DETERMINANTS OF DELIRIUM AMONG PATIENTS IN CRITICAL CARE UNITS AT KENYATTA NATIONAL HOSPITAL

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CERTIFICATE OF APPROVAL

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DEDICATION

I dedicate this research to my family, my son Jaydon and daughter Ayah, for their love. To my husband for his selfless support, encouragement, and patience, which made it possible for me to complete this thesis.

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LIST OF ABBREVIATIONS

APACHE: Acute Physiology and Chronic Health Evaluation

CAM-ICU: Confusion Assessment Method for the Intensive Care Unit

CNS: Central Nervous System

DOS: Delirium Observation Screening scale

ERC: Ethics Review Committee

HIV: Human Immunodeficiency Virus

HTN: Hypertension

ICC: Intraclass Correlation Coefficient

ICU: Intensive Care Unit

KNH: Kenyatta National Hospital

MoH: Ministry of Health

Nu-DESC: Nursing delirium-screening scale

RASS: Richmond Agitation Sedation Scale

SAS: Sedation-Agitation Scale;

GCS: Glasgow Coma Scale

SPSS: Statistical Package for Social Scientists

OPERATIONAL DEFINITIONS

Confusion: Having incoherent or non-clear speech or thoughts

Consciousness: Rousable state and awareness of the environment and surroundings

Delirium: An acutely disturbed state of mind characterized by restlessness, illusions, and Incoherence: occurring in intoxication, fever, and other disorders.

Determinants: A factor the decisively affects the nature or outcome of something.

ABSTRACT

Background: Delirium is common in patients admitted to critical care units. It is associated with morbidity and mortality, and high hospital costs. The prevalence has been found to range from 20-83% among critically ill patients. Even though delirium prevalence and factors have been described in the developed world, there is a paucity of data from low-resource settings such as Kenya. The aim of this study therefore is to determine the factors associated with the development of delirium in patients admitted to critical care units.

Objective: Assess the prevalence, risk factors, and precipitating factors for delirium among critical care patients admitted in the main or medical ICU at Kenyatta National Hospital (KNH).

Methods and Materials: A cross-sectional study of 81 patients admitted at the main or medical ICU of the KNH was done in 2020. The principal investigator administered consent to the next of kin and a study questionnaire was used to record demographic and medical data of participants from hospital records. The Richmond Agitation Sedation Scale (RASS) was used to evaluate sedation and agitation status and the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) was used to evaluate delirium. The CAM-ICU assessments were done once. Data were uploaded into a Statistical Package for Social Scientists (SPSS) spreadsheet and cleaned. Categorical data were summarized into proportions and continuous data as means with standard deviations. Clinical characteristics were evaluated by using frequencies and percentages and risk factors for delirium were evaluated using a chi-square test and logistic regression. Statistical data analysis was done at a 95% confidence level.

Results: Eighty-one patients 50 (61.7%) males and 31 (38.3%) females were recruited with a mean age of 39.67±12.09 years. A majority were self-employed 34 (42.0%), had a tertiary 60 (74.1%) education, and did not drink alcohol 54 (66.7%). A majority did not smoke cigarettes 69 (85.2%), had co-morbidity 47 (58.0%), mostly hypertension 19 (40.4%), while the mean number of medications was 10.22±3.58. Most were sedated 53 (65.4%) mostly continuously 48 (90.6%) with Remifentanyl 19 (35.8%), while 57 (70.4%) were physically restrained. The average length of hospital stay was 13.84±10.82 days. The prevalence of delirium was 34.6% (24.3-45.9%). Delirious patients were significantly older (43.68±12.72 years) than non-delirious patients (37.45±10.82), P=0.03. The odds of delirium was 12.58 fold (95% CI=3.87-32.68) higher among patients who consumed alcohol compared to those who did not, P<0.01. The odds of delirium was 6.14 fold (95% CI = 0.66-19.95) higher with cigarette smoking, P=0.01 and 7.44 fold (95% CI=1.97-25.13) higher under sedation, P<0.01, while the odds of delirium was 9.23 fold (95% CI=2.19-41.84) higher under physical restraint, P<0.01. After multivariable analysis, the adjusted odds for delirium was 60.15 fold (95% CI= 2.89-1248.1), higher among patients who consumed alcohol, P=0.008, and 22.85 fold (95% CI=1.07-487.8) higher among patients who were physically restrained, P=0.045. Metabolic conditions as the commonest precipitating factor 25 (30.9%) in the ICUs followed by infections 19 (23.5%).

Conclusion: Delirium is a common health complication at the Kenyatta National medical and main ICUs with approximately 34.6% of patients affected. Increasing age, cigarette smoking, sedation, and physical restraint, were major risk factors for delirium but only alcohol use and physical restraint could be used to predict the occurrence of delirium in the population studied.

CHAPTER 1: INTRODUCTION

1.1 Background

Delirium occurs routinely among mechanically ventilated patients and often leads to adverse health outcomes. It has different definitions with Intensive Care Unit (ICU) delirium defined as a reduction in self-awareness/clarity of the environment and lack of attention and focus due to disturbance of consciousness (Diagnostic and Statistical Manual of Mental Disorders -V (DSM-V). This neuro mental condition has been associated with acute disturbances of consciousness, fluctuating levels of cognition, and attention and is the most common cause of cognitive dysfunction among hospitalized individuals (Duceppe et al., 2019).

The occurrence of delirium in the hospital setting is reported to be high and variable by site and study design. Its prevalence is estimated to range between 20-83% and is often dependent on the severity of illness and physical age of patients (Shivanandh, Sudhakar, Mohan, Reddy & Aruna, 2015). The variability in prevalence depends on the type of ICU, type of study, the population under study, and outcomes, which include a longer stay in hospital and lengthy mechanical ventilation, persistent cognitive deficiency post-hospital discharge. The need for long-term critical care has also been shown to be higher among delirious patients, which increases ICU care costs (Mehta, Cook, Devlin, Skrobik, Meade, Fergusson, & Burry, 2015).

A study by Torres-Contreras et al. (2019) ascertaining the incidence of delirium was 20.2% within the first 24 hours in adult patients. The study used Confusion Assessment Method- Intensive Care Unit (CAM-ICU) - a frequently used protocol by researchers due to its high specificity and sensitivity. In Uganda, Kwizera et al. (2015) reported a higher prevalence of 51% in a multicenter observational study (prospective) of patients in ICU.

The occurrence of a delirious state is associated with a plethora of clinical and hospital factors. In trauma and surgical ICUs, the use of midazolam during sedation (Cavallazzi et al.,

2012; Pandharipande et al., 2008), being male and having a history of tobacco and alcohol use (Mehta et al., 2015) have been identified as being determinants for delirium in patients admitted in critical care ICUs. Other factors linked with delirium have included an Acute Physiologic and Chronic Health Evaluation II Score (APACHE II) of more than 14. This score is used to assess the severity of a patient's condition in ICU. The higher the score the more severe the condition and mortality rate may be high. use of benzodiazepines and opioids, use of sedatives, metabolic acidosis, and infection due to mechanical ventilation, and advanced age have also been associated with delirium (Torres-Contreras et al., 2019).

Critical care unit delirium is assessed using different tools that are easy to use by healthcare providers; however, the frequently used tool is CAM-ICU. The CAM-ICU is a globally accepted and extensively reviewed research item, which is suitable for assessing delirium bedside in a nonverbal ventilated ICU patient. CAM-ICU has demonstrated high sensitivity and high specificity. Only two errors are acceptable, with any discrepancy reported during its usage confirmed using a visual test (Cavallazzi et al., 2012).

Delirium has been attributed to the high prevalence of chronicity, high cost of care, and health burden (Mehta et al., 2015). However, the situation has not been characterized or mapped in low middle-income countries (LMIC). The level of attention dedicated to the identification and management of delirium in these countries including Kenya is limited. This gap needs to be addressed through research.

1.2 Problem statement

Delirium is associated with additional health and cost burden to the patients and family. Critically ill patients on admission at the ICU are in a stressful and unfamiliar setting and during their ICU stay; they not only experience discomfort from disease but also separation from family, which can trigger delirium. The prevalence of delirium ranges from 11-80% among

ICU patients depending on the population and methodology used. The changes in the physical, environmental, and psychological state are risk factors (Lin, Chen & Wang, (2015).

Several tools are available for the diagnosis of delirium in ICU, with the commonly used tools being Confusion Assessment Method-Intensive Care Unit (CAM-ICU). The tools have allowed rapid diagnosis of delirium among mechanically ventilated critical-care patients by health care providers. Even with the availability of diagnosis tools of delirium, the disorder is usually ignored and termed as a common occurrence among ICU patients not knowing the impact on patient outcome Inouye, Westendorp, & Saczynski, (2014).

Studies on predictors done elsewhere for delirium found that higher APACHE II SCORE, advanced age, and use of benzodiazepines predisposes patients to acquire delirium in ICU. At the Kenyatta National Hospital, determinants of delirium have not been studied, therefore are not well understood. However, some factors such as age especially in patients above 60 years have been associated with delirium. In addition, Agarwal et al., (2010) found that benzodiazepines, especially Midazolam, increased the risk of delirium.

Delirium increases the number of days in ICU and contributes to the persistent functional decline, high risk of mortality and morbidity, and the astronomical hospital bills that critical care attracts. According to Rueden et al., (2019) delirium increases medical costs by around 17.5 million inpatient days and approximately $5 billion in Medicare fees every year. Although data on predictors of delirium exists, most are studies done elsewhere. There exists no data on prevalence or risk factors associated with delirium in Kenya. There is a need to identify predictors associated with delirium among ICU patients at KNH.

1.3 Research Questions

- What is the prevalence of delirium among patients in critical care units at KNH?
- What are the risk factors for delirium among patients in critical care units, KNH?

- What are the precipitating factors associated to delirium among patients in critical care units, Kenyatta National Hospital?

1.4 Objectives

1.4.1 Broad Objective

To assess the determinants of delirium among patients admitted in critical care units at KNH.

1.4.2 Study Objectives

- To determine the prevalence of delirium among patients in critical care units at KNH
- To assess the risk factors for delirium among patients in critical care units, KNH.
- To determine the precipitating factors associated to delirium among patients in critical care units, KNH

1.5 Null Hypothesis

- There is no relationship between patients' clinical characteristics and the development of delirium in patients admitted to critical care units, KNH.

1.6 Study Justification

Delirium can lower the quality of life of patients after discharge from ICU. It is associated with increased length of stay, morbidity and mortality, and even progressive cognitive decline after discharge. This has increased the cost of care to the patient's families and even the health system. The patients have to be kept longer in ICU which makes patients who could benefit from the already few beds in ICU miss the chance of receiving the specialized care on offer. Many have even been turned away because of the lack of ICU beds ending up dead.

This study determined factors that are associated with delirium during ICU stay. KNH is the largest hospital in Kenya and serves as a referral from different hospitals. The results from this study will create awareness about delirium that is under-researched in the country even though several studies from elsewhere show an upward trend in the prevalence of delirium.

After understanding the determinants of delirium, the policymakers, the ICU team, and the hospital management can develop a checklist to identify the patients at high risk for delirium. The list could assist in monitoring patients at higher risk for delirium, allowing measures to be implemented for preventing the incidence or reducing the severity of delirium. The patients will have a short stay in ICU and have better cognitive outcomes post ICU care.

1.7 Variables

Independent Variables

Demographic variables

- Age
- Gender
- Alcohol use
- Smoking

Clinical variables

- Admission diagnosis
- Medications
- Number of days in ICU
- Co-morbidities

Therapeutic intervention

- Sedation
- Mechanical ventilation

Institutional factors

Physical restraint

Dependent Variable

- Delirium

1.8 Conceptual framework

Several factors are associated with a higher probability of ICU patients developing a delirious state. By age, for instance, delirium is common among the elderly. It also has a predilection for the male gender, while patients who have a history of alcohol consumption and smoking tend to have a higher risk of delirium. Clinical characteristics such as admission diagnosis and the presence of co-morbidities such as sepsis and patients under treatment with benzodiazepines have also been reported to be a high-risk group. Being in a delirious state not only increases the cost of treatment, but also the risk of suffering and death and a prolonged stay in the ICU.

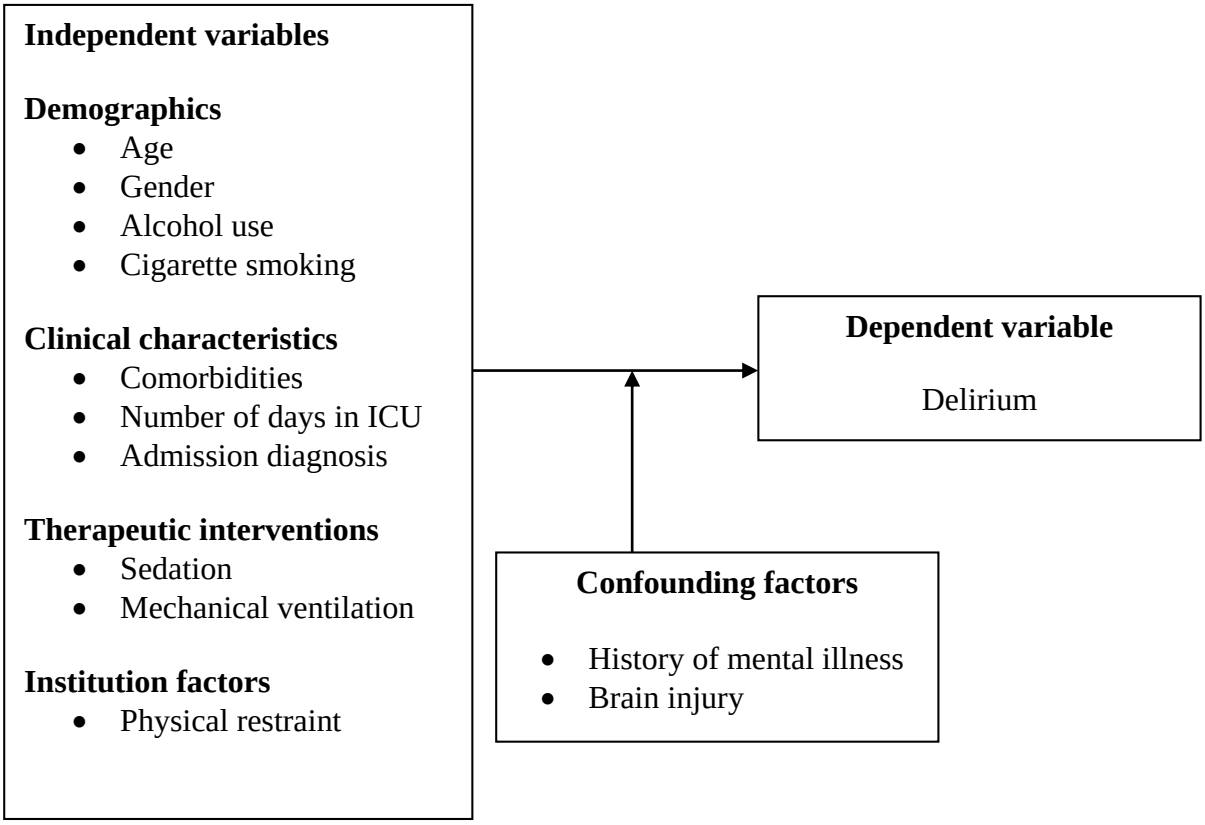

Figure 1.1. Conceptual framework on the relationship between demographic, treatment, and medical characteristics and delirium and its impact on clinical outcomes of patients

CHAPTER 2: LITERATURE REVIEW

2.1 Delirium Definition

Delirium is burdensome on health especially among men and women admitted ICUs ranging from a high probability of mortality and increased cost of care reported. Sharma, Malhotra, Grover, & Jindal (2012) characterized delirium as a mental disorder that leads to disturbances in orientation, thought, consciousness, memory, behavior, and perception. While in the ICU, the severely affected patient can remove catheters or self-extubate with serious consequences. The World Health Organization ICD-10 of 2016 refers to delirium as a cerebral syndrome that presents with concurrent disturbances in attention, consciousness, thinking, perception, emotion, psychomotor disorders, and abnormal sleep-wake cycles, but with a non-specific etiology. The duration of such episodes varies depending on the severity of the condition.

According to American Psychiatric Association (APA) Delirium can be described as deficiencies in cognition (memory and attention) and awareness of patients that develop between days or hours, lack a specific etiology such as dementia or cognitive disturbance and is directly related to the provision of medication or physical disturbance. Lewis, Banks, Paddick, Duinmaijer, Tucker, Kisoli et al. (2017) defines delirium as a fluctuating and acute disturbance of awareness, attention, and cognition, emanating from an underlying physiological problem. According to Limpawattana et al. (2016), many hospitalized patients often develop a delirious state that presents as an acute change in cognition, often with inattention, fluctuating course, and either disorganized thinking or altered consciousness.

2.2 Assessment of Delirium

Delirium is easy to diagnose using different types of internationally recognized tools. Nurses can diagnose delirium routinely during their shifts, which enables prompt action since the disorder is reversible. One of the most familiar tools is the Delirium Observation Screening Scale (DOS), which describes behavioral patterns of delirious patients in 13 questions or scored

statements that observers answers with always/sometimes (1) or never (0). Computation of DOS scores entails division of the sum of scores of patients by three. The DOS score ranges from 0-13 – a score ≥ 3 indicating a delirious state (Koster et al., 2013). In literature, its sensitivity and specificity ranged from 82-89% and 86-96%, respectively, which makes it a reliable scientific and hospital tool for diagnosing delirium in non-ICU patients (Detroyer et al., 2014; van Velthuijsen et al., 2016). The disadvantage of the tool is that it has low validity and cannot measure the three types of delirium.

The NEECHAM confusion scale, which was a creation of Neelon and Champagne is another popular diagnostic tool. It evaluates the cognitive dysfunctions associated with delirium, which include the appearance, verbal behavior, and motor skills of the patients. The third subscale of the tool measure vital functions of patients (the physiological condition, for instance), urinary continence, and oxygen saturation (Van Rompaey, Schuurmans, Shortridge-Baggett, Truijen, Elseviers, & Bossaert, 2008). Overall, the scoring system of the NEECHAM tool ranges from 0-30 – 30 is indicative of a normal or maximal reaction and 0 an abnormal or minimal one. Moreover, the NEECHAM grades the outcomes of patients into four levels - no confusion or delirium (27-30 points), not confused but at a high risk of delirium/confusion (25-26 points), mild-early delirium/confusion (20-24), and delirium/ moderate-severe confusion (0-19 points) (Immers et al., 2005).

Nursing delirium-screening scale (Nu-DESC) is a five-item scale used to evaluate patients for the presence of unsuitable behaviors, disorientation, hallucination, unfitting communication, and psychomotor retardation. In routine practice, a nurse administers the tool while clinically evaluating patients. Each item is scored on a three-point scale (0-2) after which a total score, which can range from 0-10, is computed. A score of two is the cut off for delirium. The tool takes one minute to administer and has been reported to have a specificity and sensitivity of 86.8% and 85.7% in the diagnosis of a delirious state (Grover, 2012).

The Intensive Care Delirium Screening Checklist (ICDSC) tool checks inattention, psychomotor activity, consciousness, hallucinations, disorientation, sleep/mood/speech disturbance, and fluctuation of adverse symptoms in ICU patients. Patients are considered delirious when four out of eight items are positive. The instrument has a sensitivity of 99% and specificity 64% (Tomasi et al., 2012). The diagnosis can be done every day by nurses with patients being indirectly involved. Even though this tool is administered only once over 24 hours and provided sensible data, it has poor specificity.

The CAM-ICU is currently the most studies screening tool for delirium bedside in a nonverbal ventilated ICU patient. It assesses the fluctuations or acute changes in the mental status of patients every 24 hours and has demonstrated high sensitivity and specificity. Up to two errors are allowed, with the discrepancies encountered during its administration confirmed via a visual test (Cavallazzi et al., 2012). The level of altered consciousness is evaluated guided by the patients' Richmond Agitation- Sedation Scale OR Sedation Agitation score (Sessler et al., 2002). Lastly, the assessment of disorganized thinking is determined by evaluating the ability of a patient to answer four yes/no questions and his/her ability to obey commands. If there is an indication that the patient is not delirious after these two steps, nurses do not have to complete its scoring system, which saves time and effort. CAM-ICU is easy to use and understand by personnel and has a sensitivity of 93% and specificity of 89% (Kallenbach & Amado, 2017). CAM-ICU takes 2-5 minutes and does not rely on a verbal response, making it the best tool to use in mechanically ventilated patients.

2.3 Prevalence of delirium among patients in critical care areas

The occurrence of delirium is on the rise among ICU patients with prevalence rates as high as 80% and as low as 11% as reported in the literature. In a prospective study of 65+-year-old patients using the CAM-ICU, the prevalence was 44.4% (Limpawattana et al., 2016). The higher prevalence may have been a result of the category of patients recruited in the study.

Vasilevskis, Han, Hughes, & Ely, (2012) documented that old age was associated with delirium. In a prospective multicenter observational study by Kwizera et al. (2015) in four intensive units, the prevalence of delirium was 51% using the CAM-ICU tool. Patients were age 18 years and older, while the sample size was 60 participants. The high prevalence was linked to the small sample size of the study.

ICU environment has been reported to predispose patients to delirium while admitted. However, the burns unit seems to be worse with a plethora of adverse outcomes, which range from stress to extreme pain reported because of injuries to the skin (Rossi et al., 2000). In a prospective observational trial of 18+ years old that had spent 24 hours in a Burns ICU, a CAM-ICU tool was used to assess delirium in a sample of 82 patients. The prevalence was 80%. Burns patients experience a lot of pain and psychological stress, which may have predisposed them to the high prevalence (Agarwal et al., 2010). In trauma and surgical ICUs, Pandharipande et al. (2008) reported a prevalence of 73% and 67% respectively. The population was adult men and women who required mechanical ventilation had stayed in the ICU for over 24 hours. Mechanical ventilation has been found to increase the probability of delirium in several other published studies (Bulic et al., 2017; Leite et al., 2014).

A study of 109 ICUs and 209 eligible ICU patients in the developed world reported a prevalence of 32.2%. It was a one-day study assessing the prevalence of delirium in ICU in patients above 18 years using the CAM-ICU tool (J. Salluh et al., 2010). Unlike other studies using CAM-ICU for delirium diagnosis, Sharma et al. (2012) used the revised version of the Delirium Rating Scale in a prospective cohort of 140 18+ years olds in a Respiratory Intensive Care Unit for three months. The prevalence was 64%. A study on cost estimates of delirium reported a mean expenditure of $38-$152 billion every year (Leslie et al., 2008). In Kenya, ICU care is costly and the ICU beds are not enough. World Health Organization recommends 10-20% of hospital beds should be ICU beds. Delirium increases the length of hospital stay,

increasing the cost of care. The prevalence of delirium in ICU is estimated to differ in different regions and is a key problem in ICU patients.

2.4 Factors associated with delirium among ICU patients

2.5 Demographic factors

2.5.1 Age and Gender

Critical care units pose a high risk for the development of delirium among the elderly. In a study of men and women admitted in a surgical ICU, Pipanmekaporn et al. (2015) found a significant link between the probability of development of delirium and age with old patients found to have the highest risk. Mattar, Chan, & Childs (2012) found similar results in a systematic review of studies in which being elderly predisposed patients to hypoactive delirium in ICU settings. Overall, according to Mori et al., 2016, for every increase in age by one year, the risk of delirium increases by 4%. In another study by (Shivanandh et al., 2015) in which males were a majority, the male gender was a determinant for delirium. In contrast, Van Rompaey et al. (2009), found that neither age nor gender was a determinant for delirium in a multi-center cross-sectional study of 523 patients with a mean age of 64 years.

2.5.2 Alcohol use/ smoking

The use of alcohol has been identified as a determinant for delirium when consumption is more than three units per day (Van Rompaey et al., 2009). In the study, a link between cigarette smoking and delirium was also evident with individuals who smoked more than 10 cigarettes per day found to be more prone to developing delirium. Inouye, Westendorp, & Saczynski, (2014) also identified the misuse of alcohol as a significant risk factor for the development of delirium. A randomized trial done in medical and surgical ICU, found that male patients were more at risk of developing delirium than females with alcohol consumption, smoking of cigarettes, and admission in surgical/trauma ICUs identified as other determinants for the condition (Mehta et al 2016). Male patients are known to be involved more with road traffic

accidents and use of alcohol that why they may be more predisposed to delirium. A study by Sharma, Malhotra, Grover & Jindal, (2012) in a Respiratory ICU of a tertiary care facility found that smoking predisposed patients to delirium.

2.6 Clinical factors associated with delirium

2.6.1 Medication

Benzodiazepines and opioids have been shown to enhance the risk of being delirious among ICU patients (Mori et al., 2016). However, in an observational study (prospective) in six mixed adult ICUs over 14 months, benzodiazepines and opioids were not determinants of delirium statistically in the first 24 hours (Mori et al., 2016). However, in the subsequent 24 hours, benzodiazepines seemed to influence the occurrence of delirium positively. The study was done in trauma, medical, neurological, and surgical units and concluded that extensive use of benzodiazepines predisposes patients in ICU to delirium statistically significantly. In another study, patients who developed delirium received a higher maintenance dose of and fentanyl midazolam (Yang et al., 2017). The study evaluated 140 sequential sedation patients age 18-80. In another systemic review, Mehta et al. (2015), found that patients who had a continuous infusion of benzodiazepines and opioids were at a higher risk of developing a delirious state.

2.6.2 Number of days in ICU

In a study by Van Rompaey and colleagues (2009), the risk of developing delirium increased by 26% each day a patient stayed in ICU. During an early stay in ICU, men and women with septicemia have also been found to be more likely to be delirious than other groups of patients (Lin et al., 2008). The occurrence of delirium with sepsis has been linked to the release of cytokines in response to bacterial endotoxins, which injure the central nervous system (CNS). Moreover, in other studies, endotoxins have been found to depress CNS function of patients with sepsis with interleukin (IL) 13, 10, and 1b, IL-10, and IL-13 are the most implicated.

2.6.3 Admission diagnosis

This is the condition warranting a patient to be admitted to the ICU for respiratory and hemodynamic support. It can be a respiratory, cardiovascular, or central nervous system problem. According to Lin et al., the risk of developing delirium early in the ICU is higher among patients with sepsis. According to Lin, bacterial endotoxins released in septic wounds stimulate the release of cytokines that act on the central nervous system (CNS). Furthermore, in other studies, endotoxins have been found to depress CNS function of patients with sepsis with interleukin (IL) 13, 10, and 1b, IL-10, and IL-13 is the most implicated.

2.7 Institutional factors

2.7.1 Physical Restraint

Physical restraint, defined as the use of medication or a device to restrict a patient's voluntary movements, is a common practice in hospitals with far-reaching consequences. In acute care settings, the prevalence of physical restrain is approximately 17%, and chemical restraint, or psychotropic drugs 34% in long-term care facilities (Agens, 2010). Health complications such as decubitus ulcers, documented falls, delirium, and even death have been reported to be higher in this cohort, as was the case of a 79-year-old female nursing student with spinal stenosis and frontotemporal dementia (Agens, 2010). In the case study, the use of physical and chemical restraint was linked with a significant risk of fall, confusion, and reduced cognitive function, which are associated with an increased risk of developing delirium (Magny et al., 2018). In another study in China, Pan et al. (2018) found delirium to be a common clinical syndrome of physically restrained patients with 178 of 598 evaluated patients reported to have developed a delirious state. Overall, in this nested case-control study, delirium risk was 26.3 times higher when restraint was >5 days and 2.38 and 3.62 times higher when patients experienced restraint two and three times respectively. Though early pharmacologic treatment of delirium has been

reported to lower the need for physical restrain by three days (Michaud et al., 2014), restrictions on the use of physical and chemical restraint are needed to prevent delirium.

CHAPTER 3: METHODOLOGY

3.1 Study Design

A cross-sectional study was done at the main ICU and medical ICU of the Kenyatta National Hospital. The focus was on all patients who were 18 years and older and had stayed for more than 24 hours in the 21-bed Main ICU or and 8-bed Medical ICU.

3.2 Study Area

KNH is the largest public referral hospital in Kenya. Located in the upper hill area of Nairobi, it serves a population of over a million people, from all parts of the country. KNH has a bed capacity of over 2000, of which 21 are in the main ICU and eight in the medical ICU. Admission in the two units is estimated to be around 100 patients [at 93% occupancy], with the average length of hospital stay [ALOS] and the death rate of patients estimated to be 9.7 days and 41.7% respectively. Some of the conditions managed in the main ICU are obstetric cases such as preeclampsia or poor reversal after a cesarean section, subdural hematomas, respiratory failure, shock, road traffic accident, Guillain Barre Syndrome, tetanus, gun short patients among others. In medical ICU the patients admitted there include, diabetic ketoacidosis, Acute Kidney Injury (AKI), poisoning, cardiovascular accident, and patients with myocardial infarction. Physicians, critical care nurses, registrars, medical officers, nutritionists, and physiotherapists tend to patients in these two ICU units.

3.3 Study Population

The study population entailed all patients – both males and females - of all age groups, who were being admitted at the Kenyatta National Hospital main ICU and medical ICU. Approximately 80 patients are admitted to these locations every month for injuries, which include the severe head injury. Moreover, the mean admission time is around one week, with patients admitted with serious injuries admitted for close to a month. To be included in the study, patients had been admitted to one of the two study sites, offered informed consent, and

met our inclusion criteria. Patients were admitted to ICU for at least 24 hours because delirium is known to develop over time from 24 hours to 48 hours after admission to ICU.

3.3.1 Inclusion Criteria

- Age 18 years and older (18+ years)
- Intubated at KNH main ICU or medical ICU
- Informed consent received from a relative

3.3.2 Exclusion Criteria

- Not of sound mind (history of delirium or mental problems prior to admission)
- Admitted for less than a day prior to recruitment
- Decline informed consent

3.4 Sample Size determination

The prevalence of delirium in intensive care settings is estimated to be around 51% (Kwizera et al., 2015). This data was used to calculate sample size (n) at 95% CI and a precision of 5% using the formula by Fisher (1981). Data collection was done in three months because the two units admit approximately 80 patients in two months, which is my sample size, and for logistical reasons including but not limited to money and time.

$$n = \frac{Nz^2pq}{E^2(N-1) + z^2pq}$$

n: Sample size

P: Prevalence of pancreatic cancers

Z: Normal variate for alpha

q: 1-p

E: Precision

N: Population size

Assumptions:

E = 5%

P = 51% (Kwizera et al., 2015)

N = 100

Z^2 = 1.96

Estimated sample size:

$$n = \frac{100 \text{ x } 1.96^2 \text{ x } 0.51 \text{ x } 0.49}{0.05^2(100-1) + (1.96^2 \text{ x } 0.51 \text{ x } 0.49)} = 80$$

Required sample size (n) = 80

3.5 Sampling Method

The consecutive sampling technique was used to recruit participants. Because participants were intubated and unable to offer informed consent, informed consent was sought from immediate relatives before inclusion in the study. The contacts of the next of kin were extracted from patient files and the individuals invited and during for discussion at KNH. During the discussion, the objectives of the study were explained and informed consent was sought in two steps. First, printed consent forms in Kiswahili or English were provided and relatives were given time to review. The principal investigator answered all questions and written consent got before recruiting participants in the study. A census was done in the two study sites every day and participants were recruited sequentially until the recommended sample size was reached.

3.6 Data Collection

3.6.1 Data Collection Tool

A study-designed observation checklist (Appendix 1) organized in three sections was used to collect data. The first section recorded demographic characteristics of patients such as gender, age, and marital status, and reason for admission at KNH. The tool also recorded the hospital unit of admission (main ICU and medical ICU), presence of comorbidities such as HIV, hypertension (HTN), and diabetes mellitus (DM).

The second section was the CAM-ICU-7-assessment tool for delirium bedside in non-verbal ventilated ICU patients. The tool is administered every 24 hours and is considered a reliable diagnostic tool for fluctuations and acute changes in the mental status of patients. A cut-off score of 3 means that the patient is delirious. The CAM-ICU has a high internal consistency (0.85 Cronbach's alpha) and has demonstrated good predictive value for in-hospital mortality and discharge rate (Khan et al., 2017). The third section entailed the length of hospital stay. The length of stay was retrieved from hospital records.

3.6.2 Validity and reliability

The CAM ICU has been used widely by many researchers due to its usability in non-verbal patients. CAM-ICU is easy to understand and use by health personnel and has a sensitivity of 93% and specificity of 89% (Kallenbach & Amado, 2017). The tool has been approved for use by different researchers to be more accurate in the diagnosis of delirium. The validity of CAM-ICU has been rated at 95-100% sensitivity and 89-93% specificity (Tomasi et al., 2012). Gusmao-Flores, Figueira Salluh, Chalhub, & Quarantine, 2012), found CAM-ICU to have excellent accuracy, with 95.9% and 80% pooled values for specificity and sensitivity.

3.7 Data Collection Procedures

3.7.1 Recruitment

Consecutive sampling was used to recruit participants from the 21-bed main ICU and the 8-bed medical ICU at the KNH. Patients admitted for at least a day before the inception of this study qualified. A preliminary review of the sociodemographic and medical data of patients was done to ascertain the eligibility and individuals who met the inclusion criteria recruited.

3.7.2 Consenting

The principal investigator was tasked with consenting of patients and data collection done by research assistants. Consent was written and administered by first explaining the aims of the study to the next of kin of the patients. Then, a question and answer session was held with

family members in which relatives were allowed to ask questions. Before recruitment, all questions were answered satisfactorily by the principal investigator. The risk and benefits of the study were elucidated and voluntary participation was stressed before inclusion. English and Kiswahili versions of the consent form were available for easier administration. Informed consent was offered by signing and dating consent forms. Relatives who could not write appended their signatures.

3.7.3 Data Collection

A study nurse reviewed and recorded the demographic and medical data of participants such as the age, gender, history of alcohol use, and history of cigarette smoking in the study tool. Clinical characteristics such as the presence of co-morbidities and number of days in the ICU, therapeutic interventions such as mechanical ventilation and sedation, and institution factors such as the need for physical restrain were also recorded and the RASS tool used to evaluate the agitation and sedation status of patients. The CAM-ICU-7 assessment tool was used to screen patients for delirium. The screening was done once in 24 hours between 12 noon and 1 pm and CAM-ICU-7 scores were recorded once. Patients with a score of three or higher were recorded as delirious.

3.8 Data Management and Analysis

The Statistical Package for Social Scientists (SPSS) version 25 was used to analyze data at a significance of 95%. Data was extracted from study checklists, entered into a spreadsheet. Demographic and medical data such as age, gender, unit of admission, sedation status, and the presence of co-morbidities were summarized and presented as proportions (categorical data) and means with standard deviation (if continuous). The objectives were analyzed as follows: Prevalence of delirium was calculated and the Chi-square test and Logistic regression were used to determine risk factors and predictors for delirium. A p-value <0.05 was significant. Results were presented in tables and graphs.

3.9 Variables

The independent variable was delirium in patients, as determined using the CAM-ICU 7. Other variables were demographic characteristics of patients such as gender and age, the level of agitation and anxiety and sedation, as determined using RASS, and the reasons for admission, comorbidities such as HTN and HIV, and the length of hospital stay.

Table 3.1. Dependent and independent variable and source of data

Variable			Source
Dependent	CAM-ICU score	Yes	CAM ICU-7
		No	
Independent	Age	<19	Study observation checklist and RASS tool
		20-30	
		>30	
	Gender	Male	
		Female	
	Unit	Main ICU	
		Medical ICU	
	Comorbidities	Yes/no	
		Tertiary	
	Reason for admission	Trauma	
		Burns	
	Status	Sedated	
		Not sedated	
	Hospital stay	Length in days	
	Physical restraint	Yes	
		No	

Key:
ICU – Intensive Care Unit
CAM ICU-7 - Confusion Assessment Method for the Intensive Care Unit 7-item
RASS-Richmond Agitation Sedation Scale.

3.10 Dissemination of results

Data will be disseminated through a report of our findings will be packaged into a dissertation, which will be shared with the department of nursing in the two critical Care Units and the University of Nairobi. The report will also be shared with the government of Kenya through the ministry of health (MoH), and manuscripts developed and published in peer-reviewed journals or nursing. Finally, the findings of our study will be presented in conferences

organized locally by governmental and non-governmental organizations of health and international conferences. The results will be shared in the two Critical Care Units

3.11 Ethical Considerations

Before starting the study, the proposal and data collection tool was submitted for review by the Kenyatta National Hospital/University of Nairobi Ethics Review Committee (KNH-ERC). Approval was received from the KNH-ERC (reference no: KNH-ERC/A/189, 26 June 2020) and authorization from KNH administration was received before the recruitment of participants and collecting data for the study. Written informed consent was sought from next of kin before recruitment or inclusion.

A study nurse approached a family member and explained the objectives of the study in simple English or Kiswahili. The next of kin was also allowed to read the consent themselves and ask questions, which were answered satisfactorily before consenting. The potential risk and benefits of the study were elucidated and voluntary participation stressed before recruitment of the patients. Informed consent was provided by signing and dating consent forms. Individuals who could not write appended their thumbprints. The Confidential and or personal information of participants was kept private during and after the study.

In the context of COVID-19 pandemic, ethical guidelines governing research on human subjects and measures put in place by the hospital in mitigating cross-transmission among other unit infection prevention regulations were adhered to. The following measures for preventing cross-transmission between the principal investigator and subjects were upheld:

I. Proper hand wash or use of sanitizers, use of protective gear, and ensure infection prevention criteria for Corona is adhered to by research assistants and the principal investigator.
II. The research is observational, social distancing of 1.5 meters was maintained between the researcher and the participants.

Personal identifiers such as names and hospital numbers were not recorded. Instead, participants had unique study-generated numbers, which were not be linked to personal details. The personal details of patients were not published nor shared with third parties. Participants ascertained to be delirious using the CAM ICU-7 assessment tool were referred to medical teams for further evaluation for delirium and treatment and collaborative management instituted while the patient was admitted in ICU. To respect the confidentiality of patients after completion of the study, questionnaires were filed and locked in a cabinet for safe storage and databases password protected by the PI after completing the study. Delirium assessment was part of patient care and was observational without interventions.

3.12 Limitations

Evaluation for delirium was done once in 24 hours. Therefore, patients who became delirious after 24 hours were not evaluated. Second, CAM-ICU-7 is a subjective test, which is prone to misinterpretation. In the study, we were not able to differentiate if the patients were delirious before restrain or they were delirious after physical restraint. To minimize inter-rater bias, the principal investigator, who has training on how to administer the CAM-ICU-7 tool took the research assistants through the tools before data collection.

CHAPTER 4: RESEARCH FINDINGS

4.1 Introduction

The objectives of the study were to determine the prevalence of delirium, its risk factors, and its precipitating factors in a sample of mechanically ventilated patients drawn from the Kenyatta National Hospital (KNH) Intensive Care Units (ICUs). Data collection was done for about three months from July to September 2020, using a questionnaire organized in three sections. The demographic characteristics of the patients were recorded in the first section. The second section included the CAM-ICU7 tool for detecting delirium, while the third section included the length of stay. The questionnaire was not pretested before use as the CAM-ICU7 and the Richmond Agitation Sedation Scale are standard data collection instruments that have been pre-tested and found to be reliable and able to deliver internally consistent research data. Eighty-one questionnaires were completed, analyzed, and the results presented in tables.

4.2 Demographic characteristics

The demographic characteristics evaluated included the age of patients in years, age group, and the gender of patients. The ICU type, education level, employment status, and alcohol consumption were also evaluated and presented in a table.

Eight one (81) patients were recruited, 50 (61.7%) male and 31 (38.3%) female, with a mean age of 39.67±12.09 years. A majority 61 (82.7%) were in the main ICU, self-employed 34 (42.0%), had a tertiary education 60 (74.1%), and drank alcohol 27 (33.3%). Other medical characteristics of the evaluated patients are presented in Table 4.1.

Table 4.1. Demographic and behavioral characteristics of participants admitted at Kenyatta National Hospital Intensive care Units

		n (81)	%
Age in years	Mean±Standard Deviation	39.67±12.09	100
Age group	<20	1	1.2
	20-40	49	60.5
	41-60	24	29.6
	>60	7	8.6
Gender	Male	50	61.7
	Female	31	38.3
Unit of admission	Main Intensive Care Unit	61	82.7
	Medical Intensive Care Unit	14	17.3
Alcohol use	Yes	27	33.3
	No	54	66.7
Smoking	Yes	12	14.8
	No	59	85.2
Education level	Secondary	21	25.9
	Tertiary	60	74.1
Employment	Formal employment	32	39.5
	Self-employment	34	42.0
	Unemployment	15	18.5

4.3 Medical characteristics

The medical characteristics evaluated included the presence and type of co-morbidity, the type and number of medications, and sedation status (plus sedative and type of sedation (either continuous or intermittent) if sedated. The requirement for physical restraint and the length of hospital stay (in days) were also evaluated. Frequency distributions, percentages, and averages (with standard deviations) we used to analyze data and presented it in a table.

Forty-seven (58.0%) had co-morbidity, mostly hypertension 19 (40.4%), as shown in Table 4.2. A majority were sedated 53 (65.4%). Of the 53, 19 (35.8%) were on Remifentanil. Continuous sedation was the most common 48 (90.6%), while 57 (70.4%) required physical restrain. Length of hospital stay was between 1 and 61 days, an average of 13.89±10.82 days.

Table 4.2. Medical characteristics of patients admitted at Kenyatta National Hospital Intensive Care Units

		N(81)	%
Co-morbidity	Yes	47	58
	No	34	42
Co-morbidity type	Alcohol use disorder	2	4.3
	Atrial septal defect	1	2.1
	Chronic Kidney Disease	12	25.5
	Hypertension	19	40.4
	Systemic Lupus Erythematous	1	2.1
	Convulsive Disorder	2	4.3
	Diabetes Mellitus	12	25.5
	Human Immunodeficiency Virus	8	17.0
	Asthma	1	2.1
	Cardiomyopathy	1	2.1
	Schizophrenia	1	2.1
	Leukemia	1	2.1
	Lung cancer	1	2.1
	Metastatic tumor	1	2.1
	Morbid obesity	1	2.1
	Myasthenia gravis	1	2.1
	Posterior cranial fossa tumor	1	2.1
	Sickle cell anemia	1	2.1
	Tetralogy of Fallot	1	2.1
Under medication		81	100
Number of medication	Mean±Standard Deviation	10.22±3.58	
Sedated	Yes	53	65.4
	No	28	34.6
Sedative	Dexmedetomidine	10	18.9
	Midazolam	16	30.2
	Ketamine	13	24.5
	Remifentanil	19	35.8
	Propofol	1	1.9
Type of sedation	Continuous	48	90.6
	Intermittent	5	9.4
Physical restraint	Yes	57	70.4
	No	24	29.6
Length of hospital stay (days)	Range (days)	1-61	

4.4 Prevalence of delirium

To detect delirium, the CAM-ICU7 tool was used to assess participants. The acute onset or fluctuation of mental status was evaluated and scored. Inattention, having an altered level of consciousness, and disorganized thinking were also assessed, a total score computed and

interpreted as follows – 0-2 (no delirium) and 3-7 (delirium), and prevalence computed. The prevalence of delirium was found to be 34.6%.

4.5 Risk factors for delirium

Several risk factors for delirium, which included the age of patients, gender, education level, Sedation status, physical restraint, medication (type and number), and the average length of hospital stay were evaluated using the Chi-square test. These for significance were set at 95% CI.

The average age of delirious patients (43.68±12.75 years) compared to non-delirious patients (37.45±11.25 years) was statistically significantly higher (P=0.031), as shown in Table 4.3. Of the 28 patients who developed delirium, 19 (67.9%) were males and 9 (32.1%) were female. From the data, the odds of delirium was found to be 1.49 fold higher among males compared to females (95% CI=0.59-3.77) but this difference was not statistically significant (P=0.47). Seventeen (77.3%) delirious patients were alcoholics where 11 (22.7%) were not. Chi-square analysis showed that participants who used alcohol were 12.58 fold (95% CI=3.87-38.88) more likely to develop delirium statistically significantly (P<0.01) for both drugs. Unemployed patients were less likely to develop delirium compared to patients' informal employment by statistically significantly (OR=0.10, 95% CI=0.01-0.79, P=0.01).

The mean number of medications received by delirious patients was 11.64±3.68 while non-delirious patients received (9.41±3.31). This data showed that delirious patients received significantly more medications (P=0.009). Sedation and restraint increased the odds of delirium by 7.44 times (95% CI=1.97-25.13) and 9.23 fold (95% CI=2.19-41.84) respectively with the difference found to be significant in both conditions (P<0.01), while patients who received Midazolam compared to those who did not were 68.4% more likely to develop delirium (P<0.01). Ketamine and Remifentanyl lowered the odds of delirium by 0.27 times (95% CI=0.07-1.16) and 0.72 times (95% CI=0.18-2.64) but not significantly (P>0.05). The average

length of hospital stay among delirious patients was 17.57±14.93 days and among non-delirious patients 11.86±7.11 days. Even though delirious patients stayed for longer in the intensive care unit by six days, the difference was not significant (P=0.240).

Table 4.3. Risk factors for delirium among patients admitted at Kenyatta National Hospital Intensive Care Unit

		Delirium (28)	No Delirium (53)	OR (95% CI)	P value
Age in years	Mean±SD	43.68±12.75	37.45±11.25	-	0.03
	<20	0 (0.0)	1 (1.9)	-	
	20-40	13 (46.4)	36 (67.9)	Reference	
	41-60	11 (39.3)	13 (24.5)	1.39 (0.43-4.13)	0.77
	>60	4 (14.3)	3 (5.70	1.58 (0.35-7.23)	0.69
Gender	Male	19 (67.9)	31 (58.5)	1.49 (0.59-3.77)	0.47
	Female	9 (32.1)	22 (41.5)	Reference	
Alcohol use		17 (77.3)	10 (21.3)	12.58 (3.87-38.88)	**<0.01**
Cigarette smoking		8 (36.4)	4 (8.5)	6.14 (0.66-19.95)	**0.01**
Co-morbidity present		19 (67.9)	28 (52.8)	1.89 (0.75-4.71)	0.24
Education	Secondary	5 (17.9)	16 (30.2)	Reference	
	Tertiary	23 (82.1)	37 (69.8)	1.99 (0.62-5.44)	0.29
Employment	Formal	13 (46.4)	19 (35.8)	Reference	
	Self	14 (50.0)	20 (37.7)	1.02 (0.37-2.85)	1.00
	Unemployed	1 (3.6)	14 (26.4)	0.10 (0.01-0.79)	**0.02**
Under medications		28 (100)	53 (100)	-	1.00
# medications	Mean±SD	11.64±3.68	9.41±3.31	-	<0.01
Sedated	Yes	25 (89.3)	28 (52.8)	7.44 (1.97-25.13)	<0.01
	No	3 (10.7)	25 (47.2)	Reference	
Sedative					
Midazolam	Yes	16 (84.2)	0 (0.0)	-	<0.01
	No	3 (15.8)	18 (100)	Reference	
	Not recorded	6	10		
Ketamine	Yes	4 (21.1)	9 (50.0)	0.27 (0.07-1.16)	0.09
	No	15 (78.9)	9 (50.0)	Reference	
	Not recorded	6	10		
Dexmedetomidine	Yes	6 (31.6)	4 (22.2)	1.62 (0.41-5.92)	0.71
	No	13 (68.4)	14 (78.8)	Reference	

	Not recorded	6	10		
Remifentanil	Yes	9 (47.4)	10 (55.6)	0.72 (0.18-2.64)	0.74
	No	10 (52.6)	8 (44.4)	Reference	
	Not recorded	6	10		
Propofol	Yes	0 (0.0)	1 (5.6)	-	0.49
	No	19 (100)	17 (94.4)	Reference	
	Not recorded	6	10		
Type of sedation	Continuous	23 (92.0)	25 (89.3)	1.38 (0.26-8.27)	1.00
	Intermittent	2 (8.0)	3 (10.7)	Reference	
Physical restraint	Yes	26 (92.9)	31 (58.5)	9.23 (2.19-41.84)	<0.01
	No	2 (7.1)	22 (41.5)	Reference	
Hospital stay		17.57±14.93	11.86±7.11	-	0.24

The effects of several confounding variables, which included age, gender, employment status, the sedative used, alcohol use/smoking, and the physical restraint of patients were controlled in a multivariable logistic regression and adjusted ORs with 95% confidence intervals calculated.

In Table 4.4, it is shown that alcohol consumption and physical restraint were the only statistically significant predictors for delirium. Alcohol use increased the adjusted odds for delirium 60.15 fold (95% CI=2.89-1248.1), while restraint increased the adjusted odds for delirium 22.85 fold (95% CI=1.07-487.8) statistically significantly (P<0.05). Age, cigarette smoking, sedation, and the number of medications were not predictors for delirium.

Table 4.4. Predictors for delirium among patients admitted at Kenyatta National Hospital Intensive Care Unit

	AOR (95% CI)	P value
Age in years	0.95 (0.85-1.05)	0.298
Alcohol use	60.15 (2.89-1248.1)	**0.008**
Cigarette smoking	0.35 (0.032-3.83)	0.391
Number of medication	1.093 (0.83-1.45)	0.532
Sedation	15.52^{7} (0.00-)	0.997
Physical restraint	22.85 (1.07-487.8)	**0.045**
Type of employment (reference = formal employment)		0.121

Self-employment	3.60 (0.45-28.86)	0.228
Unemployed	0.160 (0.01-2.66)	0.202

Key:
AOR – Adjusted Odds Ratio
N – Frequency

4.6 Precipitating factors for delirium

The precipitating factors for delirium such as infection, metabolic conditions, central nervous cause, post-operation, cardiac cause, and poor reversal were evaluated using a questionnaire. The cumulative frequencies and percentages were calculated and then presented in a table. As shown in Table 4.5, metabolic conditions were the commonest precipitating factors for delirium 25 (30.9%) in the population studied. Infection-induced delirium was reported in 19 (23.5%) participants, while central nervous causes were reported in 18 (22.5%) patients. Ten patients (12.3%) developed delirium after an operation, while cardiac, autoimmune, and poor reversal were the causes for 3 (3.7%), 3 (3.7%), and 2 (2.5%) patients respectively.

Table 4.5. Precipitating factors for delirium among patients admitted at Kenyatta National Hospital Intensive Care Unit

Precipitating factors	N (81)	%
Infections	19	23.5
Metabolic conditions	25	30.9
Central nervous system causes	18	22.5
Post-operation	10	12.3
Cardiac causes	3	3.7
Autoimmune causes	3	3.7
Poor reversal	2	2.5

CHAPTER 5: DISCUSSION, CONCLUSIONS, AND RECOMMENDATIONS

5.1 Discussion

The objective of this study was to establish the prevalence of delirium, risk factors, and the precipitating factors in a cohort of intubated patients at Kenyatta National Hospital intensive care units (ICU). Eighty-one (81) patients, mostly males, in the third decade of life were recruited and evaluated. A majority had co-morbidity, were sedated, and physically restrained within medical or main ICU of KNH for a mean duration of close to one week.

From the survey, delirium seemed to be a common health complication among ICU patients at KNH with one in every three patients reported to be affected. The prevalence was higher among males aged 20-40 years who were admitted to an ICU with co-morbidity such as hypertension, especially if they were sedated and physically restrained. Even though Tilouche et al., (2018) reported a slightly lower prevalence in a population study of 206 patients in Tunisia, most published data are comparable with the findings. Jayaswal et al., (2019) reported a comparable prevalence rate in an incidence study in a medical ICU in India. Salluh et al., (2010) reported a comparable prevalence in a one-day multicenter point prevalence study in 104 ICUs, while McNicoll et al. (2003) reported a similar in a medical ICU in the United States of America. Ely et al. (2001) reported a significantly higher prevalence but checked for delirium more than once (mean duration of 2.4 days). From these findings, delirium seems to be a common health complication in mechanically ventilated patients and therefore requires immediate action. The CAM-ICU 7 is a reliable tool for its diagnosis. It should be used routinely in KNH ICUs.

After bivariate analysis, alcohol use and physical restraint were associated with a high risk of delirium. From the data, the risk of delirium seemed to increase with age with delirious patients reported to be approximately six years older than non-delirious ones statistically significantly - a common finding in the literature. McNicoll et al. (2003) reported a higher

incidence of delirium among older patients in a cross-sectional study conducted in a medical ICU in the United States of America (USA), peaking among older patients with dementia. Tilouche et al. (2018) reported a significant association between age and the risk of delirium with elderly patients having a 4.1 fold higher risk of delirium compared to young patients. However, Jayaswal et al. (2019) reported contrary results in a prospective study in a medical ICU in India in which age was not a risk factor for delirium. Unlike in our study that covered both the main and medical ICU, Jayaswal et al. (2019) only collected data from the medical ICU, which might have contributed to the difference. The authors also evaluated a larger sample size (280 versus 81). Even though disparities exist between populations, screening for risk factors such as age should be standard practice.

Even though the gender of patients did not influence the odds of delirium as previously shown (Elie et al., 1998; Kolanowski et al., 2014), the risk of delirium increased statistically with alcohol consumption. Patients who consumed alcohol had a significantly higher risk of delirium, with the odds for its development found to be approximately 12.58 fold from the data before controlling confounding. These findings have been replicated in other studies in the developed and developing world. Hsieh et al. (2013) associated alcohol use with a higher risk of delirium in a systematic review of 15 ICU cohort studies. Lim et al. (2017) had similar findings in China, while Van Rompaey et al. (2009) and Nagari and Babu (2019) found a significant association between alcohol consumption (at least three pints per day) and the risk of delirium post-admission. Acute nicotine withdrawal due to hospitalization is postulated to desensitize and up-regulate nicotinic acetylcholine receptors in the brain causing a deficiency in acetylcholine release and an unoccupied state (Benowitz, 2009). Metabolic derangements and acute stress have also been reported after cigarette and alcohol withdrawal (Fong et al., 2009). For such patients, alternative treatments such as detox and or nicotine replacement therapy should be considered, as they have been shown to lower delirium (Hsieh et al., 2013).

The use of medication was not associated with the development of delirium in the population studied. However, by factoring in the number of medications received, the risk of delirium seemed to increase with the number of medications provided. Sedatives posed a high risk for delirium development (up to 7.44 fold) with the odds being significantly higher with Midazolam. Ketamine and Remifentanyl seemed to lower the odds of delirium, even though statistical testing was not significant. In a risk factors study conducted by Lee et al. (2016), antipsychotic drug use was associated with a higher risk of developing delirium. Also, van Velthuijsen et al. (2018) reported a significant interaction effect between the number of medications and the risk of delirium. Like in this study, patients who developed delirium were on significantly more medications compared to those who did not. Furthermore, van Velthuijsen et al. (2018) found shorter delirious episodes among delirious patients, with few medications compared to many. Sedation, especially with a higher maintenance dose of Midazolam and Fentanyl is also a well-recognized predisposing factor for delirium, as was the case in the study (Yang et al., 2017). Analgesia and sedation are often used in ICUs to relieve pain, anxiety, and other physical discomforts. However, they can also cause sleep disturbance, depression, and posttraumatic stress disorder (PTSD) in some patients, which predisposes them to delirium. While ignoring sedation and analgesia in ICUs is not possible, lowering the maintenance dose of sedatives such as midazolam, if appropriate, could help. Substituting drugs and robust monitoring and management of delirium can also help.

Physically restrained patients seemed to develop delirium at a significantly higher rate than non-restrained ones – a common finding in ICUs. In a cohort study of 593 intensive care unit patients, Pan et al. (2018) reported a significantly higher risk of delirium in physically restrained patients, which increased with the length of hospital stay. In China, delirium was associated with physical restraint is a cross-sectional observational study in ICUs (Gu et al., 2019). Delirium worsened with the length of physical restraint. According to (Mohr et al.,

2003), physical restraint creates an agitated state that predisposes patients to delirium. To prevent this, it requires careful application as most struggles are natural responses to subjective feelings such as lack of air (Mohr et al., 2003). Even though risk factors were diverse after bivariate analyses, only alcohol use and physical restrain were statistically significant predictors for delirium. During admission, health workers should look out for such factors and carefully monitor at-risk patients to improve outcomes.

The precipitating factors for delirium were diverse, but metabolic conditions such as uremia, hypoglycemia, and hyponatremia, and Cryptococcal infections were most common. The central nervous system causes such as traumatic brain injuries (TBI) were also reported. The data complement the findings of Nagari and Babu (2019) that metabolic factors such as hypernatremia and uremia were the commonest precipitating factors for delirium in a one-year observational study of medical ICU patients in a tertiary care hospital in India.

5.2 Conclusions

At Kenyatta National Hospital, delirium was diagnosed in 34.6%.of mechanically ventilated patients. The risk factors were diverse, key among them found to be old age, alcohol use, cigarette smoking, sedation, physical restraint, and the number of drugs. However, after controlling for confounding, only alcohol consumption and physical restraint were predictors for delirium. Metabolic disorders such as uremia were the most common precipitating factors.

5.3 Recommendations

- Regular evaluations for delirium should be done in Kenyatta National Hospital ICUs, as prevalence is high. Its assessment is not common even though tools are available.
- Regular screening for risk factors such as alcohol consumption and cigarette smoking should be done on admission. Moreover, because sedated and physically restrained patients bear the greatest risk for delirium, specialized routine care should be done.

5.4 Further research

- The prevalence of delirium in other KNH ICUs should be evaluated as data is missing
- Other risk factors like APACHE should be evaluated regarding delirium
- The outcome of patients with delirium should be assessed.

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APPENDICES

Appendix 1. Observation Checklist

DETERMINANTS OF DELIRIUM AMONG PATIENTS IN CRITICAL CARE UNITS AT KNH

[FILL ALL SECTIONS]

Study number……

Date of admission…….

Date of assessment ……..

Date of discharge/death……

SECTION 1: DEMOGRAPHIC AND MEDICAL CHARACTERISTICS

1. Age (years)……..

Categorized

☐<20

☐20-30

☐>30

2. Gender

☐Male

☐Female

3. Unit of admission

☐Main ICU

☐Medical ICU

4. Comorbidities

☐Yes

☐No

If yes: (tick all that apply)

☐HIV

☐HTN

☐CKD

☐Other……..

5. Education (tick one)

☐No formal education

☐Primary

☐Secondary

☐Tertiary

6. Employment (tick one)

☐Formal employment

☐Self-employment

☐Unemployed

7. Reason for admission……

8. Patient under medication

☐Yes

☐No

If yes, type……

9. Sedated

☐Yes

☐No

10. If yes, type of sedation

☐Continuous

☐Intermittent

11. Physical restraint

☐Yes

☐No

If yes, type:

☐Physical

☐Chemical

SECTION 2: DELLIRIUM ASSESSMENT

12. CAM-ICU-7 score

CAM-ICU-7 score		

SECTION 3: ADMISSION AND CLINICAL OUTCOMES

12. Length of hospital stay in days……

Appendix II. The CAM-ICU-7 Delirium Severity Scale

DETERMINANTS OF DELIRIUM AMONG PATIENTS IN CRITICAL CARE UNITS AT KNH
[CAM-ICU-7 Delirium Severity Scale]

Study number…….. Date…….

CAM-ICU		
Items	Grading	Score
1. Acute Onset or Fluctuation of Mental Status Is the patient different than his/her baseline mental status? OR Has the patient had any fluctuation in mental status in the past 24 hours as evidenced by fluctuation on a sedation/level of consciousness scale (i.e., RASS/SAS), GCS, or previous delirium assessment?	0 absent 1 present	
2. Inattention Say to the patient, "I am going to read you a series of 10 letters. Whenever you hear the letter 'A,' indicate by squeezing my hand." Read letters from the following letter list in a normal tone 3 seconds apart. SAVEAHAART (Errors are counted when patient fails to squeeze on the letter "A" and when the patient squeezes on any letter other than "A")	0 absent (correct ≥ 8) 1 for inattention (correct 4-7) 2 for severe inattention (correct 0-3)	
3. Altered Level of Consciousness Present if the Actual RASS score is anything other than alert and calm (zero)	0 absent (RASS 0) 1 for altered level (RASS 1, −1) 2 for severe altered level (RASS >1, < −1)	
4. Disorganized Thinking Yes/No Questions 1. Will a stone float on water? 2. Are there fish in the sea? 3. Does one pound weigh more than two pounds? 4. Can you use a hammer to pound a nail? Errors are counted when the patient incorrectly answers a question. Command: Say to patient "Hold up this many fingers" (Hold two fingers in front of patient). "Now do the same with the other hand" (Do not repeat number of fingers) An error is counted if patient is unable to complete the entire command.	0 absent (correct ≥ 4) 1 for disorganized thinking (correct 2, 3) 2 for severe disorganized thinking (correct 0, 1)	
Total Score		

CAM-ICU: Confusion Assessment Method for the Intensive Care Unit; RASS: Richmond Agitation Sedation Scale; SAS: Sedation-Agitation Scale; GCS: Glasgow Coma Scale

Appendix III. Richmond agitation–sedation scale

DETERMINANTS OF DELIRIUM AMONG PATIENTS ADMITTED IN CRITICAL UNITS AT KNH

[Richmond Agitation–Sedation Scale]

Score	Term	Description
+4	Combative	Overtly combative or violent; immediate danger to staff
+3	Very agitation	Pulls on or removes tube(s) or catheter(s) or has aggressive behavior toward staff
+2	Agitated	Frequent nonpurposeful movement or patient–ventilator dyssynchrony
+1	Restless	Anxious or apprehensive but movements not aggressive or vigorous
0	Alert and calm	
−1	Drowsy	Not fully alert, but has sustained (more than 10 seconds) awakening, with eye contact, to voice
−2	Light sedation	Briefly (less than 10 seconds) awakens with eye contact to voice
−3	Moderate sedation	Any movement (but no eye contact) to voice
−4	Deep sedation	No response to voice, but any movement to physical stimulation
−5	Unarousable	No response to voice or physical stimulation

Procedure	Score
1. Observe patient. Is patient alert and calm (score 0)?	
Does patient have behavior that is consistent with restlessness or agitation (score +1 to +4 using the criteria listed above, under DESCRIPTION)?	
2. If patient is not alert, in a loud speaking voice state patient's name and direct patient to open eyes and look at speaker. Repeat once if necessary. Can prompt patient to continue looking at speaker.	
Patient has eye opening and eye contact, which is sustained for more than 10 seconds (score −1).	
Patient has eye opening and eye contact, but this is not sustained for 10 seconds (score −2).	
Patient has any movement in response to voice, excluding eye contact (score −3).	
3. If patient does not respond to voice, physically stimulate patient by shaking shoulder and then rubbing sternum if there is no response to shaking shoulder.	
Patient has any movement to physical stimulation (score −4).	
Patient has no response to voice or physical stimulation (score −5).	

Appendix IV. Consent form (English)

DETERMINANTS OF DELIRIUM AMONG PATIENTS IN CRITICAL CARE UNITS AT KENYATTAH NATIONAL HOSPITAL

Consent Form

Background

My name is Mrs. Evelyn Mong'are. I am currently conducting a study on "Determinants of Delirium among Patients in Critical Care Units at Kenyatta National Hospital" in partial fulfillment for the requirement of a degree in Masters of Science in Nursing (critical care) of the University of Nairobi. We are recruiting patients currently admitted at the KNH-ICU with the aim of establishing the prevalence of delirium and factors that might increase your risk of developing the condition. Delirium is common in the ICU associated with an increased risk of having movement, sleep, and memory problems, and even death. However, if we can detect it early, we can implement proper techniques for its management and therefore lower the risk of such problems. To understand its occurrence, you are invited as a participant.

Who qualifies for this study?

We are targeting all patients currently admitted at the KNH ICU and age 18 years older. However, to be a participant, you should not have a history of health problems and be in a position to provide written informed consent, which we will take you through to be chosen.

What happens once selected?

If you agree that your patient can be evaluated during this study, we will do three things. First, we will ask you questions about the patients age and history of alcohol consumption and cigarette smoking. The health of the patient will be checked by a nurse two time a day and his/her information written on paper. We will not inject anything into patients and or extract blood and other bodily fluids from the patient for the purpose of this study.

What are the risks of participation?

We do not anticipate any risks to patients since this will be an observational study

What are the benefits of participating?

Information gained from this study will help to improve nursing protocols for patients admitted at the ICU and improve their well-being. Moreover, if a patient is found to be delirious, he or she will be referred to the medical team for monitoring and treatment.

Will I be remunerated?

No, we do not remunerate patients for participating in this study.

How will the confidentiality of patients be maintained?

A trained nurse with experience in the ICU will evaluate and collect data from patients. In addition, we will not record personal information such as the name and identification number on data collection tools nor share then without authorization for the patient and KNH-ERC.

Who should I contact for more information?

If you have questions during or after the study, you can reach the principle investigator through her phone number, 0726105400, and or phone or write to the KNH-ERC through:
The chairperson,
KNH/UON Ethics and Research Committee
P.O. Box 20723-00202, Nairobi.
Telephone number: (254-020) 2726300-9 Ext 44355
Email: uonknh_erc@uonbi.ac.ke

Consent:
I _____, the undersigned, acknowledge that I have been provided with adequate information about the study by Dr. /Mr. /Mrs. /Ms. _____. I have read the information, or it has been read to me. I have had the opportunity to ask questions, which have been answered to my satisfaction. I voluntarily agree to participate in the study.

Name of Patient _____

Next of Kin: Name: _____ Date _____ Signature _____

Signature of Researcher/ Assistant _____ Date _____

Appendix V. Consent form (Kiswahili)

DETERMINANTS OF DELIRIUM AMONG PATIENTS IN CRITICAL CARE UNITS AT KENYATTAH NATIONAL HOSPITAL

Consent Form

Asili

Jina langu ni Bi Evelyn Mong'are. Hivi sasa, ninafanya utafiti juu ya "Determinants of Delirium among Patients in Critical Care Units at Kenyatta National Hospital" kutimiza mahitaji ya digrii ya Masters of Science Nursing ya Chuo Kikuu cha Nairobi. Tunawahitaji wagonjwa waliolazwa sasa hive katika KNH-ICU kwa madhumuni ya kuanzisha kiwango cha maambukizi ya delirium na sababu zinazoweza kuongeza hatari ya wagonjwa kukuza hali hiyo. Delirium ni ya kawaida katika ICU na inahusishwa na hatari kubwa ya kuwa na hshida ya kulala, na shida za kumbukumbu, na hata kifo. Walakini, ikiwa tunaweza kuigundua mapema, tunaweza kutekeleza mbinu sahihi za usimamizi wake na kwa hivyo kupunguza hatari ya shida kama hizo. Ili kuelewa tukio lake, umealikwa kama mshiriki.

Nani anastahili utafiti huu?

Tunawalenga wagonjwa wote waliolazwa kwa sasa katika ICU ya KNH na wenye umri wa miaka 18. Walakini, kuwa mshiriki, haupaswi kuwa na historia ya shida za kiafya na kuwa katika nafasi ya kutoa idhini iliyoandikwa, ambayo tutakuchukua ili uchaguliwe.

Ni nini hufanyika mara moja kuchaguliwa?

Ikiwa unakubali kwamba mgonjwa wako anaweza kupimwa wakati wa uchunguzi huu, tutafanya mambo matatu. Kwanza, tutakuuliza maswali juu ya umri wa wagonjwa na historia ya unywaji pombe na sigara za sigara. Afya ya mgonjwa itaangaliwa na muuguzi mara mbili kwa siku na habari yake imeandikwa kwenye karatasi. Hatutaingiza chochote kwa wagonjwa na au kutoa damu kwenye mwili wa mgonjwa kwa madhumuni ya utafiti huu.

Kuna hatari gani za kushiriki?

Hatutarajii hatari zozote kwa wagonjwa kwani hii itakuwa uchunguzi wa uchunguzi
Je! Ni faida gani za kushiriki?

Habari inayopatikana kutoka kwa utafiti huu itasaidia kuboresha itifaki za uuguzi kwa wagonjwa waliolazwa katika ICU na kuboresha ustawi wao. Kwa kuongezea, ikiwa mgonjwa atagundulika kuwa mwema, atapelekwa kwenye timu ya matibabu kwa ajili ya kuangalia na matibabu.

Je! Nitalipwa?

Hapana, hatuwalipie wagonjwa kwa kushiriki katika utafiti huu.

Usiri wa wagonjwa utatunzwa vipi?

Muuguzi aliyefundishwa na uzoefu katika ICU atathamini na kukusanya data kutoka kwa wagonjwa. Kwa kuongezea, hatutaandika habari za kibinafsi kama vile jina na nambari ya kitambulisho kwenye zana za ukusanyaji wa data au kushiriki kisha bila idhini ya mgonjwa na KNH-ERC.

Nani ninapaswa kuwasiliana naye kwa habari zaidi?

Ikiwa una maswali wakati wa kusoma au baada ya masomo, unaweza kumfikia mpelelezi wa kanuni kupitia nambari yake ya simu, 0726105400, na au kupiga simu au kuandika kwa KNH-ERC kupitia:
Mwenyekiti,
Maadili na Kamati ya Maadili ya KNH / UON
P.O. Box 20723-00202, Nairobi.
Nambari ya simu: (254-020) 2726300-9 Ext 44355
Barua pepe: uonknh_erc@uonbi.ac.ke

Ikiwa una maswali wakati wa kusoma au baada ya masomo, unaweza kumfikia mpelelezi wa kanuni kupitia nambari yake ya simu, 07 26105400, na au kupiga simu au kuandika kwa KNH-ERC kupitia:

Mwenyekiti,

Maadili na Kamati ya Maadili ya KNH / UON

P.O. Box 20723-00202, Nairobi.

Nambari ya simu: (254-020) 2726300-9 Ext 44355

Barua pepe: uonknh_erc@uonbi.ac.ke

Dhibitisho:

Mimi _____ nakiri kuwa nimepewa habari ya kutosha juu ya utafiti huo na Dk / Mr. /Bi. / Mh. _____. Nimesoma habari hiyo, au imesomwa kwangu. Nimepata nafasi ya kuuliza maswali, ambayo yamejibiwa kwa kuridhika kwangu. Nakubali kwa hiari kushiriki katika utafiti.

Jina la Mgonjwa _____

Jamma wa Mgonjwa: Jina: _____ Tarehe _____Saini _____

Saini ya Mtafiti / Msaidizi _____ Tarehe _____

Appendix VI. KNH/UON ERC Approval

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel: (254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/189

26th June 2020

KENYATTA NATIONAL HOSPITAL APPROVED 26 JUN 2020 KNH/UoN-ERC P. O. BOX 20723 - 00202 NAIROBI

Evelyne Kwamboka Mong'are
Reg. No. H56/8500/2017
School of Nursing Sciences
College of Health Sciences
University of Nairobi

Dear Evelyne,

RESEARCH PROPOSAL – DETERMINANTS OF DELIRIUM AMONG PATIENTS IN CRITICAL CARE UNITS AT KENYATTA NATIONAL HOSPITAL (P86/02/2020)

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 26th June 2020 – 25th June 2021.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. 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*).
f. 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.

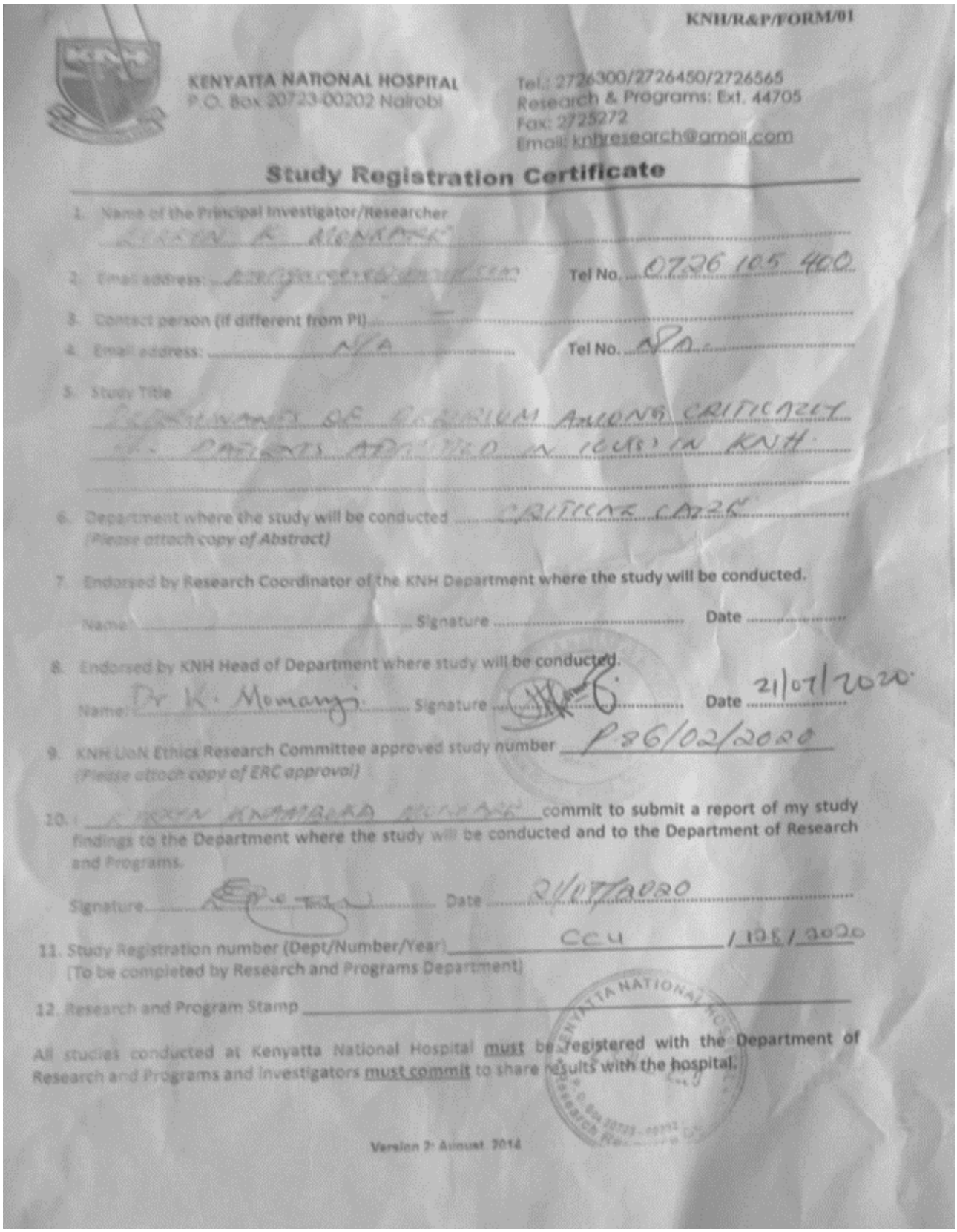
For more details consult the KNH- UoN ERC website http://www.erc.uonbi.ac.ke

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Director, School of Nursing Sciences, UoN
Supervisors: Dr. Dorcas Maina (School of Nursing Sciences, UoN)
Dr. Samuel Kimani (School of Nursing Sciences, UoN)

Appendix VII. KNH Registration Certificate



KNH/R&P/FORM/01

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

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

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
2. Email address: Tel No. 0726 105 400
3. Contact person (if different from PI)
4. Email address: N/A Tel No. N/A
5. Study Title
6. Department where the study will be conducted CRITICAL CARE
   (Please attach copy of Abstract)
7. Endorsed by Research Coordinator of the KNH Department where the study will be conducted.
   Name: Signature Date
8. Endorsed by KNH Head of Department where study will be conducted.
   Name: Dr K. Memanji Signature Date 21/07/2020
9. KNH-UoN Ethics Research Committee approved study number P86/02/2020
   (Please attach copy of ERC approval)
10. I commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Research and Programs.
    Signature Date 21/07/2020
11. Study Registration number (Dept/Number/Year) CC4 /105/2020
    (To be completed by Research and Programs Department)
12. Research and Program Stamp

All studies conducted at Kenyatta National Hospital must be registered with the Department of Research and Programs and investigators must commit to share results with the hospital.

Version 7: August 2014

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DETERMINANTS OF DELIRIUM AMONG PATIENTS IN CRITICAL CARE UNITS AT KENYATTA NATIONAL HOSPITAL
by Evelyn Mong'are
From CRITICAL CARE (Nursing)

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Dr Dvcas Mang
7.12.2020