. Yakub Rubey Juma, the nature of which has been explained to me by him/his research assistant. I have been informed and have understood that my participation is voluntary and understand that I am free to withdraw from it any time I wish and this will not in any way alter the care given to me/my patient. The results of the study may or may not benefit me/my patient directly but may benefit similar future patients. Furthermore, it will help provide important information on "THE PREVALENCE OF BACTERIAL INFECTION AND ASSOCIATED ANTIMICROBIAL SUSCEPTIBILITY IN OPEN FOOT INJURIES AT THE KENYATTA NATIONAL HOSPITAL."

SIGNED CONSENT	
(Patient/Kin)	
Date	
DD/MM/YY	
SIGNED ASSENT	Thumb print of participant if Unable to sign due to illiteracy
Date	

DD/MM/YY

Statement by a witness if participant is illiterate

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

Name of witness.....

Signature of witness.....

Date.....

Part III: Statement by the researcher

I have clearly read out the information sheet to the participant, and to the best of my ability made sure that the participant understood the following:

All information gathered will be treated with confidentiality.

Refusal to participate or withdrawal from the study will not compromise the quality of care and treatment given to the patient.

The results of this study might be published in a reputable journal to enhance the knowledge of

the "THE PREVALENCE OF INFECTION AND ASSOCIATED ANTIMICROBIAL SUSCEPTIBILITY IN OPEN FOOT INJURIES AT THE KENYATTA NATIONAL HOSPITAL."

In addition, I confirm that the participant was given opportunity to seek clarification about his concerns in the study, and all the queries clarified to the best of my ability.

I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant and duly signed by the participant.

Name of researcher taking consent
Signature of researcher taking the consent
Date

. . . .

APPENDIX III: FOMU YA IDHINI: FOMU YA IDHINI YA MSHIRIKA KWENYE UTAFITI

MADA YA UTAFITI: IDADI YA WAONJWA WANAOHABA BAKTERIA KWA JERAHA ZA MIGUU NA AINA ZA DAWA ZINAZOWEZA KUDHIBITI MAGONJWA YANAYOLETWA NA BAKTERIA HAYO KATIKA HOSPITALI YA KENYATTA

TAFSIRI YA KIWAHILI

Fomu hii ni ya kuomba idhini kutoka kwa wagonjwa na/au jamaa zao ambao wanafika Hospitali ya kitaifa ya Kenyatta na majeraha za miguu. Maudhui ya utafiti huu ni kuchunguza idadi ya wagonjwa wanoweza kuwa wanahaba bakteria kwa jeraha za miguu na aina za dawa zinazoweza kudhibiti magonjwa yanayoletwa na bacteria hayo.

Mtafiti mkuu: DKT. YAKUB RUBEY JUMA

Wahadhiri wasimamizi: PROF J.E.O ATINGA na DKT. VINCENT MUTISO

Wote wa kitengo cha upasuaji wa mifupa katika Chuo Kikuu cha Nairobi na hospitali kuu ya Kenyatta.

Makubaliano haya yana sehemu tatu:

Maelezo kuhusu utafiti huu.

Cheti cha Kibali (kitakacho tiwa sahihi na wahusika wanaokubali kujumuishwa utafitini)

Ithibati ya mtafiti

Sehemu ya kwanza: Maelezo

Utangulizi

Jina langu ni Dkt. Yakub Rubey Juma, mwanafunzi wa kuhitimu katika mafunzo ya upasuaji wa mifupa katika Chuo Kikuu cha Shule ya Dawa ya Nairobi.Lengo langu ni kufanya utafiti kuhusu "IDADI YA WAONJWA WANAOHABA BAKTERIA KWENYE JERAHA ZA MIGUU NA DAWA ZINAZOWEZA KUDHIBITI MAGONJWA YANAYOLETWA NA BACTERIA HAYO KATIKA HOSPITALI YA KENYATTA

Kiini cha utafiti huu ni kuchunguza idadi ya waonjwa wanaohaba bakteria kwenye jeraha za miguu na dawa zinazoweza kudhibiti magonjwa yanayoletwa na bacteria hayo katika hospitali ya kenyatta

Nitakuuliza maswali machache na kufanya baadhi ya uchunguzi juu ya majeraha yako.. Ninakualika kwa hiari kushiriki katika utafiti huu

Faida ya Utafiti huu

Matokeo ya utafiti huo yanaweza kutujulisha asilimia gani ya wangonjwa IDADI YA WAGONJWA WANAOHABA BAKTERIA KWENYE JERAHA ZA MIGUU NA AINA ZA DAWA ZINAZOWEZA KUDHIBITI MAGONJWA YANAYOLETWA NA BACTERIA HAYO KATIKA HOSPITALI YA KENYATTA

Matokeo yataweza kutujulisha idadi ya waonjwa wanaohaba bakteria kwenye jeraha za miguu na aina za dawa zinazoweza kudhibiti magonjwa yanayoletwa na bacteria hayo katika hospitali ya kenyatta

Kuna hospitali kadhaa nchini ambazo huudumia wagonjwa wanaohaba bakteria kwenye jeraha za miguu lakini hazina mahabara ambazo ziko na uwezo wa kufanya utafiti bakteria kwenye jeraha za miguu na aina za dawa zinazoweza kudhibiti magonjwa yanayoletwa na bacteria hayo

Gharama na Madhara za Utafiti:

Natoa hakikisho kwamba hata kama hutaki kushiriki kwenye utafiti huu, wewe au mgonjwa wako hutakashifiwa na utapata matibabu yanayostahili. Utafiti huu haupanii kuleta madhara aina yoyote kwa muathiriwa. Hautatozwa fedha za ziada kwa minajili ya utafiti huu wala hakuna fedha mhusika atapewa.

Jukumu Lako Katika Utafiti

Ukikubali kushiriki katika utafiti huu, yatakayo fanyika ni:

Utakaguliwa na mtafiti mkuu au msaidizi wake. Kiini cha ukaguzi ni kuweza kujua aina na kiasi ya majeraha uliyopata. Majeraha hayo yatakaguliwa na kuwekwa kwenye kiwango ya kisayansi ya kujumuisha majeraha ya miguu.Kwenye chumba cha upasuaji,baada ya kuwekwa dawa ya kufa ganzi,mhudumu atachukua sampuli ya aina ya "swabu" na kipande kidogo cha nyama kutoka wenye kidonda ambayo itapelekwa kwenye maabara ya Lancet,Ngong Road na itakayochonguzwa kama ina uwezekano wa kuhaba aina ya bakteria na dawa zinazoweza kudhibiti bakteria hao. Matibabu ya majeraha uliyopata yataendelea kama kawaida na inavyostahili.

Faragha ya Habari za Mhusika:

Habari zote zitakazo kusanywa kwa ajili ya utafiti zitabanwa na watafiti na hazitatolewa ovyo. Jina au kitambulisho cha mgonjwa haitanakiliwa popote ila tu atapewa nambari maalum ya utafiti. Watafiti watatumia mbinu fiche itakayo kutambulisha kwao. Licha yaliyokaririwa (2), habari za mgonjwa zitatumiwa tu kwa ajili ya utafiti huu na hazitatolewa kwa yeyote pasipo na

idhini ya Kamati ya Maadili ya Utafiti wa Hospitali Kuu ya Kenyatta na ile ya Chuo Kikuu Cha Nairobi (kwa ufupi KNH/UoN-ERC).

Uhalali wa Utafiti huu

Utafiti huu umekubaliwa na wahadhiri wasimamizi wangu, ukapigwa msasa na Mwenyekiti wa kitengo cha upasuaji wa mifupa wa chuo kikuu cha Nairobi ambaye aliuwasilisha kwa Kamati ya Maadili ya Utafiti wa Hospitali Kuu ya Kenyatta na ile ya Chuo Kikuu Cha Nairobi (KNH/UoN-ERC) ambayo iliidhinisha uweze kufanywa kwa muda wa miezi sita. Kamati hii ndio ihakikishayo usalama wa wanaohusishwa kwa utafiti na kwamba hawadhuriwi kwa vyovyote vile.

Jukwa la Malalamishi na Habari Zaidi

Waweza kutuuliza maswali yoyote wakati wowote au umuulize yeyote utakaye kuhusu mchakato wa utafiti huu kabla au hata baada ya kukubali kuhusishwa.

Iwapo una swali lolote kuhusu utafiti huu ambao waona heri lishughulikiwe na mtu mwingine isipokuwa watafiti, waweza kuwasiliana na wafuatao ambao wako tayari kuushughulikia ipasavyo:

Katibu, KNH/UON-ERC S.L.P 20723-00202 KNH, Nairobi Simu: +254-020-2726300-9 ext 44355

Barua pepe: KNHplan@Ken.Healthnet.org Au uonknh_erc@uonbi.ac.ke

Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

Facebook: https://www.facebook.com/uonknh.erc

Wahadhiri Wasimamizi Kutoka Chuo Kikuu cha Nairobi:

PROFESA J.E.O ATINGA.

Idara ya upasuaji wa mifupa, shule ya tiba, Chuo Kikuu cha Nairobi

S.L.P. Box 19676-00202, KNH, Nairobi

Seli: 0733737769

Barua pepe: atinga08@gmail.com

DR VINCENT MUTISO

Idara ya upasuaji wa mifupa, shule ya tiba, Chuo Kikuu cha Nairobi

S.L.P. Box 19676-00202, KNH, Nairobi

Tel: 0202726300

Seli: 0723289922

Barua pepe: mutiso@uonbi.ac.ke

Mtafiti Mkuu (mimi)

DKT. YAKUB RUBEY JUMA

Kitengo cha Upasuaji wa mifupa, Chuo kikuu cha Nairobi

S.L.P. 19676-00202

KNH, Nairobi

Rununu: 07188877888 (wazi usiku na mchana)

Barua pepe: yakubrubey@gmail.com

Sehemu ya Pili: Cheti cha Kibali (siri baada ya kutiwa sahihi) Nambari Maalum_____

Mimi ninakubali kwa hiari kuhusishwa kwa utafiti unaoendelezwa na Dkt. Yakub Rubey Juma kuambatana na maelezo yeye mwenyewe/ msaidizi wake amenipa. Ninaelewa kwamba nimehusishwa kwa hiari na kwamba niko huru kujiondoa wakati wowote nitakao hata bila sababu, na hii haitaathiri kwa namna yoyote matibabu ipasayo. Aidha naelewa kwamba matokeo ya utafiti huu huenda usinifaidi binafsi lakini huenda ukawa wa manufaa siku zijazo kwa waathiriwa wa hali hii ya majeraha ya miguu. Kuna uwezekano utafiti huu utaongeza maarifa kwa taaluma ya utabibu kuhusu "IDADI YA WAONJWA WANAOHABA BAKTERIA KWENYE JERAHA ZA MIGUU NA AINA ZA DAWA ZINAZOWEZA KUDHIBITI MAGONJWA YANAYOLETWA NA BAKTERIA HAYO KATIKA HOSPITALI YA KENYATTA"

SAHIHI (KIBALI HALISI)

(Mgonjwa/jamaa)

Tarehe	
Siku/mwezi/mwaka	
KIBALI MAALUM	
	Chapa cha kidole gumba cha
Tarehe	kushoto kwa wasio na eninu
Siku/mwezi/mwaka	ya kusoma na kuandika

Taarifa ya shahidi ya makubaliano na mhusika asiyejua kusoma

Nimeshuhudia mgonjwa akisomewa kwa njia inayoeleweka kwa rahisi, naye akapewa fursa nzuri ya kuulaza maswali. Nina dhibitisha mhusika alipeana kibali kwa hiari yake mwenyewe.

Jina la					
shahidi	 	 	 	 	
Sahihi la					
shahidi	 	 	 	 	
Tarehe			 	 	

Siku/mwezi/mwaka

Sehemu ya tatu: Taarifa ya Mtafiti

Nimesomea mhusika na kadiri ya uwezo wangu kumuelewesha yafuatayo:

Habari zozote zitokazo kwake zitawekwa siri.

Kukataa kupeana kibali cha kuhusishwa kwa utafiti huu haitaathiri matibabu anayostahili.

Matokeo ya utafiti huu kwa jumla utachapishwa katika jarida la kisayansi au utabibu ama upasuaji kuweza kuchangia maarifa ya "IDADI YA WAONJWA WANAOHABA BAKTERIA KWENYE JERAHA ZA MIGUU NA AINA ZA DAWA ZINAZOWEZA KUDHIBITI MAGONJWA YANAYOLETWA NA BAKTERIA HAYO KATIKA HOSPITALI YA KENYATTA."

Nimehakikisha kwamba mhusika amepewa fursa kamili ya kuuliza maswali kuhusu kuhusika kwake kwa utafiti huu na kwamba kwa kadiri ya uwezo wangu nimemuelewesha ipasavyo.

Ninahakiki kwamba mhusika hajalazimishwa kupeana kibali kuhusika kwenye utafiti huu bali amekubali kwa hiari.

Nakala ya kibali hiki kimewasilishwa kwa mhusika naye akatia sahihi ipasayvo.

Jina la mtafiti aliyepewa kibali cha mhusika
Sahihi ya mtafiti mhusika
Tarehe

Appendix IV: Work Plan

Activity	Aug 2020	Sept 2020	Oct 2020	Nov 2020	Dec 2021	Jan 2021	Feb 2021	Mar 2021	Apr 2021	May 2021	June 2021
Proposal											
development											
Ethical											
Approval											
Data											
collection											
Data Analysis											
Dissertation											
Writing and											
presentation											

APPENDIX V: TIME FRAME

PROPOSAL DEVELOPMENT:	AUG 2020-NOV 2020
ETHICAL APPROVAL :	NOV 2020-JAN 2021
DATA COLLECTION :	FEB 2021-MAY 2021
DATA ANALYSIS :	MAY/JUNE 2021
DISSERTATION WRITING AND F	PRESENTATION: MAY/JUNE 2021

APPENDIX VI: BUDGET ESTIMATE

ITEM	COST (SHS)
Research fees (KNH/ERC)	1,500
Stationery, printing and binding @	10,000
200/patient	
Statistician fee and Assistants	45,000
Contingencies	15,000
Lab culture tests(1500x50)	75,000
Total	146,500

The study will be funded by the principle investigator.

Appendix: VII: Data Collection for Research



DR.YAKUB RUBEY JUMA, REG No: H58/88939/2016, DEPT. OF ORTHOPAEDICS, UNIVERSITY OF NAIROBI, 8TH April 2021.

THE DEPUTY DIRECTOR, RESEARCH AND PROGRAMS, KENYATTA NATIONAL HOSPITAL NAIROBI.

Please register this study Dr Ngumbras Br 12/04/2021

Dear Sir/Madam,

RE: DATA COLLECTION FOR RESEARCH.

Following approval for my research proposal by the KHN-UoN ERC,I would like to start data collection at \Kenyatta National Hospital for patients presenting with open foot injuries. The main objective of the study will be to determine the prevalence of bacterial infection and antibiotic susceptibility in patients presenting with open foot injuries.

Upon grading of the foot injuries, a swab and tissue culture samples will be taken for microscopy, culture and sensitivity. A questionnaire will be used in data collection and an informed consent will be obtained from each patient recruited for the study or from their next of kin. A trained health care worker will assist in data collection.

The principal researcher is a doctor working in the Orthopedic surgery unit while the Research assistant is a medical officer working in the orthopedic surgery unit to avoid unnecessary risk of exposure tro covid 19 infection, all precautions and preventive measures will be taken to ensure that both the patient and the doctors undertaking the exercise will be protected from covid-19 infection as outlined below:

1. All patients will have their temperatures taken before the exercise.

2. All patients will always have masks. Masks will be provided for those without.

3. Social distancing will be observed strictly according to MoH guidelines at all times during the exercise.

 Hand sanitizers will be used at the entrance of every ward to ensure patients and their kin sanitise their hands.

5. Both the Principal researcher and his assistant will wear N95 masks.

6. The Principal researcher and his assistant will ensure hand sanitization before and after examination of each patient.

The measures have been included in the ethical section of my application.

Thank you for your good work and support.

I will greatly appreciate your feedback

Yours sincerely,

Halt.

DR.YAKUB RUBEY JUMA. 0718687788. yakubrubey/Øgmail.com

Appendix VIII: Approval Letter



- 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.
- 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.

Protect to discover

Appendix IX: Study Registration Certificate

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	кенуатта на Р.О. Вох 2072	TIONAL HOSPITAL 3-00202 Nairobi	Tel., 2726300/2726450/2726565 Research & Programs, Ext. 44705 Fox: 2725272 Email: <u>knhresearch@gmail.com</u>
	Stu	idy Registrat	ion Certificate
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3. Conta	ct person (if different	from PI)	
4. Email	address:	he investigation of the second	tel No
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Version 2: August, 2014

The Prevalence Of Bacterial Infection And Antibiotic Susceptibilities Of Open Foot Injuries At The Kenyatta National Hospital

by Dr Yakub Rubey Juma

Submission date: 14-Dec-2020 02:04PM (UTC+0300) Submission ID: 1474587973 File name: Dr_Yakub_Rubey_Juma.docx (134.54K) Word count: 6680 Character count: 36991 The Prevalence Of Bacterial Infection And Antibiotic Susceptibilities Of Open Foot Injuries At The Kenyatta National Hospital

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