INCIDENCE AND RISK FACTORS OF PRESSURE ULCER AMONG CRITICALLY ILL PATIENTS AT KENYATTA NATIONAL HOSPITAL

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STUDENT'S DECLARATION

I, Dr Franck Ngoma Nguvulu, do hereby declare that this dissertation is my original work and has not been previously submitted to any university or institution for examination or otherwise. All resources have been duly acknowledged.

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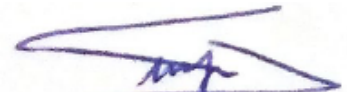

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Contents

LIST OF ABBREVIATIONS AND ACRONYMS

APACHE II: Acute Physiology and Chronic Health Evaluation II

BAI: Body adiposity index

BMI: Body mass index

CCU: Critical care unit

CKD: Chronic Kidney disease

EPUAP: European Pressure ulcer advisory Panel

GCS: Glasgow Coma Scale

Hb: Hemoglobin

ICU: Intensive care unit

IV: intravenous

KNH: Kenyatta National Hospital

LOS: Length of stay

NPUAP: National Pressure ulcer advisory Panel

PU: Pressure ulcer

PURAS: Pressure ulcer risk assessment scale

UON : University of Nairobi

OPERATIONAL DEFINITIONS

Pressure ulcer: The National Pressure ulcer advisory Panel defined Pressure ulcer also known as decubitus ulcer or bed sore or pressure injury as localized damage to the skin and/or underlying tissues**,** as a result of intense or prolonged pressure or pressure in combination with shear.

Shear: is created by a parallel load forcing the skeleton to slide against resistance which develops between the skin and its contact surface.

Friction: is the resistance to motion of one object moving relative to another. .

Moisture: is a tiny drop of water in the air, on a surface, or in the ground.

ABSTRACT

Background

Pressure ulcer represents a significant burden in a healthcare setup. Patients admitted to the critical care unit are at high risk of PU development with an incidence ranging from 7% to 71.6% across countries. Identifying potential risk factors and implementation of preventive measures can help reduce its incidence in the critical care unit.

Broad objective

To determine PU incidence and risk factors among the critically ill patients at Kenyatta National Hospital – main critical care Unit.

Study Methods

The Study is a prospective observational single-center study conducted over 3 months at KNH. All patients admitted to KNH-main CCU without pre-existing pressure ulcers were included into the study. Data were analyzed using SPSS version 23. They were presented as frequencies and percentages for categorical data and as means with standard deviations for continuous data. The incidence of PU was calculated as a proportion of those patients who developed ulcers over the total sample size and presented as a percentage. Associated risk factors were assessed with the use of Chi-square. Logistic regression was used to identify risk factors. All statistical tests shall be considered significant where the p-value < 0.05.

Results

The majority of the patients were aged between 21 to 40 years (47, 41.6%), where the mean age was 37.0 (SD 20.8) years. Of the 113 patients recruited, 17 patients developed PU giving rise to an incidence of 15%. The gluteal region was the commonest location (70.6%). There was indifferences in the odds and no statistical differences (p=0.509) for age and development of PU. Mechanical ventilation was a significant risk factor for PU (p=0.001). Malnutrition (OR=3.5, p=0.091), fecal incontinence (OR= 2.4, p=0.315), hemiplegia (OR=2.4, p=0.315) increased the probability of developing PU. Increasing sedation time (OR=14.0, CI 2.63 – 74.59, p=0.002) and each unit increase to the LOS (OR=1.91, p<**0.001)** were independently associated with PU development.

Conclusion

The incidence of pressure ulcer was 15% and all of them were stage I. The most common location of ulcers was the gluteal region. Mechanical ventilation, LOS in the unit and increasing sedation time were found to be independent risk factors for PU development.

Repositioning had little effect on pressure ulcer development, which could be explained by the lack of preventive and screening strategies in patients at high risk of developing pressure ulcers.

1.0. INTRODUCTION

Pressure ulcers represent a major burden but potentially avoidable condition most often seen in bedridden, elderly and critically ill patients. A pressure ulcer is an injury to the skin and underlying soft tissues due to prolonged pressure, moisture, friction and shear or an association of these, generally over a medical device or a bony prominence. Effective preventive measures have been shown to reduce the duration and the severity of pressure and shearing forces. Frequent change in posture, cushions, and pressure relieving mattresses have been shown to reduce the effect of pressure on the skin.[1]

Critical care unit patients have more than 10-folds higher hospital acquired pressure ulcer incidence rates compared to the non-critical care unit patients. Length of ICU stay and cost of care for hospitalized patients with pressure ulcers have been found to be higher compared to patients without pressure injuries.[2-3] A study by Lim ML, et al: (2017) found that the median total cost of care is $17,200 in a patient without pressure injuries. In contrast, the median cost of care for patients with pressure ulcers was significantly higher at $36,500. Pressure ulcer incidence rates vary from one country to another. Studies done across the countries have shown an incidence rate ranging from 5% to 71.6%.[4] The high incidence rates among the critically ill patients are due to multiple risk factors associated with pressure ulcers development. Shahin ES et al, have shown that pressure ulcer is a complex phenomenon that involves multiple factors rather than single risk factors in the patient. Tayyib N, et al conceptualized risk factors into intrinsic (inherent factors of critical illness) and extrinsic (related to external forces) factors. [5-6]

Pressure ulcer occurrence is a serious problem in a healthcare facility. However its incidence and associated risk factors remain unknown in KNH main-CCU. This study aims at determining the incidence and risk factors associated with Pressure ulcer development in critically ill patients admitted in KNH-main CCU. Knowledge of potential risk factors will enable critical care providers prevent pressure ulcers occurrence thus, reducing incidence rates among the critically ill patients.

2.0. LITERATURE REVIEW

2. 1. Epidemiology of pressure ulcer in Critical care unit

Data on the epidemiology of pressure ulcers in the hospital have shown the magnitude of the problem and help guide therapy and prevention.[7]

Nangole FW et al, conducted a study on pressure ulcer management and presentations at Kenyatta National hospital and spinal injury Hospital. The nine month prospective study evaluated 1175 patients admitted in the medical and surgical wards of KNH and 25 patients from the spinal injury Hospital. The study demonstrated that overall prevalence of pressure ulcers at Kenyatta National Hospital was 4.2% and 68% at the National spinal injury Hospital. They found that incidence rates were much higher, approximately 50%. Paraplegia was the major risk factor associated with pressure ulcers development.[8]

Pressure ulcers incidence rate has been shown to be high among the critically ill patients, up to 71.6% in Europe.[9] A study by Mutabazi G. et al, has demonstrated that the incidence of pressure ulcer in the large critical care unit at the referral hospital of Kigali was 15%. The study also revealed that the commonest location for pressure ulcers was the buttocks and Stage 2 was the most common severity for pressure ulcers.[10] In two hospitals in Saudi Arabia, Tayyib N, et al. demonstrated that up to 40 % of patients develop pressure ulcers during their admission to CCU. A total of 84 patients were recruited and screened daily until their discharge or death for a period of 30 days. They also found that age and length of stay were among the risk factors.

Borojeny LA; et al found that the combined incidence of stage 1, stage 2, stage 3 and stage 4 ulcers were approximately 45%. The highest incidence was found among orthopedic patients. In one study of Pressure ulcer incidence in the CCU, close observation showed that as many as 98% of the developing ulcers are first detected at stages I and II. [11] Thus, most ulcers can be detected in early stages, when they can be treated most easily.

2.2 Aetiology of pressure ulcers

Pressure ulcers occurrence is due to the compression of soft tissues during a prolonged period. Pressure ulcers can involve different tissues including epidermis, dermis, subcutaneous fat, muscles and bone. Four factors have been shown to contribute to pressure ulcers development[12]:

External (interface) pressure, applied over a bony prominence may result in occlusion of the blood vessels which deprives tissues of nutrients and oxygen, leading to hypoxia, ischemia, inflammation and ulcer formation. Pressure ulcers due to interface usually develop over the coccyx, trochanter, sacrum and the calcaneus.

Shearing occurs when the skin is separated from its supportive tissue. When a patient is partially sitting up or sliding down while sitting in a chair, his skin may stick to the sheet or the blanket, making him vulnerable to shearing forces in case supportive tissues move with the body towards the foot of the bed.

Friction develops where two surfaces are in close contact. Friction can lead to the injury of the skin over the elbows and the back when patients are slid over bed sheets while being moved on a stretcher. Friction creates a resistance that stops the patient from slipping over. However, friction is not a primary cause of pressure ulcer development.

Moisture causes tissue breakdown which may worsen the effect of pressure on the skin. Moisture can be in form of sweat, urine or feces. Moisture can further aggravate the damage caused by pressure, shear, and friction.

2.3 Pathophysiology

Pressure ulcer is the end result of poor blood supply to the tissues. Effects of ischemia on the skin and underlying tissues are essential in pressure ulcers development. Mechanical loading may affect functional units of soft tissues (cells, lymph and blood vessels, extracellular compartment, etc) to varying degrees and hence have different relevance for tissue breakdown.[13] The following mechanisms explain pressure ulcer occurrence:

2.3.1 Localized ischemia

In patients with normal sensation, mental status and mobility, sustained pressure triggers a feedback response that gives rise to a change of position; when the feedback response is absent or impaired, prolonged pressure ultimately causes injuries, ischemia and necrosis. Pressure injuries mostly develop when the patient's body weight applies a downhill force on soft tissues that lie between an external surface and a bony prominence. The external surface can be a mattress, wheelchair cushion or a medical device.

It has been shown that force resulting in an external pressure higher than the arterial capillary pressure (about 32 mmHg) and more than the venous capillary pressure (8 to 12 mmHg), results in local tissue hypoxia due to inhibition of blood flow. Sustained pressures

above a threshold lead to prolonged hypoxia and set soft tissues down a path towards ischemia and necrosis. In response to external pressure, tissue blood flow in healthy subjects is preserved by local auto regulation of the microcirculation. In the elderly, Spinal Cord injury and severely ill patients where auto regulation is impaired, external pressure less than 20 mmHg may cause capillary collapse.[14]

2.3.2 Reperfusion injury

This is an additional source of tissue damage that causes pressure ulcer. Reperfusion injury occurs because of the restoration of circulation after a certain period of ischemia. Return of blood supply can lead to increased formation of reactive oxygen species and trigger tissue inflammation. A study by Peirce SM et al, showed that in rats, ischemia-reperfusion cycles can affect more tissues than persistent ischemia alone.[15]

2.3.3 Impaired interstitial fluid flow and lymphatic drainage

This leads to accumulation of metabolic waste products.

2.3.4 Sustained deformation of cells

It causes local cell damage and death.

2.4. Classification of pressure ulcers

The classification developed by the US NPUAP is probably the most commonly used classification tool. This classification was later adopted by the European Pressure injury advisory Panel (EPUAP) with some minimal textual changes (e.g. NPUAP refers to stages and EPUAP to grades).[16]

Our study will use the US National Pressure injury Advisory Panel (NPUAP) grading system to classify different stages of pressure ulcers.

STAGES	Description
Stage I	Nonblanchable erythema of intact skin with the lesion being limited to the epidermis and dermis. Persistent erythema
Stage II	Partial-thickness skin loss with exposed dermis. It is a Full-thickness ulceration of the skin extending through to the subcutaneous adipose tissue at any level above muscle fascia. It

	clinically ranges from abrasion, blister to shallow crater.
Stage III	Ulceration extends down through the subcutaneous tissue to the underlying muscle. The Muscle fascia is exposed but not violated.
Stage IV	Ulceration extends through muscle to bone. It may involve any joint space or support structures such as tendon.
Unstageable/Unclassified	full – thickness skin or tissue loss but the depth is unknown.
Suspected deep tissue injury	Characterized by Persistent nonblanchable, deep red, maroon, or purple discoloration.

Ref. US National Pressure ulcer Advisory Panel (NPUAP) grading system

2.5. Risk factors

Deeks et al have defined risk as the probability of a patient to develop a specific problem such as pressure injury. Any factor which can expose the skin to excessive pressure, or reduce its tolerance to pressure, is considered a 'risk factor' to pressure ulcer formation. Risk factors can be related to the duration and intensity of pressure or tissue tolerance.

2.5.1 Duration and intensity of pressure

Nijs N, et al (2009) demonstrated that diminished activity and Immobility were the most commonly identified risk factors in both prospective and retrospective studies. Spinal injury, altered level of consciousness or an impaired cognitive state, loss of sensory, motor function and complete paralysis are considered risk factors under this category. Some studies have shown that Intra-operative period exceeding three hours is a predisposing factor for pressure injuries development.[18-19] A study by Chou CL et al (2015) revealed that inadequate preparation for anesthesia and poorly coordinated anesthesia and surgery times increase the risk of developing pressure ulcer.

2.5.1.2. Tissue tolerance for pressure

The ability of the skin and its underlying tissues to sustain the effects of pressure without sequelae is known as Tissue tolerance. In other words, tolerance is how well the tissue acts

as a cushion, transferring pressure loads from the skin surface through the skeleton below. Tissue tolerance may be affected by both extrinsic and intrinsic factors. In the absence of external pressure these factors will not cause pressure ulcers.[20]

a. Extrinsic factors

A study by Braden B et al, demonstrated that Extrinsic factors can affect the skin surface and determine the degree to which the skin is exposed to friction, shear, and moisture.

In pressure ulcers development the primary force in generating mechanical occlusion is pressure, but shear can play a significant contributory role**.** According to a study by Dinsdale SM, Friction is not an essential factor in pressure ulcer formation but was demonstrated to make the skin vulnerable to pressure. Moisture may be in the form of feces, urine, perspiration, and drainage from fistulae or wounds. Studies revealed that patients admitted to the critical care units have increased risk for pressure ulcers due to fluid loss, fecal and/or urinary incontinence. Nurse-to-patient ratio also affect the risk of pressure ulcer development .[21] Makleburst et al demonstrated that fecal incontinence is more important than urinary incontinence in pressure ulcer formation.

b. Intrinsic factors

Factors affecting the vascular lymphatic system or the skin's supporting structures are known as intrinsic factors. Such factors consist of nutritional status, mobility status, age (>65years), circulatory factors and neurological conditions of the patient.[22] Compton et al revealed other intrinsic risk factors associated with pressure injuries development including length of stay body, temperature, gender, body mass index, oxygenation, C-reactive protein level, blood pressure, edema, APACHE II score, nurse-to-patient ratio, and comorbid medical conditions. Nijs et al (2008) conducted a prospective observational study to scrutinize the risk factors for Grade 2 to 4 pressure ulcers 48hours following an admission to a surgical critical care unit. They found that hemodialysis, history of cardiovascular disease, use of vasopressors, and mechanical ventilation correlated with Stage 2 to 4 pressure ulcers.[23-24]

A study by Wilczwesil et al(2012) revealed that incontinence, bowel management program, hypotension, use of support surfaces, use of steroids were all associated with the development of pressure ulcers in traumatic spinal cord injured patients in the critical care unit. Several prospective and retrospective studies reported malnutrition, poor energy intake or hypoalbuminemia and recent weight loss to be significant risk factors.[25]

Factors affecting oxygen delivery to the tissues have been shown to be implicated in predisposing to pressure ulcer development. Such factors can be: anaemia, low diastolic or systolic blood pressures, circulatory abnormalities, and autonomic dysfunction due to spinal cord. A study by Wright et al has identified dry skin as a sign associated with pressure ulcer formation. However; excessive skin washing has not been identified as a risk factor in any studies, despite it being a theoretical risk factor.[26]

2.6 Risk Assessment tool for predicting the risk of pressure ulcer development

Pressure ulcer risk assessment tool can be defined as a scale used to recognize patients at risk of developing pressure ulcers according to a set of variables regarded as risk factors for the development of such injuries. Most Risk assessment scales use a numerical scoring tool to weigh the severity of risk into groups of: no risk, medium, low, or high risk. Risk assessment tools cannot replace clinical judgment but rather to assist in decision making in order to channel resources appropriately. When a pressure ulcer prevention program is to be started, one of the first steps or the most important should be the selection of a PURAS.[27]

A good risk assessment scale should meet basic requirements of reliability and validity. The tool must be able to identify those patients it claims to identify (validity) and must identify the same patient regardless of who uses the tool (reliability). Few PURAS described in the literature were tested for sensitivity, specificity, predictive value or reliability. Most health care institutions that use PURAS either the Braden Scale or Norton scale, with the Braden scale being the most commonly used.

The Braden scale was described in 1985 in the United States of America, as part of a research proposal in residential care Home, to handle some of the limitations of the Norton scale. It is available in plenty of languages and used among various tribes and ethnicities in more than 30 countries.[29] It comprises six subscales including nutritional status, sensory perception, activity, skin moisture, friction and shear, and mobility. Regardless of the screening tool, the most important factor is starting preventive measures as soon as patients at risk are identified.

The Braden scale is a reverse scoring tool i.e the lowest score indicates high risk, with values ranging from 5 to 23 points. Patients are considered “at risk” when the scores equal to

or below 16 points on this scale; 15–16 is “low risk,”13–14 “moderate risk,” and between 5 and 12 “high risk.” More than a dozen studies have validated the Braden scale in different care settings, varying from hospitals for acute patients to long-term facilities, including nursing homes for the elderly, intensive care, and home care. Of all the risk assessment tools described in the literature, evidence suggested that the Braden Scale has the best specificity and sensitivity for predicting pressure ulcers occurrence among critical care unit patients.[30]

2.5.3. Prevention

Pressure ulcers prevention in the CCU begins with education of the entire hospital care providers. Recruitment of patients at high risk is the initial step. All patients should be routinely screened on admission for risk factors which may predispose them to the development of pressure sores. The basic rules of prevention include pressure reduction over a bony prominence, alternation of weight-bearing surfaces, good skin hygiene, and the maintenance or restoration of adequate nutrition.[31]

a. Skin care: All patients who are identified as ‘at risk’ of pressure ulcers development should have a management plan that aims at aspects of care including:

Skin inspection is essential to the early detection of skin injury and provides a baseline for evaluation and planning of preventive strategies. Patients ‘at risk’ of developing pressure ulcers should have a thorough skin examination at least daily for signs of skin damage. Localized skin checks should be done with each turn or repositioning. More attention is needed for the skin overlying bony surfaces, e.g. the heels, sacral area, and greater trochanter.

Skin hygiene must be optimized. The skin pH varies between 4 and 6.8 and its maintenance protects the skin against colonization of bacteria and decreases the risk of skin infections. All irritating substances should be eliminated or minimized to maintain the skin integrity. The Skin must be kept dry and clean, and excessive dryness must be avoided. Skin cleansing products should be personalized according to the patient need and preference. Dermatological safety and pH value of the skin care products should be evaluated. Alkaline soaps can damage the skin’s acid mantle. The use of detergents and soaps may result in physical and chemical irritation that may compromise the skin’s water-holding capacity and interfere with bacterial resistance.[32]

The maintenance of the skin moisture promotes comfort, dignity and the integrity of the skin. Elimination of extrinsic and intrinsic factors results in maceration or dryness of the skin and may aid the skin to resist trauma. Dryness decreases the tissue's resistance to load forces such as pressure, friction and shear. Dry, flaky or scaling skin must be treated with a topical moisturizer. Clothing items and wound dressings that obstruct the cutaneous blood flow increase the skin's pH and in the presence of feces, elevate the activity of fecal enzymes. The irritant effect of fecal enzymes on the skin is enhanced in the presence of urine.[33]

Overheating of the skin has been shown to predispose patients to pressure ulcer development. Increased perspiration due to increased skin and body temperature may compromise the maintenance of moisture. A good maintenance of the skin's body temperature is required to decrease the metabolic demands of the skin. Intervals between turning schedules and repositioning may significantly affect the skin surface temperature. Knox *et al*. have demonstrated an increased skin surface temperature with 2 hourly turns when compared to repositioning or turning intervals shorter than 2 hours .[34]

A balanced diet is recommended to provide adequate caloric requirements for tissue maintenance and repair and for the maintenance of an adequate BMI. The patient's dietary intake must be assessed systematically, particularly in critical care unit where interruptions to diet due to surgical procedures, treatments, diagnostic tests frequently occur. In the context of underlying disease, what may normally be considered an adequate and balanced diet may surprisingly be inadequate. A study by Tayyib and Coyer on a nutritional strategies described as the "intervention diet" was highly associated with reduction of hospital-acquired pressure ulcers incidence.[35]

b. Mechanical loading and support surfaces.

To protect the skin and its structures from external forces of pressure, friction and shear requires a management plan that includes the following:

Positioning and repositioning: The skin's tolerance to pressure should dictate how often patients must be repositioned. Studies have failed to demonstrate the ideal frequency of manual repositioning. A study by Tayyib and Coyer showed improvement with 2-hour repositioning using a 2-person turn team.[35] However, scheduling intervals can vary between patients from less than one hour to more than two hours. Skin assessment with each repositioning help determine effectiveness of any turning schedule. Foam wedges and pillows may be used when turning to assist in avoiding contact between bony surfaces and

external pressure and maintaining body alignment. A direct positioning on the ischium, sacrum and the greater trochanter must be avoided where possible. Patients 'at risk' of developing pressure ulcers should avoid uninterrupted sitting in a bed, wheelchair or chair. A study by Bengstom et al revealed that shifting or repositioning of pressure points should be done as often as every fifteen minutes and at least every hour. When sitting on the bed, foot placement must be kept below the level of the hips.

Eliminating shear and friction: friction can be avoided by proper lifting. Manual handling techniques should be used when transferring or repositioning the patient. There are many devices available to assist carers with transferring and lifting, for example hoists, slide sheets, turning devices, and slide boards. Dressing and Padding can be used to protect the skin and soft tissues exposed to friction. When patients are unable to support their own body weight or move independently, the force of shear can be reduced by elevating the foot of the bed by 10 to 20 degrees. This helps prevent sliding when sitting or semi-recumbent.

Heel pressure reduction aims at lowering the risk of pressure ulcers development on the heel. This is vulnerable to pressure as the heel bone (calcaneum) exerts pressure on a small surface area that provides negligible protection from a thin layer of subcutaneous tissue. Patients who are bedridden or have immobilized lower limbs are at high risk of pressure ulcers development on their heels. Preventive measures should provide total relief of pressure from the heel of the foot. Standard heel protectors including cushioned booties or gel can largely assist in reducing the intensity of shear and friction. However, they provide minimal pressure relief. Some Devices can be used to offer the best heel protection from any heel surface by elevating the entire lower limb.[31]

Activity and mobilization affect pressure on weight bearing surfaces, relieve damaged tissue and improve blood supply to the underlying tissue and its skin. Patients are encouraged to maximize mobilization and activity compatible with their energy level, medical condition and ability. Early mobilization should be encouraged after stroke, surgery, or other major illnesses.[36]

There are multitude support surfaces on the market that offer a variety of features and varying degrees of pressure relief including:

Basic hospital mattresses, emergency department trolleys, and radiology and operating room tables consist of a single piece of polyurethane foam confined by a non-stretch nylon/plastic

cover, thus offering very little in the way of pressure relief. They should be regularly assessed for "core fatigue" because of their short life of expectancy.[37]

Foam pressure reducing devices are available in different sizes. Foam pressure reducing device has been used for several years as a convenient and inexpensive support surface. Foam can be easily shaped for specific bony prominences, such as heads and heels. The main advantages of foam as a pressure reducing device comprise ease of transport and installation, minimal maintenance and resistance to puncture by sharp objects. Foam's disadvantage is its limited life expectancy; two to three years for an overlay and around five years for a replacement mattress. Foam also absorbs body heat, traps perspiration, retains odor, stains easily, and may be difficult to clean.[31]

Sheepskins, fibre-filled overlays and gel pads are well recognized by the general population as a pressure ulcer preventative device, generally a natural fleece sheepskin is considered to be a comfort measure that can potentially reduce friction and improve vapor loss.

Static air mattresses and overlays are suitable for patients at moderate risk of pressure ulceration. They are economical, low in maintenance and easy to clean. They must be regularly checked and adjusted to the patient body weight as over or under-inflation of static air overlays can increase the interface pressure.[38]

Alternating pressure devices are available as overlays for chairs and beds or as replacement mattresses. Overlays may be small 'bubble cell overlays" with diameters of 3-5 cm or large cell overlays with cell diameters of 10 cm or more. A study by Cullum N et al revealed that alternating pressure devices significantly lower tissue interface when compared with a basic mattress and decrease pressure ulcers incidence when cell diameter is greater than 10 cm. These devices are suitable for moderate to high risk patients.[37]

Turning beds are a variety of devices or beds which assist in turning the patient. They may be mechanically controlled and may provide continuous or intermittent movement. Studies have not demonstrated any benefit in the reduction of pressure ulcers (Cullum et al).

Low air loss devices: a continuous flow of air is provided from the entire surface of the mattress; this is achieved by using a microporous material for the transverse air cells that constitute the support surface. Air cell inflation is maintained at the lowest possible level by a powerful fan despite constant air loss. This level of inflation provides adequate body alignment and patient support. Low air loss devices are available as a replacement mattress,

an overlay, or a specialty bed. The overlay and mattress are suitable for moderate to high risk individuals while the specialty beds cater for high risk patients.[31]

High air loss or air fluidized beds minimize pressure over bony prominences through body "flotation" on fine ceramic beads that are set in motion by warm, pressurized **air** to simulate the movement of a fluid. The **bed** consists of a tank filled with silicone-coated microsphere beads. High air loss or air fluidized beds are used for high risk patients who cannot tolerate any pressure.

2. 6. Management

Pressure Relief from the wound site is the initial step in managing pressure ulcers. Pressure ulcers preventive measures described above must be applied to the treatment. A strict adherence to repositioning the patient regularly is needed for bedridden patients.[39]

Infection control is a mainstay of treatment of pressure ulcers. The initial assessment of a pressure ulcer is to rule out any evidence of inadequately controlled infection. If there is evidence of inadequate infection control, the patient should be taken to the operating theater for debridement and adequate abscess drainage. The wound can be initially treated with locally applied antiseptics. Intravenous antibiotics are recommended in patients with systemic infection or cellulitis. There is no need of intravenous antibiotics in patients with clean pressure ulcers. Treatment protocols would recommend the use of intravenous antibiotics in patients who develop osteomyelitis. Normal saline is recommended for the wound cleansing. Topical antibiotics should be started if there is no wound healing after 14 days.[40]

Debridement and abscess drainage are very useful in the management of pressure ulcers. The initial debridement must be performed in the operating theater in cases where the amount of necrotic tissue is significant. Subsequent debridements can be easily performed at the bedside. Studies have shown that significant debridement is not needed or should not be done in some cases. Debridement should be done with caution if there is little subcutaneous tissue under eschar. Repeated debridements are usually recommended after the initial debridement as the extent of necrotic tissues can be difficult to assess .[41]

The choice of topical agents and dressings should depend on the ulcer being treated. It should be noted that dressings are superior to one another. Things to consider include depth, shape, size, location of the wound, type of tissue in wound bed, presence of tunneling,

presence and volume of exudates, and the neighboring skin condition. To prevent further tissue breakdown, it is encouraged to protect the skin surrounding the wound from friction, excessive moisture and shear. Dressings have to be changed regularly and as soon as they become contaminated with feces or urine to prevent ulcer contamination. Concurrent pressure ulcer reassessment must accompany each change of dressing. Many types of dressings exist in the market including biologic dressings, gauze dressings, alignate dressings, Honey- containing dressings, foam dressings, Hydrogel dressings, Hydrocolloid dressings, silver containing dressings, transparent film dressings.[42]

Biophysical treatments are used to promote wound healing. They include pulsed electromagnetic field, direct electric stimulation, and pulse radio frequency energy. Phototherapy treatment of ulcers is being performed with the use of laser, ultraviolet waves and infrared. Ultraviolet C light therapy reduces the bacterial load and may be used following wound debridement in regularly infected ulcers. Topical oxygen therapy and hyperbaric oxygen therapy are used for pressure ulcer management with ambiguous results.[43]

2.7. STUDY JUSTIFICATION

Pressure ulcers incidence is a quality of care indicator in a healthcare set up, failure to provide adequate preventive measures may lead to overall poor outcomes and may increase the risk of litigation.

Pressure ulcers usually occur in bedridden and critically ill patients. KNH main CCU is a surgical icu mainly catering for trauma patients with severe head injury being the commonest cause of admission. These patients are bedridden for long periods thus at high risk of developing pressure ulcers.

No studies have been done locally, as far as this condition is concerned. There is no clear protocol guiding management of pressure ulcer from admission to discharge in KNH-main CCU. This study will put more light on the condition and will form a basis for the formation of a protocol on the management of pressure ulcers at KNH-main CCU.

2.8. STUDY QUESTION

What is the incidence and risk factors associated with Pressure ulcers development among the patients admitted to KNH-main CCU?

2.9. STUDY OBJECTIVES

2.9.1. Broad Objective

To determine pressure ulcers incidence and risk factors among the critically ill patients at Kenyatta national Hospital – main critical care Unit.

2.9.1. Specific objectives

1. To determine pressure ulcers incidence in KNH-Main CCU.

2. To determine the risk factors associated with pressure ulcers development among the critically ill patients at KNH-main CCU.

3.0 STUDY METHODOLOGY

3.1 Design

The Study is a 3 month prospective observational single-center study. Patients were recruited on admission and followed up during the data collection period.

3.2 Study area

The study will be carried out at the main critical care unit of the Kenyatta National Hospital. Kenyatta National Hospital is a public, tertiary, referral hospital for the ministry of health with a bed capacity of 2500 patients. It is also the teaching hospital of the University of Nairobi. KNH-main CCU is a 21-bed open unit and the largest CCU in the Hospital. Critically ill patients are admitted from various wards, accident and emergency and operating theaters. Patients are also admitted to the unit as referrals from other private and public hospitals all over the country.

3.3 Study Population

These are patients admitted at KNH-main critical care unit.

3.3.1 Inclusion criteria

- All Patients admitted to KNH-main CCU during the data collection period are included.

3.3.2 Exclusion Criteria

- Patients admitted to the unit with pre-existing pressure ulcers.
- Patients who declined to sign consent.

3.4 Sample Size determination

Sample size was calculated using Fisher's formula:

$$n = \frac{Z^2\, p(1-p)}{d^2}$$

Where: n is the desired sample size

Z= statistic corresponding to level of confidence (Z=1.96 for 95% CI)

P= expected incidence based on previous studies (Incidence of pressure ulcer was 8%, from a study conducted in the ICU of alkhadhimia teaching hospital by Sayhowd).[44]

d= Absolute precision required (0.05)

$$n= \frac{1.96^2 \, x \, 0.08(1-0.08)}{0.05^2} = 113$$

A targeted sample size of 113 patients was consecutively enrolled into this study.

3.5 Sampling procedure/ Selection of study participants.

All Patients admitted to KNH-main CCU during the data collection period were included in the study and actively monitored for pressure ulcers. Consecutive sampling method was used to select study participants until the desired sample size was achieved. Patients were followed from admission until their discharge or death. The average length of stay in the unit (20 days) was used as the end of follow up for patients who are not discharged or die within the study period.

3.6 Recruitment and consenting

All patients admitted at KNH main critical care unit who met the inclusion criteria were enrolled into the study after the consent was signed by their next of kin. The principal investigator recruited study participants.

3.7 Variables

The dependent variables are stages of pressure ulcers. Independent variables are demographic variables (age, gender), Laboratory variables (Hb, blood sugar, creatinin, Albumin, WBC), history of Co-morbid medical conditions (DM, cardiovascular disease, kidney failure, diagnosis on admission), prognostic variables (Braden scale for pressure ulcer risk and APACHE II score), mechanical ventilation and sedation, treatment with steroids, variables related to pressure relief area, Length of ICU stay, Nutritional status (BAI).

3.8 Data Collection Procedures.

3.8.1 Principal investigator

Study participants were recruited by the principal investigator. Voluntary participants were enrolled on the basis of informed consent obtained from their next of Kin after the nature of the study was explained to them. Prior to data collection, the principal investigator trained research assistants on data collection tools.

3.8.2 Research assistants

Four critical care nurses were trained as research assistants. An educational session on US NPUAP and the Braden scale was given to research assistants prior to data collection. The

research assistants were inspecting the study participants from the head to toe at the time of nursing care in the early morning. Information was collected by means of the research assistant administered questionnaire. Additional Data were collected from patients' clinical records, clinical examination and interaction with primary nurses; laboratory and radiologic investigations requested by the CCU team using a research assistant administered questionnaire. Data were taken every 48hrs by the principal investigator and research assistants.

3.9 Data Analysis

Data were coded and entered into Epi data version 3.1 and exported to SPSS version 23 statistical software for analysis. Demographic and clinical characteristics of patients are presented as frequencies and percentages for categorical data and as means with standard deviations for continuous data. The incidence of pressure ulcers was calculated as a proportion of those patients who developed pressure ulcers over the total sample size and presented as a percentage. The risk factors associated with pressure ulcers development among the critically ill patients were assessed with the use of Chi-square tests, and those found to be significant were subjected to multivariate analysis with the use of logistic regression. Odds ratio as well as 95% confidence intervals were calculated and reported where appropriate. All statistical tests were considered significant where the p-value < 0.05.

3.10 Quality Assurance Protocol

Collection of data was done by means of a data collection tool. Four critical care nurses were trained and enlisted to assist the principal investigator in data collection. Data were collected from patient clinical files, clinical observation, nurse reports and interaction with the primary care team (nurses and doctors). The research assistants adhered to the following quality assurance protocol to ensure reproducibility and validity of their observations: Organization: The principal investigator supervised and was responsible for the activity of the research assistants enlisted to aid in the data collection. Training: the research assistants were trained on the study protocol, NPUAP 2007 classification, data collection and ethical considerations of the study. Study documentation: data were collected using a data collection tool (researcher administered questionnaire). Confidentiality was maintained throughout the study. Most of the data to be collected and filled in the questionnaire were obtained from the patient files and nurse reports. The rest of the data were obtained by clinical observation and four standard clinical tools were utilized: the Glasgow Coma Scale

(GCS), Braden scale for pressure ulcer risk assessment, APACHE II score on admission and the NPUAP 2007 classification. In addition, the research assistants were trained on how to score the patients using these tools. The tools was printed and included as part of the questionnaire. Communication procedures: The research team was meeting every 3 days with the principal investigator for periodic reports, as well as to submit their deliverables.

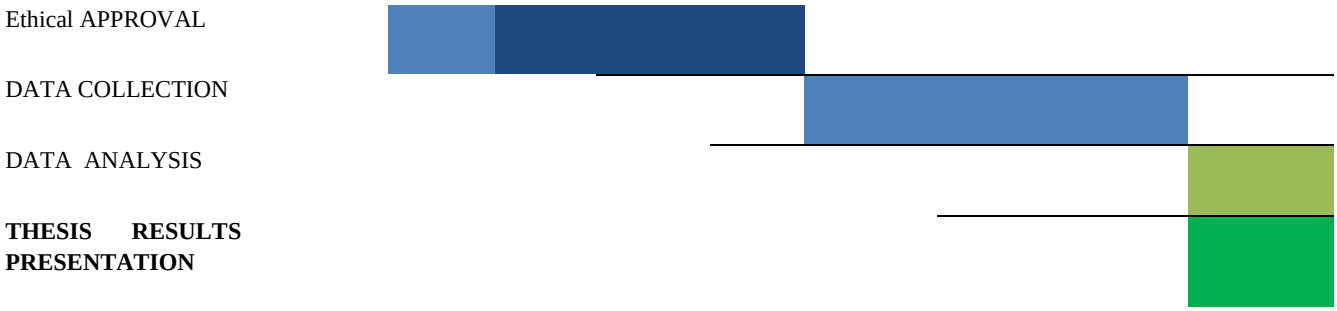
3. 11 Ethical Considerations

Authorization was requested from KNH/ University of Nairobi Ethics and Research Committee to conduct this study. Authorization to conduct the study was sought from KNH administration. Our study is a prospective observational study. Voluntary participants were enrolled on the basis of informed consent obtained from their next of kin after the nature of the study was explained to them. Adequate Confidentiality was ensured at all stages of the study. Participants had rights to withdraw from the study at any stage if they wish to do so without victimization. Patient's identification was only recorded using a serial number. Any unexpected event during data collection was reported to the ICU primary team. No additional intervention or treatment was denied or given to any patient participating in this study. Patients did not incur any extra cost for participating in the study. No financial incentive was given to patients or their next of kin for participation in this study. The principal investigator declares no conflict of interest. Precautions were taken to prevent COVID-19 disease transmission. Hand hygiene, PPEs and mask-wearing were mandatory during data collection. This study was conducted in accordance with the ethical principles adopted by the Declaration of Helsinki (2013) and the ICH-Good Clinical Practice Guidelines.

3.12 STUDY RESULTS DISSEMINATION PLAN

The study was presented to the University of Nairobi – Department of Anesthesia. A Copy of the study was shared with the KNH/UON ERC and Published in peer –reviewed academic journals. A face to face meeting will be organized with KNH-main CCU team.

3.13 STUDY TIMELINE



3.15 BUDGET

ITEMS	COST(Ksh)
STATISTICIAN	50,000
STATIONERY	25,000
ERC FEE	2,000
INTERNET	15,000
CONTINGENCY	15,000
RESEARCH ASSISTANTS	120, 000
TOTAL	227,000

4.0 RESULTS

A total of 113 patients were recruited and followed up during the study period in Kenyatta National Hospital- Main critical care unit.

4.1 Demographic characteristics and admitting diagnosis

Results of the demographic characteristics indicate that majority of the patients were aged between 21 to 40 years (47, 41.6%), where the mean age was 37.0 (SD 20.8) years, and the minimum and maximum age being 5 months and 88.0 years. The median age was 35.0 (23.0 – 50.0) years.

Table 1: Demographic characteristics

		Frequency *(n=113)*	**Percent**
Age	<10	15	13.3
	10 – 20	7	6.2
	21 – 40	47	41.6
	41 – 60	25	22.1
	61 – 80	18	15.9
	>80	1	0.9
Gender	Male	77	68.1
	Female	36	31.9
Admission diagnosis	Traumatic Brain Injury	55	48.7
	Cerebrovascular accident	2	1.8
	Acute/Chronic kidney disease	6	5.3
	Cardiovascular disease	3	2.7
	Other	47	41.6

4.2 Incidence

113 patients were recruited and followed up between July 10th and October 9th 2021. Of these patients, 17 patients developed pressure ulcers giving an incidence of 15%.

Table 2: Incidence of Pressure Ulcers

	Frequency *(n=113)*	**Percent**
Yes	17	15.0
No	96	85.0

4.3 Date of occurrence

The onset of pressure ulcer development occurred within a *mean*±*SD* of 8.8±*3.3* days after admission to the critical care unit. The minimum was 3 days and the maximum was 16 days.

Table 13: Patient distribution according to the date of occurence

		Frequency	**Percent**
Stage	I	17	100.0
Date of occurrence	≤5 days	2	11.8
	6 – 10 days	10	58.8
	>10 days	5	29.4

4.4 Location of pressure ulcers

The majority of pressure ulcers developed in the gluteal region (70.6%), followed by the back of the thigh (17.6%).

Table 3: Distribution for anatomical sites

Site	**Frequency(n=17)**	**Percent**
Hip	1	5.9
Gluteal region	12	70.6
Back of the thigh	3	17.6
Occipital	1	5.9

4.5 Progession of Pressure ulcers to the most severe stage

Of the 17 patients who had pressure ulcers (Stage I), 4 patients (23.5%) progressed to a stage II ulcer during their stay in the unit.

4.6 Univariate analysis of patient characteristics and presence of pressure ulcer

4.6.1 Demographic characteristics

There was indifference in the odds and no statistical differences (p=0.509)for age and development of pressure ulcer, and on gender the odds of developing pressure ulcer was 1.63 times more for males than for female, but there was no statistical association (p=0.427)

Table 4: Patient distribution according to the demographic characteristics

		Pressure ulcer			
		Yes *(n=17)*	**No** *(n=96)*	**OR (95% CI)**	**p-value**
Age, *mean±SD*		40.0±23.2	36.4±20.4	1.00 (0.98 – 1.03)	0.509
Gender, *n (%)*	Male	13 (76.5)	64 (66.7)	1.63 (0.49 – 5.39)	0.427
	Female	4 (23.5)	32 (33.3)	Reference	

4.6.2 Duration of mechanical ventilation

Each unit increase of duration of mechanical ventilation increased the odds of developing pressure ulcers by 3 times and this was statistically significant (p=0.001).

Table 5: Patient distribution according to the duration of mechanical ventilation

	Pressure ulcer			
	Yes *(n=12)*	**No** *(n=72)*	**OR (95% CI)**	**p-value**
Duration, *mean±SD*	10.2±2.9	3.8±2.0	3.06 (1.54 – 6.10)	**0.001**

4.6.3 History of co-morbid medical condition

Having comorbid conditions such cardiovascular, diabetes, and CKD, increased the odds by 2.4, 1.7 and 1.4 times of developing pressure ulcer, though these associations were not statistically significant. However, having hypertension was associated with less odds of developing pressure ulcer, though this association was also not statistically significant.

Table 6: Patient distribution according to history of co-morbid medical condition

		Pressure ulcer			
		Yes *(n=17)*	**No** *(n=96)*	**OR (95% CI)**	**p-value**
Cardiovascular, *n (%)*	Yes	2 (11.8)	5 (5.2)	2.43 (0.43 – 13.67)	0.315
	No	15 (88.2)	91 (94.8)	Reference	
Diabetes, *n (%)*	Yes	2 (11.8)	7 (7.3)	1.70 (0.32 – 8.95)	0.534
	No	15 (88.2)	89 (92.7)	Reference	
CKD, *n (%)*	Yes	1 (5.9)	4 (4.2)	1.44 (0.15 – 13.70)	0.752
	No	16 (94.1)	92 (95.8)	Reference	
HTN, *n (%)*	Yes	2 (11.8)	17 (17.7)	0.62 (0.13 – 3.00)	0.549
	No	15 (88.2)	79 (82.3)	Reference	

4.6.4. Sedation

The odds of developing pressure ulcer increased with increasing sedation time, and the results revealed a statistically significant difference between those not sedated who were the reference point and those patients who had sedation time greater than 72 hours (OR=14.0, CI 2.63 – 74.59, p=0.002).

Table 7: Patient distribution according to sedation

		Pressure ulcer			
		Yes *(n=17)*	**No** *(n=96)*	**OR (95% CI)**	**p-value**
Sedation, *n (%)*	Not sedated	3 (17.6)	35 (36.5)	Reference	
	<48 hours	1 (5.9)	19 (19.8)	0.61 (0.06 – 6.32)	0.682
	48 – 72 hours	7 (41.2)	37 (38.5)	2.21 (0.53 – 9.22)	0.278
	>72 hours	6 (35.3)	5 (5.2)	14.00 (2.63 – 74.59)	**0.002**

4.6.5 Systolic blood pressure

The odds of developing pressure ulcers was almost 2 folds for those having SBP of between 90 to 120 mmHg (OR=1.91, CI 0.22 – 16.29, p=0.556), and above 120 mmHg (OR=1.74, CI 0.17 – 17.59, p=0.639) when compared with the reference group of patients having SBP below 90 mmHg, though these were found not statistically significant.

Table 8: Patient distribution according to the systolic pressure

		Pressure ulcer			
		Yes *(n=17)*	**No** *(n=96)*	**OR (95% CI)**	**p-value**
SBP, *n (%)*	<90 mmHg	1 (5.9)	10 (10.4)	Reference	
	90 – 120 mmHg	12 (70.6)	63 (65.6)	1.91 (0.22 – 16.29)	0.556
	> 120 mmHg	4 (23.5)	23 (24.0)	1.74 (0.17 – 17.59)	0.639

4.6.6 Surgical procedures

Surgical patients were less likely to develop pressure ulcer than the non-surgical patients though this was not statistically significant (OR=0.71, CI=0.25-2.05, p=0.532).

Table 9: Patient distribution according to the surgical procedure

		Pressure ulcer			
		Yes *(n=17)*	**No** *(n=96)*	**OR (95% CI)**	**p-value**
Procedure, *n (%)*	Surgical	10 (58.8)	64 (66.7)	0.71 (0.25 – 2.05)	0.532
	Non-surgical	7 (41.2)	32 (33.3)	Reference	

4.6.7 Associated symptoms

Having symptoms such as fecal incontinence, excessive sweating and hemiplegia increased the odds by more than 2 times for developing pressure ulcers but these were not statistically significant.

Table 10: Patient distribution according to associated symptoms

		Pressure ulcer			
Associated signs/Syndrome		**Yes** *(n=17)*	**No** *(n=96)*	**OR (95% CI)**	**p-value**
Fecal incontinence, *n (%)*	Yes	2 (11.8)	5 (5.2)	2.4 (0.4 – 13.7)	0.315
	No	15 (88.2)	91 (94.8)	Reference	
Fever/Hyperthermia, *n (%)*	Yes	0 (0.0)	11 (11.5)	-	
	No	17 (100.0)	85 (88.5)	Reference	
Excessive sweating, *n (%)*	Yes	7 (41.2)	21 (21.9)	2.5 (0.8 – 7.4)	0.096
	No	10 (58.8)	75 (78.1)	Reference	
Hemiplegia, *n (%)*	Yes	2 (11.8)	5 (5.2)	2.4 (0.4 – 13.7)	0.315
	No	15 (88.2)	91 (94.8)	Reference	

4.6.8 Steroids

Patients on steroids were 1.7 times more likely to develop pressure ulcers, but this was not statistically significant (p=0.534).

Table 11: Patient distribution according to the use of steroids

		Pressure ulcer			
		Yes *(n=17)*	**No** *(n=96)*	**OR (95% CI)**	**p-value**
Steroidal agent, *n (%)*	Yes	2 (11.8)	7 (7.3)	1.7 (0.3 – 9.0)	0.534
	No	15 (88.2)	89 (92.7)	Reference	

4.6.9 Pressure relief/technique

There was no statistical association between use and non-use of basic hospital mattress with pressure ulcer, though the odds indicated that those using basic hospital mattress were approximately 1.6 times of developing pressure ulcer. Association was significant for those using sheep skin, where the patients were 3.6 times more likely to develop pressure ulcer. Patients were turned every 4 hours.

Table 12: Patient distribution according to Pressure relief/technique

		Pressure ulcer			
		Yes *(n=17)*	**No** *(n=96)*	**OR (95% CI)**	**p-value**
Pressure device, *n (%)*	Turning schedule	17 (100.0)	77 (80.2)	-	
	Support surfaces	0 (0.0)	19 (19.8)	Reference	
Support surfaces					
Basic hospital mattress, *n (%)*	Yes	14 (82.4)	72 (75.0)	1.56 (0.41 – 5.88)	0.515
	No	3 (17.6)	24 (25.0)	Reference	
Sheep skin, *n (%)*	Yes	8 (47.1)	19 (19.8)	3.60 (1.23 – 10.57)	**0.020**
	No	9 (52.9)	77 (80.2)	Reference	
Fibre overlay, *n (%)*	Yes	-	-	-	
	No	17 (100.0)	96 (100.0)	Reference	

4.6.10 Nurse to patient ratio

Patients who had a nurse-to-patient ratio of 1:1 were less likely to develop pressure ulcer than those with a 1:2 ratio, but this was not statistically significant.

Table 14: Patient distribution according to the nurse to patient ratio

		Pressure ulcer			
		Yes *(n=17)*	**No** *(n=96)*	**OR (95% CI)**	**p-value**
Nurse to patient ratio, *n (%)*	1:1	9 (52.9)	64 (66.7)	0.6 (0.2 – 1.6)	0.279
	1:2	8 (47.1)	32 (33.3)	Reference	

4.6.11 Nutritional status

The underweight patients were 3.5 times more likely to develop pressure ulcer than the overweight patients, while the normal weight patients the odds were even with the overweight patients. These associations were not statistically significant.

Table 15: Distribution for nutritional status

		Pressure ulcer			
		Yes *(n=17)*	**No** *(n=96)*	**OR (95% CI)**	**p-value**
Body adiposity index, *n (%)*	Underweight	8 (47.1)	19 (19.8)	3.5 (0.8 – 15.0)	0.091
	Normal weight	6 (35.3)	52 (54.2)	1.0 (0.2 – 4.2)	0.958
	Overweight	3 (17.6)	25 (26.0)	Reference	

4.6.12 Length of stay in the unit

Each unit increase to the length of stay in the unit increases the odds of developing pressure ulcer by 1.9 times, and this was statistically significant.

Table 16: Patient distribution according to the length of stay in the unit

	Pressure ulcer			
	Yes *(n=17)*	**No** *(n=96)*	**OR (95% CI)**	**p-value**
Days, *mean±SD*	14.7±5.6	4.5±2.4	1.91 (1.38 – 2.65)	**<0.001**

4.6.13 Prognostic variables

APACHE II score of less than 34 reduced the likelihood of developing pressure ulcer, while the Braden score of less than 16 indicated a 2.1 times the likelihood of developing pressure ulcer, but these were found to be not statistically significant. Glasgow coma scale of 9-13 had a 1.3 times the odds of developing pressure ulcers when compared to the reference of 3-8, but this was not statistically significant.

Table 17: Patient distribution according to the prognostic variables

		Pressure ulcer			
		Yes *(n=17)*	**No** *(n=96)*	**OR (95% CI)**	**p-value**
APACHE II Score, *n (%)*	≤34	14 (82.4)	88 (91.7)	0.4 (0.1 – 1.8)	0.244
	>34	3 (17.6)	8 (8.3)	Reference	
Braden scale, *n (%)*	≤16	16 (94.1)	85 (88.5)	2.1 (0.3 – 17.2)	0.500
	>16	1 (5.9)	11 (11.5)	Reference	
Glasgow coma scale, *n (%)*	14 – 15	0 (0.0)	13 (13.5)	-	
	9 – 13	7 (41.2)	29 (30.2)	1.3 (0.4 – 3.8)	0.626
	3 – 8	10 (58.8)	54 (56.3)	Reference	

4.6.14 Laboratory investigations

Having low creatinine levels increased the odds by 1.3 times of developing pressure ulcer than the normal level, while the high creatinine levels reduced the odds of developing pressure ulcer, but these were not statistically significant.

Patients who had low hemoglobin were less likely to develop pressure ulcer than the normal level, while low blood sugars increased the odds ratio by 12 times of developing pressure ulcer but these were not statistically significant. Results also indicate that high albumin level had 6 times the odds of pressure ulcer development, while low albumin level increased the odds by 1.02 times of developing pressure ulcer, though these associations were not statistically significant. High WBC had less odds of developing pressure ulcer development and this was not statistically significant.

Table 18: Laboratory investigations

		Pressure ulcer			
		Yes *(n=17)*	**No** *(n=96)*	**OR (95% CI)**	**p-value**
Creatinine, *n (%)*	Normal	11 (64.7)	58 (60.4)	Reference	
	Low	3 (17.6)	12 (12.5)	1.32 (0.32 – 5.45)	0.703
	High	3 (17.6)	26 (27.1)	0.61 (0.16 – 2.37)	0.473
Hb (g/dl), *n (%)*	Normal	12 (70.6)	46 (47.9)	Reference	
	Low	5 (29.4)	44 (45.8)	0.44 (0.14 – 1.34)	0.147
	High	0 (0.0)	6 (6.3)	-	
Blood sugar (mmol/L), *n (%)*	Normal	2 (11.8)	12 (12.5)	Reference	
	Low	2 (11.8)	1 (1.0)	12.00 (0.71 – 203.14)	0.085
	High	13 (76.5)	83 (86.5)	0.94 (0.19 – 4.69)	0.940
WBC (cells/mcl), *n (%)*	Normal	8 (47.1)	31 (32.3)	Reference	
	Low	0 (0.0)	4 (4.2)	-	
	High	9 (52.9)	61 (63.5)	0.57 (0.20 – 1.63)	0.295
Albumin, *n (%)*	Normal	8 (47.1)	48 (50.0)	Reference	
	Low	8 (47.1)	47 (49.0)	1.02 (0.35 – 2.95)	0.969
	High	1 (5.9)	1 (1.0)	6.00 (0.34 – 105.94)	0.221

5.0 DISCUSSION

This study is aimed at identifying the incidence rate and the potential risk factors of pressure ulcers among patients in the main critical care unit in Kenyatta National Hospital.

The present study exhibits that the incidence of pressure ulcers at Kenyatta National Hospital was 15% and the gluteal region was found to be the commonest location. This is in keeping with the study done by Mutabazi G. et al, which revealed that the incidence of pressure ulcer in the large critical care unit at the referral hospital of Kigali was 15%. They also found that the commonest location for pressure ulcers was the buttocks and Stage 2 was the most common severity for pressure ulcers.[10] However, other studies quoted a higher incidence rate with Tayyib N et al who demonstrated that up to 40 % of patients develop pressure ulcers during their admission to CCU.[6]

The results of the present study indicate that there is no significant association between age and development of pressure ulcer (p-value=0.509). This contrasts with the study carried out by Tayyib N et al that revealed that increased age independently predicted the development of pressure ulcer. The present study showed that males were more prone to develop pressure ulcers than females. However this was not statistically significant. Our findings are supported by other studies[6, 45] that showed a high incidence of pressure ulcers in men admitted to the critical care unit. This study contrasts with the study by Lindgren M., et al that demonstrated that more women than men developed pressure ulcers and the female gender was one of those risk factors identified in multiple stepwise regression analyses. There was a significant association between each unit of increase in the duration of mechanical ventilation and the development of pressure ulcers. This study is similar to the study done in Saudi Arabia by Tayyib N et al, that found that prolonged mechanical ventilation was an independent risk factor for pressure ulcer development.[6] our findings were also similar to the study by Celia L. et al that revealed that the presence of organ failure and the duration of mechanical ventilation were significantly associated with the development of pressure ulcers.

Steroids, nurse-to-patient ratio were found to increase the odds of developing pressure ulcer but were not statistically significant. This study is consistent with other studies which demonstrated an association between development of pressure ulcer and nurse-to-patient ratio and the use of steroids .[23, 24, 25] The present study also found that having comorbid conditions such cardiac disease, diabetes, and CKD was likely associated with pressure ulcer

occurrence, whereas hypertension was less likely to be associated with pressure ulcer development. These findings are consistent with the study by Efraim J., et al that identified diabetes, cardiovascular and renal diseases as risk factors for developing pressure ulcer. They also found that lack of sensory perception from diabetic neuropathy is a major risk factor for pressure ulcer.

The present study showed that the odds of developing pressure ulcer were not reduced with the use of basic hospital mattress and sheepskins. This study contrasts with the study by Mc Gowan et al which compared the effects of the standard hospital mattress with or without, sheepskin overlays and found that pressure ulcer incidence was significantly reduced in those assigned an Australian medical sheepskin (RR for sheepskins relative to standard treatment was 0.30; 95% CI 0.17 to 0.52).[46]

The underweight patients were more likely to develop pressure ulcer than obese patients. Therefore, routine and formal assessment of nutritional status is important to enable the identification of patients at high risk. Our findings are consistent with the study carried out in Palestine by Jamal A.S et al that found that obesity was not associated with the development of pressure ulcer, whereas malnutrition could be a potential risk factor for pressure ulcer development. [47]This study contrasts with the study by Hyun S. et al who found that obese patients were about two times more likely to develop a pressure ulcer than patients with normal weight.

The length of stay in the unit was significantly associated with pressure ulcer development. Each unit increase to the length of stay in the unit increases the odds of developing pressure ulcer by 1.9 times. This finding was supported by the study conducted in Sweden by L. Gunningberg, et al, which revealed that more days of hospitalization were significantly associated with pressure ulcer.[48] These findings can be explained by suggesting that most CCU patients stay for long periods in hospital and little attention is given to their turning schedule and nutrition, thus increasing pressure on the small points and decreasing perfusion to these sites.

APACHE II score of less than 34 reduced the likelihood of developing pressure ulcer, while the Braden score of less than 16 indicated a 2.1 times the likelihood of developing pressure ulcer. But these were found to be not statistically significant. These findings are supported by a study by Francine S.G et al that revealed that APACHE II score was probably associated with pressure ulcer occurrence. These findings are also similar to the study

conducted in Saudi Arabia by Tayyib N et al that revealed that APACHE II score and Braden scale are probably associated with pressure ulcer development. [6, 49]

Having low creatinine, low blood sugar, low albumin level, high WBC increased the likelihood of developing pressure ulcer but these were not found to be statistically significant. Similar observations were reported by Montalcini et al, who pointed out that low serum albumin is a predictor for pressure ulcer onset.[50] Serra et al. (2014) found that low serum albumin level was an independent determinant of pressure ulcer occurrence in critically ill patients.

Our study reveals that fecal incontinence, excessive sweating and hemiplegia increased the probability of developing pressure ulcer, though they were not found to be statistically significant. Our findings are consistent with the study by Maklebust J et al that revealed that Patients with fecal incontinence are 22 times more likely to develop a PU compared to patients without fecal incontinence. In addition to managing pressure and shearing forces, pressure ulcer prevention requires the strict management of incontinence, which poses an important risk factor in PU development.

6.0 CONCLUSION

The incidence of pressure ulcer was 15% and all of them were stage I. Four patients (23.5%) progressed to a stage II ulcer during their stay in the unit. Pressure ulcers occurred within the mean of 8 days after admission. The most common location of ulcers was the gluteal region. Many factors were found to be likely associated with pressure ulcer development, including male gender, diabetes, chronic kidney disease, cardiovascular disease, excessive sweating, fecal incontinence, nurse-to-patient ratio higher than 1:1, hypoalbuminemia, low creatinine level, malnutrition, high blood sugars, high WBC, use of steroids, APACHE II score, Braden scale, increasing sedation time and the use of basic hospital mattresses. Mechanical ventilation, length of stay in the unit and increasing sedation time were found to be independent risk factors for pressure ulcer development. Repositioning had little effect on pressure ulcer development, which could be explained by the lack of preventive and screening strategies in patients at high risk of developing pressure ulcers.

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7.0 STUDY LIMITATIONS

The use of a single site limits the generalizability of the study findings. Data about the severity of the illness or prognosis at admission (APACHE II score) were difficult to retrieve in patients' clinical records.

8.0 RECOMMENDATIONS

Pressure ulcer risk assessment should be performed regularly upon admission and during the patient's stay in the unit. Patient repositioning should be individualized. The turning schedule should be determined by the pressure ulcer risk assessment score. The Braden scale should be used to assess and predict patient's risk for developing pressure injuries. The patient's risk factors for pressure ulcer should be determined on admission and during the icu stay. Special pressure-relieving devices should be available for high risk patients. There is a need to improve nutritional support for high risk patients or patients with ulcers.

REFERENCES

1. Bauer K, Rock K, Nazzal M, Jones O, Qu W (2016) Pressure Ulcers in the United States' inpatients population From 2008 to 2012: Results of a retrospective nationwide Study. Ostomy Wound Manage 62: 30-38.

2. Coyer F, Miles S, Gosley S, Fulbrook P, Sketcher-Baker K, et al. (2017) Pressure injury prevalence in intensive care versus nonintensive care patients: A state-wide comparison. Aust Crit Care 30: 244-250.

3. Bauer K, Rock K, Nazzal M, Jones O, Qu W (2016) Pressure Ulcers in the United States' inpatients population From 2008 to 2012: Results of a Retrospective nationwide Study. Ostomy Wound Manage 62: 30-38.

4. Skerritt, L. & Moore, Z. The prevalence, aetiology and management of wounds in a community care area in Ireland. Br J Community Nurs Suppl, S11-17 (2014).

5. Shahin ES, et al. incidence, prevention and treatment of pressure ulcers in intensive care patients: a longitudinal study. Int J Nurs Stud. 2009 Apr; 46(4):413-21.

6. Tayyib N, et al. (2016) *Saudi Arabian adult intensive care unit pressure ulcer incidence and risk factors: A prospective cohort study. Int Wound J 13: 912-919.*

7. Eugene F. et al (2007), Pressure ulcers in the intensive care unit: The 'forgotten' enemy, OPUS 12 Scientist 2007 Vol. 1, No. 2

8. F.W. Nangole et al; Pressure ulcers presentation and management at Kenyatta National Hospital and spinal injury Hospital, East African Medical Journal Vol. 86. No. 12 December 2009.

9. Moore Z, Johanssen E, van Etten M. A review of PU prevalence and incidence across Scandinavia, Iceland and Ireland (Part I). J Wound Care 2013; 22(7): 361-362, 364-368.

10. Mutabazi G. et al, Establishing Baseline Data for Pressure Ulcers in a Rwandan intensive Care Unit, *Medicine and Health Sciences Vol. 2 No. 2, 2015.*

11. Knutsdottir S (1993) Spinal cord injuries in Iceland 1973-1989: a follow up study. Paraplegia 31:68-72.

12. Reilly, E. F., Karakousis, G. C., Schrag, S. P., & Stawicki, S. P. (2007). Pressure ulcers inthe intensive care unit: The 'forgotten enemy'. *OPUS 12 Scientist, 1*(2), 17-30.

13. Bouten CVC,Oomens CWJ, Baaijens FPT, Bader DL. The etiology of pressure sores: Skin deep or muscle bound? Arch Phys Med Rehabil 2003; 84:616–619.

14. Kirman NC et al, Pressure Injuries (Pressure Ulcers) and Wound Care; March 2020

15. Peirce SM, Skalak TC, Rodeheaver GT. Ischemia-reperfusion injury in chronic pressure ulcer formation: a skin model in the rat. Wound Repair Regen. 2000;8:68-76.

16. EPUAP. Guidelines on the treatment of pressure ulcers.EPUAP Review 1999;2:31–33

17. Russell L, Reynolds T. How accurate are pressure ulcer grades? An image-based survey of nurse performance. J Tissue Viability 2001; 11(2):67–75.

18. Nijs N, Toppets A, Defloor T, Bernaerts K, Milisen K. Incidence and risk factors for pressure ulcers in the intensive care unit. J Clin Nurs, 2009; 18(9): 1258-66.

19. Joshua S et al, Pressure ulcers: Pathophysiology,epidemiology, risk factors,and presentation, December 2018.

20. Krouskop TA. A synthesis of the factors that contribute to pressure sore formation. Med Hypotheses. 1983; **11**:255-267

21. Cox, J. (*20*11). Predictors of pressure ulcers in adult critical care patients. *American Journal of Critical Care*, 20(5), 364-375. http://doi.org/10.4037/ajcc2011934.

22. Terekeci, H., Kucukardali, Y., Top, C., Onem, Y., Celik, S., & Oktenli, C. (2009). Risk assessment study of pressure ulcers in intensive care patients. *European Journal of Internal Medicine, 20*(4), 394-397. http://doi.org/10.1016/j.ejim.2008.11.001.

23. Compton, F., Hoffmann, F., Hortig, T., Straub, M., Frey, J., Zidek, W., & Schafer, J. H. (2008). Pressure ulcer predictors in ICU patients: Nursing skin assessment versus objective parameters. *Journal of Wound Care, 17*(10), 417-424. http://doi.org/10.12968/jowc.2008.17.10.31304

24. Nijs, N., Toppets, A., Defloor, T., Bernaerts, K., Milisen, K., & Berghe, G. (2008).Incidence and risk factors for pressure ulcers in the intensive care unit. *Journal of Clinical Nursing*, *18*(9), 1258-1266. http://doi.org/10.1111/j.1365-2702.2008.02554.x

25. Finucane TE. Malnutrition, tube feeding and pressure sores: data are incomplete. J Am GeriatrSoc. 1995; **43**:447-451.

26. Wright R & Tiziani A. Pressure ulcer point prevalence study. Primary Intention. 1996; **4**:18-23.

27. Moore ZE, Cowman S. Risk assessment tools for the prevention of pressure ulcers. Cochrane Database Syst Rev. 2014;2:CD006471.

28. O'Tuathail C, Taqi R. Evaluation of three commonly used pressure ulcer risk assessment scales. Br J Nurs. 2011;20:S27- S28, S30, S32 Passim.

29. Ayello, E. (2012). *Predicting pressure ulcer risk: Best practices in nursing care to older adults.* Retrieved from https://consultgeri.org/try-this/general-assessment/issue-5.

30. Cox, J. (2012). Predictive power of the Braden scale for pressure sore risk in adult criticalcare patients. *Journal of the Wound, Ostomy, Continence Nurse*, *39*(6), 613-621. http://doi.org/10.1097/WON.0b013e31826a4d83.

31. Clinical practice guidelines (Australian Wound Management Association), August 2001.

32. Fiers SA. Breaking the cycle: the etiology of incontinence, dermatitis and evaluating and using skin care products. Ostomy Wound Managment.1996; **42**:32-40.

33. Byers P, Ryan P, Regan M, Shields A & Carta S. Effects of incontinence care cleansing regimes on skin integrity. Journal of WOCN. 1995; **22**:187-192.

34. Knox D, Anderson T & Anderson P. Effects of different turn intervals on skin of healthy older adults. Adv Wound Care. 1994; **7**:48-56.

35. Tayyib, N., & Coyer, F. (2016). Effectiveness of pressure ulcer prevention strategies for adult patients in intensive care units: A systematic review. *Worldviews Evidence Based Nursing*, *13*(6), 432-444. http://doi.org/10.1111/wvn.12177.

36. Pase M. Pressure relief devices, risk factors, and development of pressure ulcer in elderly patients with limited mobility. Adv Wound Care. 1994;**7**:38-42.

37. Cullum N, Deeks J, Sheldon T, Song F & Fletcher A. Beds, mattresses and cushions for pressure sore prevention and treatment [Review] The Cochrane Database of Systematic Reviews . 1999.

38. McLean J. Pressure reduction or pressure relief: making the right choice. J ET Nurs. 1993; **20**:211-215.

39. Clancy MJ J. Pressure redistribution devices: what works, at what cost and what's next? Tissue Viability. 2013 Aug; 22(3):57-62.

40. Antibiotics and antiseptics for pressure ulcers.Norman G, Dumville JC, Moore ZE, Tanner J, Christie J, Goto S Cochrane Database Syst Rev. 2016 Apr 4; 4():CD011586.

41. Operative debridement of pressure ulcers. Schiffman J, Golinko MS, Yan A, Flattau A, Tomic-Canic M, Brem H World J Surg. 2009 Jul; 33(7):1396-402.

42. Recent accomplishments in wound healing. Mudge EJ Int Wound J. 2015 Feb; 12(1):4-9.

43. Current thoughts for the prevention and treatment of pressure ulcers: using the evidence to determine fact or fiction. Levine SM, Sinno S, Levine JP, Saadeh PB Ann Surg. 2013 Apr; 257(4):603-8.

44. Sayhowd E, et al; Incidence of pressure sore development in icu of alkadhimia teaching hospital, Colmed, May 2016.

APPENDICES

Appendix I (a): Consent Explanation Form (English)

I am Dr. Franck Ngoma, a postgraduate student pursuing a Masters' degree in Anesthesiology at the University of Nairobi. I am conducting a study on Pressure ulcer incidence and risk factors among the critically ill patients.

Dear Sir or Madam: Your relative is invited to participate in our study to determine the incidence and risk factors for pressure ulcer among the critically ill patients in KNH-main CCU. Before deciding whether or not He/she should take part in this study, we request that you carefully read the following information which explains the study's objectives and the implications of his/ her possible participation.

Study Description & procedure

The study is expected to show the incidence of pressure ulcer at KNH-main CCU and determine associated risk factors. We will collect information regarding the occurrence of pressure ulcers. During the intensive care unit course, the investigator and research assistants will be inspecting the study participants from the head to toe at the time of nursing care in the early morning. Information will be collected by means of the research assistant administered questionnaire. Additional Data will be collected from patients' clinical records, clinical examination and interaction with primary nurses; laboratory and radiologic investigations requested by the CCU team using a research assistant administered questionnaire. Data will be collected every 48 hours. We will analyze the laboratory and radiologic investigations done in the course of the patient's ICU stay**.**

Study Objective

The main objective is to determine pressure ulcers incidence and associated risk factors among the critically ill patients at Kenyatta national Hospital – main critical care Unit.

Voluntariness of participation

Your relative's participation is voluntary and withdrawal from this study will not alter the medical care He/ She receives. A decision not to participate in the study will not affect his/ her treatment.

Benefits and Risks

No additional intervention, laboratory or radiological investigations will be performed for the need of the study outside of the patient's necessary care. No financial benefits will be granted to patients or their next of kin for their participation in this study.

Right of withdrawal

Even though you have agreed that your relative participates, both the patient and the next of kin can withdraw care. You will not be asked to justify your decision.

Confidentiality

To conduct this study, the principal investigator will need to consult and make use of some of the Information found in the medical record. Your acceptance will allow us to consult and process the information in the following manner:

• Information obtained from the medical record will be stored in a computerized database for all the participants.

• All information will be anonymized. All clinical information that is obtained for the study will be identified by a number. No data concerning personal identification will be stored in the database.

Results of the Research Study

Study participants will not be contacted upon completion of the study, but will be allowed to contact the principal investigator to learn more about the research. The results obtained in the present study will be used to guide the prevention and therapy of pressure ulcers in KNH-main CCU. The study will also be published in a medical journal and the Information and knowledge gained will be of benefit to many critically ill patients.

For further information and clarification, you may contact:

Principal Investigator: **Dr. Franck Ngoma**

Telephone: 0711941154

Or,

Researcher Supervisors: **Dr. Susane Nabulindo/ Dr. Faith Wanjiru**

Telephone 1: 0721418587

Telephone 2: 0720459798

If you have any questions related to the patients' rights as a participant in the study you can get in touch with (Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee):

Telephone: 2726300

Thank you for taking time to read this information sheet. I wish your loved one a quick recovery.

Appendix II (a) Consent Form

I, (Your name) _____, have been explained the purpose and condition of my involvement in the study by Dr. Franck Ngoma. I agree to the above and do give consent for my inclusion in the study

Signature: _____

Thumb print: _____

Date:_____

Appendix II (b): Consent Form (Swahili)

Mimi, (jina lako) _____, nimeelezwa madhumuni na masharti ya kushirikishwa katika utafiti wa Dkt. Frank Gitonga. Nakubaliana na maelezo hayo na nimemruhusu daktari kunishirikisha katika utafiti huo.

Sahihi: _____

Kidole Cha Gumba: _____

Tarehe: _____

Appendix II (c): Assent Form (English)

I, (Your name) _____, have been explained the purpose and condition of my Next of Kin's/ relative's involvement in the study by Dr. Franck Ngoma. I agree to the above and do give consent for:

(Patient's name) _____

To be included in the study, by virtue of being a critically ill patient admitted to KNH main CCU.

Name: _____

Signature: _____

Thumb print: _____

Date: _____

Appendix II (d): Assent Form (Swahili)

Mimi, (jina lako) _____, nimeelezwa madhumuni

na masharti ya mgonjwa wangu kushirikishwa katika utafiti wa Dkt. Franck Ngoma.

Nakubaliana na maelezo hayo na nimemruhusu daktari kufanya utafiti huo kwa jamaa wangu:

(Jina la mgonjwa) _____.

Naidhinisha ruhusa kwa niaba ya mgonjwa kwa sababu kwa wakati huu, ugonjwa mahututi wa ubongo haumwezeshi kutoa idhini kamilifu.

Jina: _____

Sahihi: _____

Kidole Cha Gumba: _____

Tarehe: _____

Appendix III: Data Collection Form

Questionnaire Serial Number:…….

I. **Data to be collected at admission**

a. Biodata

1. Age: ……..Months …….Years

2. Gender: ……..Male ……..Female

b. What is the admitting diagnosis?

Diagnosis	Tick as appropriate
1. Traumatic Brain Injury	
2. Cerebrovascular accident	
3. CNS Infection	
4. Acute/Chronic kidney disease	
5. Cardiovascular disease	
6. Other	

c. What are the prognostic variables at admission?

Prognostic variables	Score
1. Acute physiology and chronic health evaluation II (APACHE II) Score	
2. Braden scale:	
3. Glasgow Coma Scale:	

II. Data to be collected during ICU stay

1. Does the patient have a history of medical comorbidities?

Yes…. Or ……No (tick as appropriate)

If yes, please specify:

a. cardiovascular disease

b. Diabetes Mellitus

c. Chronic kidney disease

d. HIV

e.Other……

2. Does the patient have any of the following signs or symptom?

(Tick as appropriate)

- Fecal incontinence
- Fever/ Hyperthermia
- Hemiplegia
- Excessive sweating

3. Was the patient mechanically ventilated?

Yes…….. or ……..No

If yes, what was the duration of mechanical ventilation?

Please, specify…….

4. Did the patient undergo surgery?

Yes…… or ……..No

If yes,

a. What was the surgical procedure? Please, specify ……

b. What was the mode of anaesthesia used? Please, specify.....

c. What was the duration of the surgery? Please, specify ……..

5. What are the laboratory parameters every 7 days?

Labs Week1 Week2 Week3

- Creatinine umol/L
- Hb (g/dl)
- Blood sugar (mmol/L)
- WBC(cells/mcl)
- Albumin (g/dl)

6. What was the nutritional status (Body Adiposity Index)?

Body Adiposity index Week1 Week2 Week3

Male

- < 8%
- 8 to 19%
- 19 to 25%
- > 25%

Female

- < 21%
- 21 to 33%
- 33 to 39%
- > 39%

7. What was the lowest Blood pressure (BP) in the last 24 hours?

Days	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	D13	D14	D15	D16	D17	D18	D19	D20
BP																				

8. What was the nurse to patient (N/P) ratio from day 1 to 20?

Days	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	D13	D14	D15	D16	D17	D18	D19	D20
N/P																				

9. Was the patient sedated?

Yes…….. or ……No (tick as appropriate)

If yes, How long has the patient been sedated? Please, Specify……..

10. Was the patient on steroids?

Yes ……. or ……..No (tick as appropriate)

If yes, what was the duration of treatment? Please, specify…….

11. Which Pressure relief device/technique was used?

- Turning schedule
- Support surfaces:
  - Basic hospital mattresses
  - Sheepskins
  - fibre overlays and gel pads
  - Other…….

12. Did the patient develop pressure ulcer?

Yes…… or …….No

If yes,

a. on which day? Please, specify……

b. What was the stage of pressure ulcer? Please, specify……

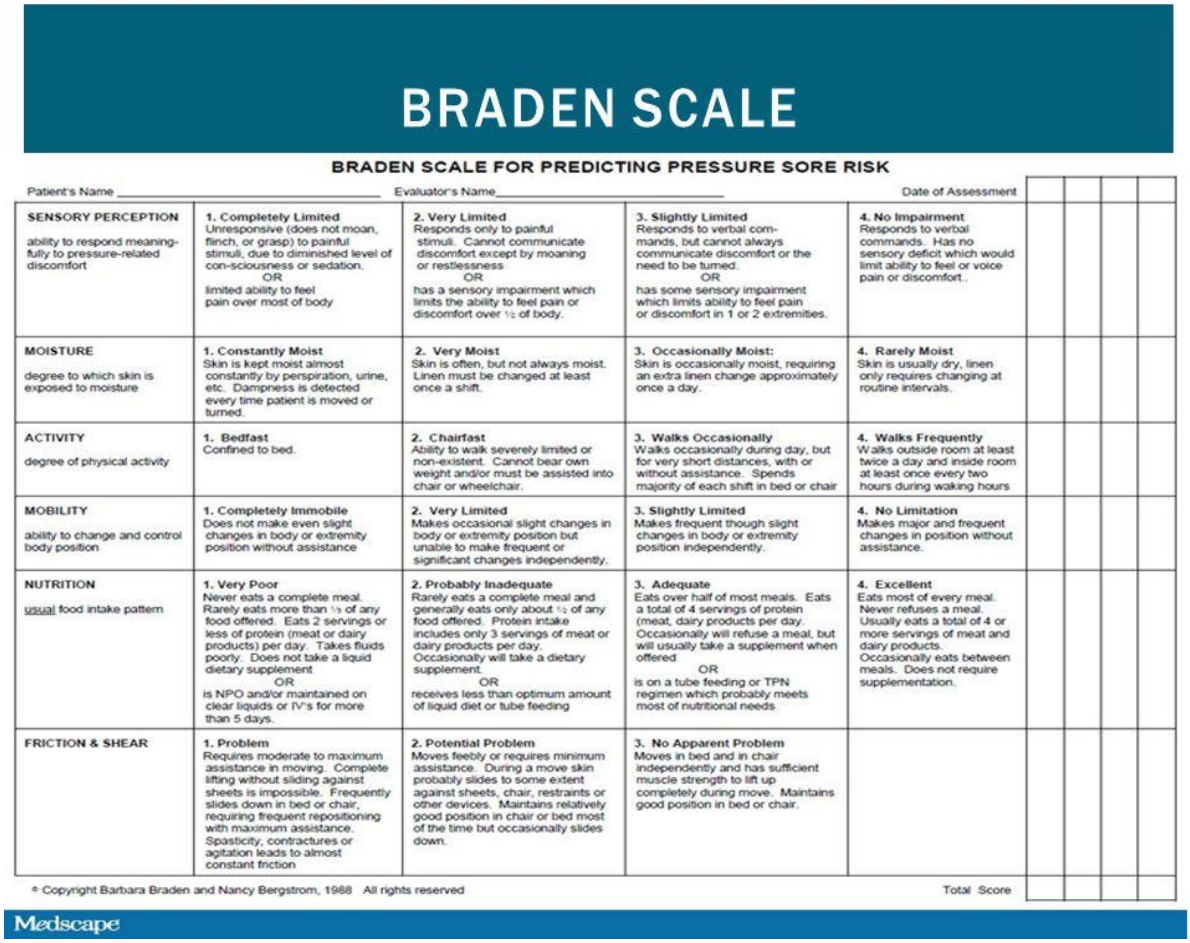
c. What was the site of pressure ulcer? Please, Specify……..

d. Has the pressure ulcer progressed to the most severe stage at discharge? If yes, please specify……

13. What was the length of Stay in the unit? Please, specify……..

SCORES

APPENDIX IV: BRADEN SCALE



BRADEN SCALE

BRADEN SCALE FOR PREDICTING PRESSURE SORE RISK

Patient's Name _____ Evaluator's Name_____ Date of Assessment

SENSORY PERCEPTION ability to respond meaningfully to pressure-related discomfort	**1. Completely Limited** Unresponsive (does not moan, flinch, or grasp) to painful stimuli, due to diminished level of consciousness or sedation. OR limited ability to feel pain over most of body	**2. Very Limited** Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness OR has a sensory impairment which limits the ability to feel pain or discomfort over ½ of body.	**3. Slightly Limited** Responds to verbal commands, but cannot always communicate discomfort or the need to be turned. OR has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.	**4. No Impairment** Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort..				
MOISTURE degree to which skin is exposed to moisture	**1. Constantly Moist** Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned.	**2. Very Moist** Skin is often, but not always moist. Linen must be changed at least once a shift.	**3. Occasionally Moist:** Skin is occasionally moist, requiring an extra linen change approximately once a day.	**4. Rarely Moist** Skin is usually dry, linen only requires changing at routine intervals.				
ACTIVITY degree of physical activity	**1. Bedfast** Confined to bed.	**2. Chairfast** Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair.	**3. Walks Occasionally** Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair	**4. Walks Frequently** Walks outside room at least twice a day and inside room at least once every two hours during waking hours				
MOBILITY ability to change and control body position	**1. Completely Immobile** Does not make even slight changes in body or extremity position without assistance	**2. Very Limited** Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.	**3. Slightly Limited** Makes frequent though slight changes in body or extremity position independently.	**4. No Limitation** Makes major and frequent changes in position without assistance.				
NUTRITION usual food intake pattern	**1. Very Poor** Never eats a complete meal. Rarely eats more than ⅓ of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement OR is NPO and/or maintained on clear liquids or IV's for more than 5 days.	**2. Probably Inadequate** Rarely eats a complete meal and generally eats only about ½ of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement. OR receives less than optimum amount of liquid diet or tube feeding	**3. Adequate** Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products per day. Occasionally will refuse a meal, but will usually take a supplement when offered OR is on a tube feeding or TPN regimen which probably meets most of nutritional needs	**4. Excellent** Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.				
FRICTION & SHEAR	**1. Problem** Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures or agitation leads to almost constant friction	**2. Potential Problem** Moves feebly or requires minimum assistance. During a move skin probably slides to some extent against sheets, chair, restraints or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down.	**3. No Apparent Problem** Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair.					
				Total Score				

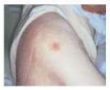
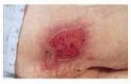
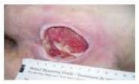
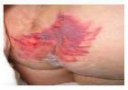
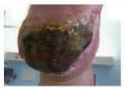
Medscape

APPENDIX V: GLASGOW COMA SCALE

Feature	Response	Score
Best eye response	Open spontaneously	4
	Open to verbal command	3
	Open to pain	2
	No eye opening	1
Best verbal response	Orientated	5
	Confused	4
	Inappropriate words	3
	Incomprehensible sounds	2
	No verbal response	1
Best motor response	Obeys commands	6
	Localising pain	5
	Withdrawal from pain	4
	Flexion to pain	3
	Extension to pain	2
	No motor response	1

British Columbia Patient Safety & Learning System

Pressure Ulcer Stages

Stage I	Stage II	Stage III	Stage IV	Suspected Deep Tissue Injury (SDTI)	Unstageable
• Intact skin with localized, non-blanchable erythema over a bony prominence. • The area may be painful, firm or soft and warmer or cooler when compared to surrounding tissue. • Darkly pigmented skin may not show visible blanching, however the colour of the Stage I ulcer will appear different than the colour of surrounding skin. • Indicates the patient is at risk for further tissue damage if pressure is not relieved.	• A partial thickness wound presenting as a shallow, open ulcer with a red/pink wound bed. • May also present as an intact or open/ruptured serum-filled or serosanguinous-filled blister. • Slough may be present but does not obscure the depth of tissue loss.	• A full thickness wound. • Subcutaneous tissue may be visible but bone, tendon and muscle are not exposed. • May include undermining or sinus tracks. • Slough or eschar may be present but does not obscure the depth of tissue loss.	• A full thickness wound with exposed bone, tendon or muscle. • Often includes undermining and/or sinus tracks. • Slough or eschar may be present on some parts of the wound bed but does not obscure the depth of tissue loss.	• A localized purple or maroon area of intact skin or a blood-filled blister that occurs when underlying soft tissue is damaged from friction or shear. • May start as an area that is painful, firm or mushy/ boggy, and warmer or cooler than the surrounding tissue but can deteriorate into a thin blister over a dark wound bed or a wound covered in thin eschar. • Deterioration may be rapid, exposing additional layers of tissue even with optimal treatment, and may be difficult to detect in individuals with dark skin tones.	• A wound in which the wound bed is covered by sufficient slough and/or eschar to preclude staging.
					
	 			 	

Developed by the BC Provincial Nursing Skin & Wound Care Committee. Images Stage 1, 2, & 3 retrieved June 14, 2012 from www.npuap.org. Images Stage 4, SDTI, Unstageble and the definitions are from the BC Provincial Nursing Skin & Wound Committee Guideline: Pressure Ulcer Management Decision Support Tool found at www.clwk.ca.

APPENDIX VII: APACHE II SCORE

	Physiologic variable[b]	Point score							
		+4	+3	+2	+1	0	+1	+2	+3
1	Temperature	⩾41°	39–40.9°	–	38.5–38.9°	36–38.4°	34–35.9°	32–33.9°	30
2	Mean arterial pressure (mm Hg)	⩾160	130–159	110–129	–	70–109	–	50–69	–
3	Heart rate	⩾180	140–179	110–139	–	70-109	–	55–69	40
4	Respiratory rate(non-ventilated or ventilated)	⩾50	35–49	–	25–34	12–24	10–11	6-9	–
5	Oxygenation:								
	a) FiO_2 ⩾ 0.5: use A-aDO_2	⩾500	350–499	200–349	–	<200	–	–	–
	b) FiO_2 < 0.5: use PaO_2 (mm Hg)	–	–	–	–	>70	61–70	–	55
6	Arterial pH	⩾7.7	7.6–7.69	–	7.5–7.59	7.33–7.49	–	7.25–7.32	7.1
7	Serum Na (mMol/L)	⩾180	160–179	155–159	150–154	130–149	–	120–129	11
8	Serum K (mMol/L)	⩾7	6–6.9	–	5.5–5.9	3.5-5.4	3–3.4	2.5–2.9	–
9	Serum creatinine (mg/dL): double point score for acute renal failure	⩾++++3.5	2–3.4	1.5–1.9	–	0.6–1.4	–	<0.6	–
10	Hct (%)	⩾60	–	50–59.9	46–49.9	30–45.9	–	20–29.9	–
11	WBC (in l000s)	⩾40	–	20–39.9	15–19.9	3–14.9	–	1–2.9	–
12	Glasgow coma score (GCS)	Score = 15 minus actual GCS							
Acute physiology score is the sum of the 12 individual variable points									
Add 0 points for the age <44.2 points. 45–54 years: three points. 55–64 years: five points. 65–74 years: six points ⩾75 years									
APACHE II score = acute physiology score + age points + chronic health points. Minimum score = 0; maximum score = 71. Increasing score is associated with of hospital death									
Add chronic health ststus points: two points if elective postoperative patient with immunocompromise or history of severe organ insufficiency: five points patient or emergency postperative patient with immunocompromise or severe organ insufficiency[c]									
13[d]	Serum HCO_3(venous-mMol/L) use only if no ABGs52	⩾52	41–51.9	–	32–40.9	22–31.9	–	18–21.9	15

Adapted from Knaus WA. Draper EA. Wagner DP. Zimmermam JB: APACHE II: A severity of disease classification system. *Critial care medicine* 13: 818–82

Interpretation of APACHE II scores (predicted mortality rate).

0–4 = ∼4% death rate 10–14 = ∼15% death rate 20–24 = ∼40% death rate 30–34 = ∼75% death rate.

5–9 = ∼8% death rate 15–19 = ∼25% death rate 25–29 = ∼55% death rate Over 34 = ∼85% death rate.

[a] APACHE II Score = acute physiology score + age points + chronic health points. Minimum score = 0; maximum score = 71. Increasing score is associate risk of hospital death.

[b] Choose worst value in the past 24 h.

[c] Chronic health status: Organ sufficiency (e.g. hepatic, cardiovascular, renal, pulmonary) or immuno-compromised state must have preceded current a

[d] Optional variable: use only if no ABGs.

APPENDIX VIII. DUMMY TABLES

Table 1: Patient Characteristics

Biodata	Frequency	%
Age		
• < 10		
• 10 -20		
• 21 – 40		
• 41 – 60		
• 61 – 80		
• >80		
Gender		
• Male		
• Female		

Table 2: Incidence of Pressure Ulcers

	Frequency	Percent
Yes		
No		

Table 3: Univariate analysis of patient characteristics and presence of pressure ulcer

	Pressure ulcer			
Biodata	**Yes**	**No**	**OR (95% CI)**	**p-value**
Age				
• < 10				
• 10 -20				
• 21 – 40				
• 41 – 60				
• 61 – 80				
• >80				

Gender

- Male
- Female

Univariate analysis of patient clinical characteristics and presence of pressure ulcer

Table 4. Patient distribution according to the duration of mechanical ventilation

Duration	Pressure ulcer			
	Yes	**No**	**OR (95% CI)**	**p-value**
○ ≤ 24 hours				
○ 24 to 72 hours				
○ > 72 hours				

Table 5. Patient distribution according to history of co-morbid medical condition

Condition	Pressure ulcer			
	yes	No	**OR (95% CI)**	**p-value**
○ Cardiovascular disease				
○ Diabetes				
○ Chronic kidney disease				
○ HIV				
○ Other:……				

Table 6. Sedation

Sedation	**Pressure ulcer**			
	Yes	**No**	**OR (95% CI)**	**p-value**
○ Not sedated:				
○ <48 hours:				
○ 48 – 72 hours:				
○ > 72 hours				

Table7. Patient distribution according to the diastolic pressure

Diastolic Blood Pressure	Pressure ulcer			
	Yes	No	**OR (95% CI)**	**p-value**
○ < 80 mmHg				
○ 85 –89 mmHg				
○ ≥ 90mmHg				

Table8. Patient distribution according to the surgical procedure

Surgery	Pressure ulcer			
	yes	No	**OR (95% CI)**	**p-value**
○ Type of Surgery				
○ Mode of anesthesia				
○ Duration of Surgery				

Table 9. Patient distribution according to the diagnosis

Diagnosis	Pressure ulcer			
	Yes	No	**OR (95% CI)**	**p-value**
• Traumatic Brain Injury				
• Stroke				
• CNS Infection				
• Acute/Chronic kidney disease				

Cardiovascular disease Sepsis

Other:_____

Table10. Patient distribution according to associated symptoms

Associated signs/Syndrome	Pressure ulcer			
	Yes	No	**OR (95% CI)**	**p-value**
o Fecal incontinence				
o Fever/ Hyperthermia				
o Urinary incontinence				
o Hemiplegia				
o Excessive sweating				

Table 11. Patient distribution according to the use of steroids

	Pressure ulcer			
	Yes	No	**OR (95% CI)**	**p-value**
o Steroidal agent				
o Duration of treatment:				

Table 12. Patient distribution according to Pressure relief/technique

Pressure relief device/technique	Pressure ulcer			
	Yes	No	**OR (95% CI)**	**p-value**
o Repositioning:				
o Support surfaces:				
• Basic hospital mattresses				
• Sheepskins,				
• Static air mattresses and overlays				
• Turning beds				
• Foam pressure reducing				

Table 13. Patient distribution according to the stage of pressure ulcer

Stage	Pressure ulcer			
	Yes	No	**OR (95% CI)**	**p-value**
• Stage I				
• Stage II				
• Stage III				
• Stage IV				
• Unclassified				
• Suspected deep tissue injury				
o Date of occurrence:				

Table 14. Patient distribution according to the nurse to patient ratio

	Pressure ulcer			
	Yes	No	**OR (95% CI)**	**p-value**
Nurse to patient ratio				
• 1:5				
• 1:4				
• 1:3				
• 1:2 or fewer				

Table 15. Nutritional status

Body adiposity index	Pressure ulcer			
	Yes	No	**OR(95% CI)**	**p-value**
• Under weight				
• Normal				
• Overweight				

- Obese

Table 16. Patient distribution according to the length of stay in the unit

	Pressure ulcer			
	Yes	No	**OR(95% CI**	**p-value**
• <30 days				
• > 30 days				

Table 17. Patient distribution according to the prognostic variables

APACHE II Score	Pressure ulcer			
	Yes	No	**OR(95% CI)**	**p-value**
• < 34				
• >34				
Braden scale				
• < 16				
• >16				
Glasgow Coma Scale				
• 14 – 15				
• 9 – 13				
• 3 – 8				

Table 18. Laboratory investigations

Investigation	Pressure ulcer			
	Yes	No	**OR(95% CI**	**p-value**
o Creatinine				
- Normal				
- Low				
- High				
o Hb (11g/dl)				
– Normal				

- Low
- High

- Blood sugar (mmol/L)
  - Low
  - Normal:
  - High
- WBC(cells/mcl)
  - Low
  - Normal
  - High
- Albumin
  - Low
  - Normal
  - High

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29th July, 2021

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KENYATTA NATIONAL HOSPITAL APPROVED 29 JUL 2021 KNH/UoN-ERC P. O. BOX 20723 - 00202 NAIROBI

Dear Dr. Nguvulu

RESEARCH PROPOSAL: INCIDENCE AND RISK FACTORS OF PRESSURE ULCER AMONG CRITICALLY ILL PATIENTS AT KENYATTA NATIONAL HOSPITAL (P275/04/ 2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 29th July, 2021 – 28th July, 2022.

This approval is subject to compliance with the following requirements:

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

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

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

Yours sincerely,

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

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