A COMPARISON OF THE GLASGOW COMA SCALE WITH FULL OUTLINE OF UNRESPONSIVENESS SCALE IN PREDICTION OF PATIENT OUTCOMES IN THE CRITICAL CARE UNIT AT KENYATTA NATIONAL HOSPITAL

ABIRA DELILAH KWAMBOKA

H56/11310/2018

A RESEARCH THESIS SUBMITTED IN THE PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF SCIENCE IN NURSING (CRITICAL CARE NURSING) OF THE UNIVERSITY OF NAIROBI

DECEMBER 2020

DECLARATION

I, **ABIRA DELILAH KWAMBOKA**, declare that this research thesis titled, **"A COMPARISON OF THE GLASGOW COMA SCALE WITH FULL OUTLINE OF UNRESPONSIVENESS SCALE IN THE PREDICTION OF PATIENT OUTCOMES IN THE CRITICAL CARE UNIT AT KENYATTA NATIONAL HOSPITAL"** is my original work, and has not been submitted for the award of any degree at any university or any other purpose.

SIGNATURE: _____   DATE: _____

Abira Delilah Kwamboka

H56/11310/2018

CERTIFICATE OF APPROVAL

We, the undersigned certify that this research thesis has been submitted for the award of the degree of Master of Science in Nursing (Critical Care) of the University of Nairobi with our support and approval as supervisors:

1.   Dr. Dorcas Maina

Ph.D., MScN (Critical Care), BScN

Lecturer, School of Nursing Sciences

University of Nairobi

Sign: ……………………………………….. Date: ………………….

2.   Dr. Mwaura James

Ph.D. MSc, BScN

Lecturer, School of Nursing Sciences

University of Nairobi

Sign: ……………………………………...... Date: ……………………

DEDICATION

I wish to dedicate this research thesis to my parents, Mr. and Mrs. Abira for their continued support and words of encouragement throughout my studies. I also thank my son Kendrick for enduring my absence during this study period and always being there for me and my family and friends for their prayers and support.

ACKNOWLEDGMENT

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ABBREVIATIONS AND ACRONYMS

APACHE II SCORE   Acute Physiology and Chronic Health Evaluation II

Score

CCU   Critical Care Unit

FOUR   Full outline of unresponsiveness

GCS   Glasgow Coma Scale

ICU   Intensive care unit

KNH   Kenyatta national hospital

KNH-UON ERC   Kenyatta National Hospital- University of Nairobi Ethics

and   Research Committee

LOC   Level of consciousness

SAH   Subarachnoid hemorrhage

SPSS: Statistical Package for Social Scientists

TBI   Traumatic brain injury

UON   University of Nairobi

USA   United States of America

WFNS   World Federation of Neurological Societies

WHO   World health organization

OPERATIONAL DEFINITIONS

Brainstem reflexes –These are tests done on a patient to determine brain stem death by assessing the reflexes; papillary reactivity, spontaneous eye position, and movements, corneal, cough, and gag reflex.

Critical care unit – This is a specialized unit in the hospital where severely ill patients are admitted and managed. It is used interchangeably with the Intensive care unit.

Critically ill patient - This refers to any person who has come to seek healthcare services at Kenyatta National Hospital and has been admitted to the critical care unit due to his illness.

Glasgow coma scale – This is a neurological assessment scale used to assess the patient's level of consciousness, by use of three components; Eye, motor, and verbal responses.

The full outline of Unresponsiveness scale – A neurological assessment tool used to assess the level of consciousness of critically ill patients with regards to those who are intubated, aphasic, and sedated especially in the Intensive care unit.

Outcome – the result of admission at the critical care unit on day seven, which is the average length of stay of patients in the Critical care unit, Kenyatta National Hospital. The aftermath of our study is either mortality or survival of the patient.

Patient Mortality – This is the death of a patient admitted in the Critical care unit during the study period.

Patient survival – it is the ability of a patient to be alive during the day of the study evaluation

Reliability – the ability and the extent to which a scale produces scores that are accurate, reproducible, and consistent with regards to patient outcomes during the study.

ABSTRACT

Background: Neurological assessment is essential in determining the condition, prognosis, and management of critically ill patients. An appropriate scale is essential in the early stage of patient assessment for proper decision making and prediction of patient outcomes. The Glasgow Coma Scale (GCS) and Full Outline of Unresponsiveness scale (FOUR) are some of the scoring tools used for assessment of critically ill patients.

Broad objective: The main goal of the study was to compare the performance of the GCS with FOUR scales in the prediction of patient outcomes in ICU, Kenyatta National Hospital (KNH).

Methodology: This was an analytical prospective study carried out at the critical care units at KNH. Census method was used to select 55 ICU clients who met the study criteria. Data was analyzed using SPSS version 24. Categorical data was analyzed using percentages while continuous data was analyzed using standard deviation and mean. The performance of the GCS and FOUR scores in predicting survival was analyzed using binary logistic regression. Survival analysis was performed by the use of Kaplan Meier method. A Spearman rank correlation analysis was performed to determine the strength of the relationship between GCS prediction, FOUR scale prediction in relation to the actual outcome. Sensitivity analysis was used to determine the reliability of GCS and FOUR scale in predicting actual outcome. ROC curves were computed to assess the accuracy of GCS and FOUR scale based on Area Under the Curve analysis. Calculation of cut-off points was calculated and determination of overall accuracy of prediction of results, sensitivity, and specificity was identified.

Results: Of the 55 patients assessed, 67% of the patients were male; the mean age was 41 years, the average length of stay was ten days. Most patients were referrals from other facilities. Patients with a low level of GCS below 6, at admission, were 40%, at 48 hours they were 39% and for low scores of FOUR(less than 9) at admission were 47%, at 48 hours were 39% while those with high scores(above 14) were 40%. The survival rate for both scales at 48 hours was 100%, which continued to decrease as the days went by. On the 14th day, the predicted survival was 50% while the actual survival for the patients was 65%. The sensitivity of GCS at admission was 47.4% and 98% on the day of evaluation while FOUR score at admission was 68.4% and on day 14 was 100%. At 48 hours and 14 days of admission to the ICU, FOUR score was able to accurately predict the survival rate of patient outcomes.

Dissemination: Findings were delivered to the School of Nursing for thesis defense, Ethics, and review committee, published in one of the international journals and will be presented during the annual general scientific conference.

Recommendations: The researcher recommends a larger study to be done to confirm that FOUR score is a more reliable tool for assessment of ICU patients.

CHAPTER ONE: INTRODUCTION

1.1.Background

The knowledge of neurological assessment has been on the rise. To ensure accurate determination of prognosis when hospital discharge can take place, the neurological assessment is used to predict mortality and ensure appropriate resource administration by health care workers. Choosing and utilizing a suitable scoring scale is important in the early stages of patient assessment, for an appropriate decision making of the initial diagnosis, management, and the likely course of a medical condition (Hosseini, Akbari, heidari, 2017).

Several prognostic models have been used in predicting patient outcomes (Akavipat, Sookplung, Kaewsingha, & Maunsaiyat, 2011). These scales include; the Edinburgh-2 coma scale, the Glasgow-Liege scale, Pittsburgh brain stem score, Comprehensive level of consciousness scale, Reaction Level Scale, the Innsbruck Coma Scale, the Glasgow coma scale (GCS), and the Full outline of unresponsive scale (FOUR), (Wijdicks & Eelco, 2005). Most of these scales are not in use because of their complexity and similarity to the GCS and health care workers' preference to use the GCS. The Glasgow –Liege scale, the Pittsburgh brainstem score, and the FOUR score assesses brainstem functions and are more sensitive than the GCS though they are not commonly used.

As much as these scoring systems are an important part of making clinical decisions and relevant in the identification of clients with unknown outcomes (Raj, Bansal, Philip, 2014) they, however, have various disadvantages and there is no perfect scoring tool so far though some have shown superior outcomes when used compared to others. The commonly used scale is the GCS while the recently developed FOUR score is scantly used.

The History of Glasgow Coma Scale (GCS) dates back to the year 1974, at the Institute of neurological sciences, University of Glasgow. Two professors, Graham Teasdale and Bryan J. Junnuett (Alhassan, Fuseini & Musah, 2019) made a scale known as the Glasgow coma scale. The scale was used to measure the level of consciousness in trauma and acute medical clients in the hospital and at the field level by medical personnel. Advances to have an accurate and better scoring system have seen the birth of many other tools including the FOUR score and Glasgow Liege scale.

The Full outline of unresponsiveness scale, (FOUR) was developed by Wijdicks in 2005. This scale is more reliable in determining the patient's neurological status. The FOUR score was first validated at the Mayo clinic. It is a 16-point scale, with scores ranging from 0 to 16. (Akavipat, 2009). The FOUR score has shown to be a more reliable tool in the assessment of ICU patients because it assesses the brain stem reflexes and takes into account the inability to assess the verbal component of these clients, unlike the GCS.

The Glasgow coma scale is a tool that determines the level of consciousness of patients in three identified classes of responsiveness; eye response, motor activity, and verbal response. The examiner has to assess each of these three responses independent of each other and then give a score. The sum of the score from each component response is the GCS score (Wijdicks et al., 2018). The GCS has remained the most objective way to measure the mental status of the patients. Independently the component was summed from Best eye response, which has scores of four to one. Best verbal response, with scores of five to one and motor response with scores of six to one. (Alhassan, Fuseini & Musah, 2019).

The first edition of advanced Trauma and life support recommended the use of Glasgow coma scale in the assessment of trauma clients. The World Federation of Neurological Societies (WFNS) also used GCS to classify patients who had presented with subarachnoid hemorrhage (Jalali & Rezaei, 2014). Four decades later the GCS has remained a golden standard of assessment, ongoing assessment, prognosis, and judgment of conscious states in clients with injuries to the brain and several acute cares of neurological diseases (McNarry & Goldhill, 2014). However, there have been a few criticisms of GCS such as the lack of interpreter reliabilities as it can be as good as the person doing the assessment (Michelson et al., 2018).

Regardless of its worldwide use, the GCS has several disadvantages that make it less reliable and accurate. They include the inability to score the verbal component for those patients who are aphasic, intubated, and sedated, also inconsistent inter-observer agreement (Saika, Bansal, Philip, Devi, & Shukla, 2015). The FOUR score stands out because of such limitations exposed by the GCS, which includes its ability for use in scoring intubated and sedated patients by excluding the verbal response in GCS and replaced it with brainstem reflexes and respiratory assessment. Decreasing scores of GCS and FOUR are linked with the worsening level of consciousness and a high mortality rate.

Wijdicks (2005) developed a scoring system, known as the FOUR that is used for assessment of coma in patients at Intensive care units. The importance of the tool was to improve standardized assessment of intubated, sedated, and those with neurological conditions and disorders. The tool has four components; each with five points, ranging from zero to four. The scores are summed up from the four components resulting in a range of 0 to 16. Sixteen termed as the highest score and it relates to the highest level of consciousness. In the eye component of the scale, the eyes are required to track or

blink in response to a command for the client to get the highest score of four, unlike in the GCS where the patient is only required to open the eyes.

According to a study conducted by Ramazani and Hosseini (2019), the FOUR score and GCS demonstrated an allowable difference between the patient's highest and lowest scores in relation to their outcomes. Only the FOUR scale showed a better association between scores and the predicted patient outcomes in the critical care units. The findings of a study by Gorji (2011) revealed a higher predictive power of the end results for the FOUR in patients with traumatic brain injuries.

Globally there has been a need to identify a tool that is more reliable in evaluating the neurological status of patients. Most healthcare providers in the past have either used the FOUR score or GCS. The existence of the two scales for assessing patients seems to be sufficient reason for a comparative study on their performance in prognosis and predicting outcomes for critically ill patients. The fact that most studies that have been conducted since 2005 and have come into an agreement that the FOUR scoring tool is more reliable at the prediction of patient outcomes at ICUs.

1.2 Problem Statement

The Glasgow Coma Scale (GCS) and the Full Outline of Unresponsiveness (FOUR) are neurological grading scales designed for the assessment of patients with an impaired level of consciousness and neurological deficits. The Glasgow coma scale has three assessment elements; the eye, verbal, and motor components (Alhassan, 2019) while the FOUR is comprised of four elements of patient assessment; the eye, motor, brainstem reflexes, and respirations components (Wijdicks, 2005). The FOUR score has replaced the verbal response in GCS with the brainstem reflexes and respiration which makes it easy to assess intubated patients.

Globally the Glasgow coma scale has been in use by more than eighty countries and it is still the golden measure in the evaluation of the neurological status of patients for ongoing monitoring, prognosis, and clinical judgment (Alhassan, Fuseini, & Musah, 2019). However, it has limitations that make it not reliable, more so in the assessment of verbal response in patients who are intubated, aphasic, and sedated.

In Kenya, there are a few studies that have been conducted on the neurological assessment of patients and they have advocated for the use of the GCS. A study by Shishoka (2019) revealed that GCS is commonly used in providing care to patients with TBIs. Another study comparing seven injury severity measures among them the GCS, in predicting patient outcomes among children, found out that the Glasgow coma scale is better at grading the coma levels.

The Full Outline of Unresponsive Scale score is gradually getting acceptable in more countries as an alternative for GCS in the assessment of consciousness in severely brain-damaged and critically ill patients. A study conducted in Iran by Ramazani and Hosseini (2019) on both GCS and the FOUR score showed that both had acceptable discrimination power. Though the FOUR showed better calibration which resulted in more accuracy in the FOUR scores than the GCS, which makes it more predictive of the patient outcomes for patients admitted in ICU. While this is the case in many studies done, there have been issues of most health care providers being used to the GCS tool and find it not easy to move to the more current FOUR scoring system.

In Africa, there are a few studies conducted on the subject of the FOUR score while more studies have focused on the GCS. A study conducted in Uganda on the comparison of the two scoring systems in predicting mortality in patients with a decreased level of consciousness showed that Full outline of Unresponsiveness is

similar to the GCS score for predicting mortality of clients. However, the study supported the use of the FOUR score in practice to guide the clinical assessment of clients with a decreased level of consciousness in Africa (Abdallah, 2019). Findings from several other studies have come to the conclusion that the FOUR scale is a more accurate and reliable tool for assessment of critically ill patients and prediction of discharge and mortality in ICU.

Despite the FOUR scale being more reliable and superior, it has not been used in the Kenyan setting to validate it. Currently, there is no hospital documented in Kenya as having embraced the scoring tool in the neurological assessment of its clients. The purpose of the study is therefore to compare the performance of FOUR score and GCS in outcome predictions of clients in ICU. This is why the study will endeavor to find out the reliability of the FOUR scale and its ability in predicting outcomes of critically ill patients in ICU on the fourteenth day since admission, KNH.

1.3 Study Justification

A good patient assessment at the Critical Care Unit (CCU) looks at every system of critically ill patients and identifies the changes in the patients' health status to make it possible for the nurse to have a more convenient plan for the patient as well as initiate immediate interventions.

The limitations of the use of GCS in ICU especially those patients who are intubated, sedated, and the fact that when it is performed it gives inconsistent results among the nurses (Saika, et al 2015), has made it not reliable for use in ICU.

The study results will therefore be used to inform registered nurses and other health providers working at CCU of an accurate alternative method of evaluating the mental status of critically ill clients in CCU. This will benefit patients, by promoting proper

management and outcome prediction depending on the level of consciousness. The results will help the hospital and other organizations and the government at large to recognize, appreciate the existence of an alternative assessment scale (FOUR scale) apart from GCS that is suitable for intubated, aphasic, and sedated ICU patients.

This study will guide the government on the development of guidelines on the use of FOUR score by health care workers in ICU. It will also help in reinforcing policy-making and therefore lead to improved assessment and outcomes for clients in ICU. Policymakers can carry out more researches on the FOUR score to validate it and develop learning materials to aid in teaching the nurses and other clinicians about the tool and its reliability in ICU.

Lastly, the results of the study will add knowledge and improve clinical practice in the management of ICU patients. The results will also be available in journals and the university repository, to guide other hospitals and learning institutions with the required knowledge and understanding of the FOUR scale as a better tool for assessment of patients in ICU.

1.4 Study Questions

   i.   What is the difference between the level of consciousness obtained by the GCS and FOUR scale in the prediction of patient outcomes in ICU, KNH?

  ii.   What is the survival rate and mortality rate of critically ill patients in ICU, KNH by day fourteen?

 iii.   What are the reliability of the GCS and the FOUR scales in the prediction of patient outcomes in ICU, KNH?

1.5 Study Objectives

1.5.1 Main objective

To compare the performance of GCS with FOUR score in predicting patient outcomes in ICU, KNH.

1.5.2 Specific objectives

i. To assess the level of consciousness obtained from the GCS and FOUR in the prediction of patient outcomes in ICU, KNH.

ii. To determine the survival rate and mortality rate of critically ill patients by day fourteen in ICU, KNH.

iii. To determine the reliability of the GCS and FOUR scales in the prediction of patient outcomes in ICU, KNH

1.6 Hypothesis

There is no difference between the Full Outline of Unresponsiveness and Glasgow coma scale at predicting patient outcomes at the intensive care unit.

1.7 Study Variables

The categories of variables addressed in this study are dependent, independent, and confounding variables.

1.7.1 Dependent Variable

Prediction of outcomes

1.7.2 Independent variables

GCS scores

FOUR scores

1.7.3 Confounding variables

Nurses' competence and expertise

APACHE score

Patient co-morbid factors

1.7.4 Outcomes

The primary outcomes for this study are survivors and non-survivors

1.7.5 Conceptual Framework

INDEPENDENT VARIABLE   **DEPENDENT VARIABLE**
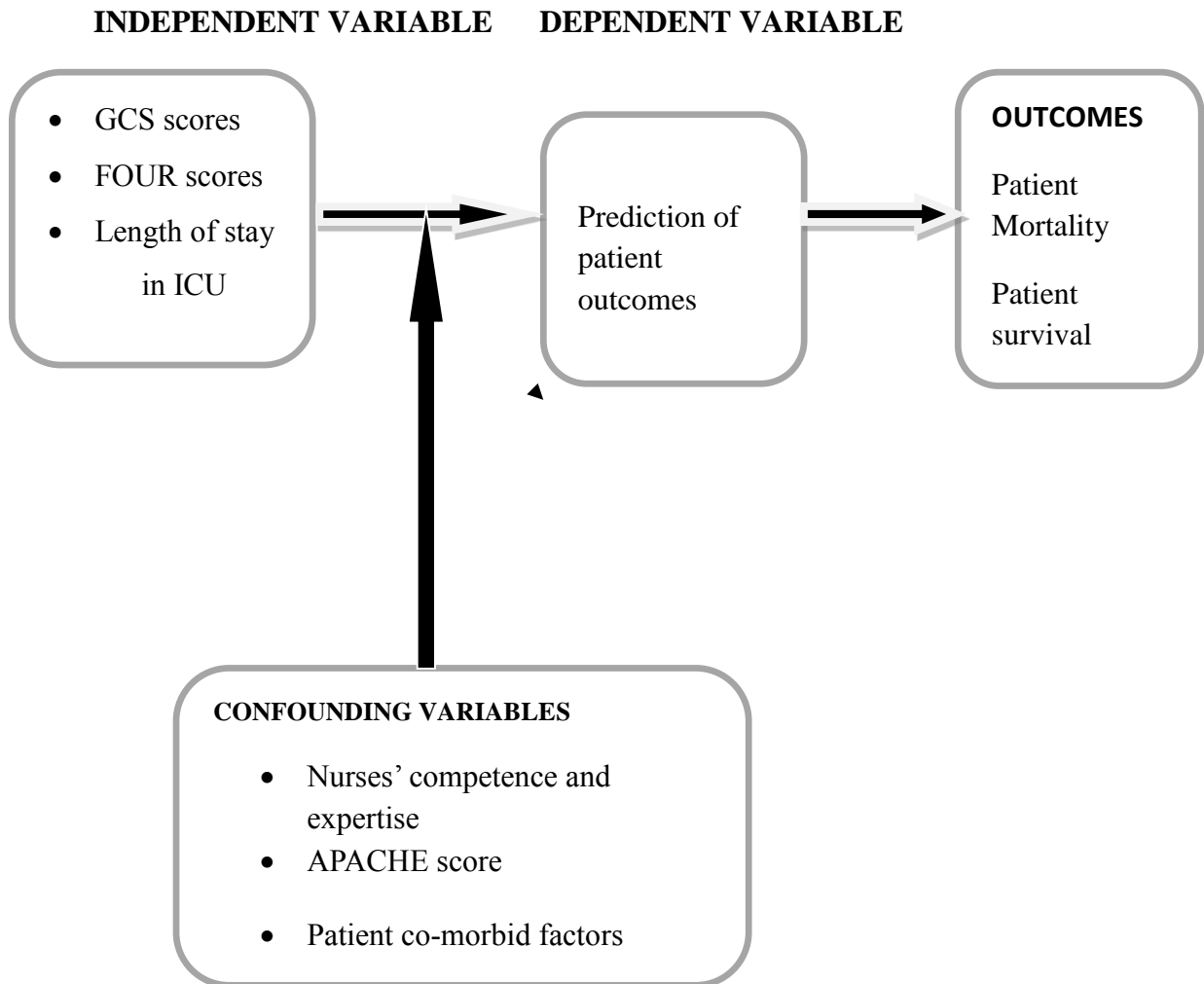
Figure 1.1: Conceptual Framework

CHAPTER TWO: LITERATURE REVIEW

In this section, I will discuss the current literature on neurological assessment scales available for the patient's assessment of the level of consciousness with an in-depth discussion on GCS and the FOUR scale. A discussion on the comparison between the two scales and their predictive nature on patient outcomes with supporting literature from previous studies and articles will be presented.

2.1.Introduction to Neurological Assessment

Neurological examination is important in the assessment of severely ill patients and a part of early warning signs used to identify a neurological disease, follow up on disease progression, and the decision on the kind of management to give (Phil, 2008; Resuscitation Council UK, 2006). The first examination involves a detailed assessment encompassing various components, which include consciousness, orientation to person, place and time, speech, the functioning of the motor and sensory system, and reflex assessment. In addition to the above, cranial nerves and cerebellar functions are assessed (Nadine, 2013).

Consciousness as part of the neurological examination is being in a state of awareness of the surroundings. Conscious patients are alert, awake, and respond appropriately to external stimuli around them (Marcovitch, 2005). The level of consciousness is the measurement of a client's ability to be aroused and responsive to environmental stimuli. A change in the level of consciousness is one of the most common findings encountered by healthcare providers in the hospital; it is a condition of being less responsive to and aware of external stimuli. There are several etiologies for altered level of consciousness including, trauma; infections; neoplasms; metabolic causes like; toxicities from drugs, heavy metals, and carbon monoxide; extremes of body temperature; hypoxic

encephalopathy, stroke; convulsions; SAH and alcohol toxicity (Resuscitation Council UK, 2006; Wyatt et al, 2006).

In the critical care unit, it is important to examine comatose patients. Unlike temperature and blood pressure that are objectively measured, coma cannot be measured objectively. In clinical setups, the neurological examination of the mental status of patients relies on scores obtained from scoring tools like the GCS and FOUR scale. In 1974, Jennet and Teasdale initially developed the Glasgow Coma Scale to evaluate patients with head trauma and since then it has been the common tool used worldwide to assess patients with an altered level of consciousness in the ICU. Scoring systems are commonly used in predicting mortality by evaluating the intensity of disease in the critical care units. Apart from GCS, Karnofsky Performance Scale (KPS) and APACHE II are used in the prediction for critical care unit patients. According to Gill (2004), the common disadvantages of GCS such as variability in reliability by different observers, worries on the value of its prediction power for brain injury clients. In addition, its inability to assess the verbal response for intubated and sedated patients, elimination of brainstem reflexes has made it not reliable for neurological assessment of patients in the CCU. For a few years, several neurological assessment tools have been established, but GCS remains the major ones in use in most countries.

2.2. Glasgow Coma Scale

2.2.1. Definition and use of Glasgow Coma Scale

The Glasgow Coma Scale (GCS) is a valid and objective scoring tool used for neurological assessment. The tool has been in use to assess and give information that describes the conscious state of patients during an initial assessment of the first

encounter and subsequent neurological assessments. Doctors and Nurses are considered to have the primary action skills in assessing and documentation of the GCS of patients with neurological problems (Jansen et al., 2008). This assessment is documented on a scale then is used to identify a patient's neurological status or problems and evaluate various health interventions (Jalali & Rezaei, 2014). Weir, Brandford, and lee affirm that it is useful as a measure in the provision of care in emergency situations.

Globally it is has been in use since 1974, because of its simplicity and it has been assimilated into many trauma and critical conditions classification systems, and in trauma outcome prediction models. Its application on patients' needs prior knowledge and skills on its application on clients. The clinician needs to score the patient in a systematic and accurate manner to ensure reliability, that is proper management and accurate results (Santos et al., 2016).

The application of GCS became common in the 1980s when the Advanced Trauma and life support (ATLS) recommended the use of GCS to assess trauma victims and the World Federation of Neurological Societies (WFNS) used the tool to grade clients who had subarachnoid hemorrhage (Jalali & Rezaei, 2014). In line with this, it is therefore useful in different clinical setups and by all cadres of healthcare workers in the assessment of different categories of patients.

2.2.2. Components of the Glasgow Coma Scale

It measures the patient's consciousness in the three identified components; eye-opening, motor activity, and verbal response, the examiner has to assess each of these three responses independent of each other and then gives a score, the sum of the score from each component response is the GCS score (Wijdicks et al.,2018). The GCS has remained the most objective way to measure the mental status of the patients. Independently the component is summed from Best eye response, which has scores of between 4 and1. The best verbal response, scores of between 5 and 1, and best motor response with scores of between 6 and 1 (Alhassan et al., 2019).

The Glasgow Coma Scale components above are graded as follows; Eye-opening: A score of 4 there is spontaneous eye-opening noticed by an examiner who is reviewing the patient. In scoring a 3, the patient responds to speech or voice, you can ask the patient to perform some activity or in some cases, a continuous verbal stimulus is needed, for a score of 2, the patient responds to a painful stimulus like endotracheal suctioning or an injection. When the patient does not open eyes in response to any stimulation the client scores one.

The verbal component: In score five, there is an orientation to place, person, and time; the nurse can ask "what day or time it is, or do you know where you are and what is your name." With a score of four, the patient converses and maybe in a confusion state. To score three, the patient replies with inappropriate words, making incomprehensible words the patient will score two, and if there is no response at all, the patient scores one. The motor component: A score of six, when the client follows commands for movement. Five when there is a purposive movement to a painful stimulus and able to localize pain, four is given if a patient withdraws or flexes from pain, a three if there is abnormal flexion to pain or decorticate posture. A score of two, if patient extends to

pain or decerebrate posture and lastly if no response at all despite the use of stimuli a score of one, is given.

2.3. Full Outline of Unresponsiveness (FOUR) scale

2.3.1. Definition and use of FOUR scale

The Full Outline of Unresponsive scale is a neurological scoring scale with four elements of assessment: eye and motor response, brainstem reflexes, and respiratory assessment, used for patient assessment in the CCU. Scientists at the Mayo Clinic (Wijdicks et al., 2004) first proposed it. It was established for neurological evaluation of patients with coma states who were being treated in the neurological ICU (Wijdicks, 2005), the main function was to improve the quality of care and for diagnostic purposes in intubated patients and those with problems with the nervous system.

2.3.2 Components of FOUR scale

The components of the FOUR scale contain four elements; each with five points that are graded from zero to four and the total score ranging from zero to sixteen depending on the patient's condition. A patient with a score of 16, is interpreted as being fully alert, awake, and aware of the surrounding. The client's eyes must track or blink when commanded to obtain a higher score of four. The FOUR also does not assess the verbal response as it is done in the GCS. Many cases of patients being sedated, intubated or delirious need to be accurately assessed, because of the inability of the patient to respond to commands by the health care provider and lack of awareness and responding ability. Hence this makes FOUR a better scale of assessment (Stephan, 2010).

The four elements are eye, motor, brainstem reflexes, and respiration responses. The eye response in the FOUR enables the clinician to distinguish if a patient is in a coma vigil whereby the patient can sleep, awake or open eyes without showing any sign of

awareness or in locked-in syndrome. During an assessment of the motor component, there is a combination of the withdrawal reflex and decortication response owing to the fact that these conditions are difficult to clinically recognize.

The motor component also can point out signs of severe cerebral dysfunction, which is a sign of anoxic brain injury. Brainstem reflexes assess the pons, mesencephalon, and medulla oblongata. In the respiratory pattern, there is an assessment for progressive, deeper, and faster breathing that is followed by a period of apnea, which indicates that the respiratory center in the brain may have a dysfunction. In intubated patients, it determines if there is an effort to make their own breaths.

The FOUR components are assessed as follows: Eye response; a score of 4 is given when the eyelids open and track on command. A score of 3 is given if eyelids open that do not track sound, a score of 2 is given when the eyelids are closed and only opens to loud noise. A score of one is given when eyelids are closed but opens to pain, and a score of zero is given when the eyelids remain closed with pain stimuli.

The second component is the Motor response; a score of 4 is given when the patient makes a sign like the sign of peace. A score of 3, when he or she is localizing pain; a score 2 if there is flexion in response to pain, in case of pain sensation there is an extension response then it is 1 and 0 if there is no response at all to pain. The third component is the Brainstem reflexes; a score of 4 if the pupil, corneal and cough reflexes are present. A score of 3, when a pupil is wide and fixed, 2 if the pupil reflex is absent and corneal reflexes is present. A score of 1, when both pupil and corneal reflexes absent but the cough is present, and 0 when there is absence all reflexes.

Lastly is the Respiration assessment; normal and regular breaths and when the patient has not been intubated a score of 4 is given. A score of 3 is given when the patient is not intubated and has Cheyne-Stokes breathing pattern. Two, if there is irregular breathing and patient is not intubated, when the patient triggers ventilator or has a higher rate than the set ventilatory rate 1, is given and 0 when there are periods of no breath or patient is breathing at machine set rate (Vivek, 2009).

The table below shows how the scoring for GCS and FOUR scales are presented and done.

Table 1: Components of the FOUR Score and Glasgow Coma Scale

2.3. Comparison of the GCS and FOUR scales

Full Outline of Unresponsiveness Score	Glasgow Coma Scale
Eye response 4 = eyelids open or opened, tracking, or blinking to command 3 = eyelids open but not tracking2 = eyelids closed, but open to a loud voice 1 = eyelids closed, but open to pain 0 = eyelids remain closed with pain	**Eye-opening** 4 = spontaneous 3 = to speech 2 = to pain 1 = none
Motor response 4 = thumbs-up, fist, or peace sign 3 = localizing to pain 2 = flexion response to pain 1 = extension response to pain 0 = no response to pain or generalized myoclonus status	**Best motor response** 6 = obeying commands 5 = localizing to pain 4 = withdrawal from pain 3 = abnormal flexion response to pain 2 = extension response to pain 1 = none
Brainstem reflexes 4 = pupil and corneal reflexes present 3 = one pupil wide and fixed 2 = pupil or corneal reflexes absent 1 = pupil and corneal reflexes absent0 = absent pupil, corneal, and cough reflex	**Verbal response** 5 = orientated 4 = confused 3 = inappropriate words 2 = incomprehensible sounds 1 = none
Respiration 4 = not intubated, regular breathing pattern 3 = not intubated, Cheyne-Stokes breathing pattern 2 = not intubated, irregular breathing1 = breathes above the ventilator rate 0 = breathes at ventilator rate or apnea	**For children 2 to 5 Years** Appropriate words or phrases 6 Inappropriate words 5 Persistent cries and/or screams 4 Incomprehensible speech 3 Grunts 2 No response 1 For children 0 To 23 Months Smiles or coos appropriately 5 Cries and consolable 4 Persistent inappropriate crying &/or screaming 3 Grunts or is agitated or restless 2 No response 1

A reliable assessment of the intensity of coma relies on five variables that are examined for classification of the degree of injury: they are the state of consciousness, brainstem function, respiratory rate, size of the pupil and its reaction to light, movements of the eyes, ocular reflexes and motor assessment (Plum & Posner, 2007). The GCS only evaluates two variables and hence it does not detect the definitive level of coma. Low blood pressure, inadequate oxygen level in the body, and metabolic conditions lead to inaccurate GCS scores. In addition, the scoring is not an accurate measure of altered level of consciousness in those patients with intoxication. Intubation affects the overall score because the verbal response is not tested and the presence of inconsistencies in recording the scores by different hospitals, hence a decreased validity of the GCS.

On the other hand, the FOUR a new scoring system was developed to counteract the disadvantages of the GCS and provide the health care provider with more knowledge on the condition of the patient (Wijdicks, 2005). The FOUR Scale has significant advantages like detecting patients with locked-in syndrome, the start of a vigil coma, and the ability to assess patients on intubation (Wijdicks et al 2005). The two scales give clinicians and nurses in ICU significant information in evaluating and care to offer to clients. It is, therefore, necessary to study their advantages, accuracy, and validity.

Several studies have advocated for the use of the FOUR scale in the critical care units because of its reliability, although a few studies still support the fact that GCS is better and simple in the assessment of patients. According to a study conducted by Ramazani and Hosseini (2019), the two scoring systems demonstrated the required power of discrimination, but the FOUR had a better calibration, hence making it a superior tool to predict patient outcomes in the CCUs. Other studies showed high prediction power of results of traumatic brain injury patients.

In Gorji et al. (2014), the two scales had a high prediction power of patient end results on the time of discharge and they had an almost similar level of effectiveness in predicting in-hospital deaths. The results from the study showed that in the prediction of mortality and poor outcomes the GCS cut-off points were four and seven respectively and six for the FOUR in predicting poor outcomes. This was not in harmony with the studies by Avakist and Vijidic (2011), which suggested ten and fourteen for prediction of mortality and poor end results respectively for the FOUR score.

In a study conducted by Bakhtiari and Amiri, both scores were obtained on the day of admission, two weeks and follow-up done after a month to evaluate all patients' outcomes. The study concluded that the FOUR score is better at predicting mortality and neurological deficit rate.

In another study by Sancer conducted over a period of three months concluded that for hospital death the patient has to have a score of nine and five for the FOUR and GCS respectively. Vijidic suggested seven and nine scores for death in the hospital for GCS and FOUR respectively, this is in relation to various levels of injury of clients and heterogeneous samples chosen for the studies.

In another study, measuring the two scales on patients in the CCU in the first twenty-four hours found out that scores from both tools were less in nonsurvivors than in those who survived.   A score of 6.5 in the two tools was identified as the best by use of the Youden index. Any score of 6.5 and below is interpreted as a higher chance of death for these scales. Several other studies in the USA, Switzerland, Amsterdam, and Iran are in support of the FOUR scale as a more valid tool for assessment of critically ill patients and prediction of patient outcomes (Braksick et al, 2018, Van et al, 2019, Fischer, 2010 and Ghelichkani et al 2018).

2.4. Outcome predictions of patients using the GCS and FOUR scale

Several studies have been conducted globally comparing the accuracy in predicting end results using the GCS and the FOUR score. In Africa, only a few studies have been conducted and validated the use of the FOUR scale as being the better scale in CCU patient evaluation. A study by Bixia (2013), pointed out the limitations of GCS, which led to the different and continuous suggestions of modifying and coming up with other alternative scales such as; Edinburgh-2-coma scale, reaction level scale, comprehensive level of consciousness scale, and Innsbruck coma scale. The simplicity of the GCS has made it impossible for the introduction and use of other scales.

The same study revealed the FOUR was advantageous over the GCS in predicting mortality. There was a higher mortality rate of patients with a low FOUR score than those with a low GCS score. A range of FOUR score from 0-6 was observed for patients with a GCS of 3. Akavipat's study in 2011, 122 patients (40.1 %) had a poor outcome with a GCS of 3-5 and 12.5% of these patients died and 96% of patients with a FOUR score of more than 10 survived to the day of discharge. The founder of the FOUR scale, Wijdicks validated nine as the cutoff point for mortality on discharge. Generally, most studies have shown 14 as the cutoff point for poor outcomes and 10 as the in-hospital mortality cut off point.

In Africa, most studies have focused on the GCS but not on the FOUR scale. In Nigeria, a study by Amos (2012) complemented the GCS as a reliable tool and simple to learn, used in a variety of clinical setups. In spite of this, people still doubted its strengths on adequacy and flexibility, inter-rater reliability as shown by healthcare providers using the tool. There is a need for a scoring tool that facilitates the nursing care of critically ill patients in addition to it being accurate, precise, and simple to use. There is a vast difference in information from studies, a multicenter study by Wijdicks revealed that

the two scales don't differ in the prediction of mortality but the FOUR is an effective diagnostic for assessing brainstem reflexes and respiration.

A study conducted in Uganda on the comparison of the FOUR and GCS to the prediction of death in patients who have decreased LOC, found out that FOUR is compared to GCS in scoring clients and determining mortality. However, the study supported the use of FOUR score in practice to guide clinicians in managing clients with a decreased level of consciousness in Africa (Abdallah, 2019). Findings from several other studies have come to the conclusion that the FOUR scale is the best scoring system for providing end results inclusive of discharge and mortality amongst critically ill patients.

Rostam and Mansour's (2014) study on 104 patients revealed the sensitivity of the two scales being 68.4%, the specificity of GCS as 63.6%, and FOUR score as 77.3%, while the positive predictive power of GCS and FOUR score were 52% and 63.4% respectively. The negative predictive power was 77.8% in GCS and 81% for the FOUR score. The accuracy of the FOUR scale was 74% while the GCS was 65.4%. The similarity between FOUR and GCS on the client's result was 30% and the FOUR with patient outcomes was 44.9%. The similarity between GCS and FOUR was 43.8%.

In summary, most of the studies have revealed that both GCS and FOUR scores are significant in the prediction of outcomes in patients, but the FOUR is more reliable, superior, and convenient for prediction of outcomes of ICU patients. The FOUR scale is easy to apply with fewer requirements on the assessment of the nervous system in checking mental status and most importantly identifies some unconscious states. The new scoring system classifies coma and identifies relevant conditions in patients with altered level of consciousness, which enables further differentiation of in-ICU mortality

prediction for patients on admission with a low GCS. Since patients in ICU are on

intubation and sedation, the FOUR is therefore important and reliable to apply it in

assessing the comatose clients.

CHAPTER THREE: METHODOLOGY

3.1 Introduction

This chapter covers the study design with methods that were used in identifying study respondents, collecting and analyzing data in the study. They include study population, study area, eligibility criteria, data collection, sampling method, data collection tools and planned analysis, ethical clearance, and dissemination of the study results.

3.2 Study Design

The study adopted an analytical prospective study design to compare the GCS and FOUR scales in prediction of patient outcomes. The study focused on patients at the main, cardiac, and medical ICU of the Kenyatta National Hospital in April 2020. Data was collected using an observation checklist to determine the similarities and differences in the prediction of outcomes using the two assessment scales.

3.3 Study Site

The study was done at the Intensive care unit of Kenyatta National Hospital, which is the largest teaching and referral hospital in East and Central Africa. The Intensive care units of KNH were chosen because the assessment was to be done on critically ill patients. KNH is situated in Nairobi West Sub County, Nairobi County. The hospital offers specialized services as to both outpatient and inpatient care to patients from other counties within Kenya and also from neighboring countries like Namibia, Burundi, Rwanda, Tanzania, and Uganda.

It can accommodate 1800 patients, with over 6000 employees. It has various departments both inpatient and outpatient that include 50 inpatient wards, 22 out-patient consultation clinics, 24 fully equipped operating theatres, and the Accident & Emergency Department. The medical ICU is located on the 8th-floor and the 7th floor,

both with a bed capacity of 10, but 8 functional beds, though geographically separated they are treated as one department. The main ICU is located on the first floor with a 21-bed capacity and is opposite the burn's unit and renal department. The cardiac ICU is on the fourth floor with a bed capacity of five. The area was chosen because of its

3.4 Study Population

This study included patients in the main, cardiac, and medical critical care units of Kenyatta National Hospital. The target population included adult patients above the age of 16 years, admitted at main, cardiac, and medical ICU. The estimated number of patients admitted in all the three ICUs per month is 65; this is according to data retrieved from the KNH records office. A study sample was recruited from the population.

3.5 Inclusion-Exclusion Criteria

To qualify for the study, patients admitted were required to satisfy the following eligibility criteria:

3.5.1. Inclusion criteria

- Participants above 16 years of age in main, cardiac, neurological and medical ICU
- Admitted to the ICU for less than 48 hours
- Informed consent given by the next of kin

3.5.2 Exclusion criteria

- Patients with spinal cord injury because of paralysis of the limbs hence inability to assess the motor system appropriately.
- Patients heavily sedated or receiving neuromuscular blockers, this is because the drugs affects their response to stimuli and decreases the GCS and FOUR

scores.

3.6 Sample size calculation

The sample size calculation was guided by Fisher et al. method found in Mugenda and Mugenda (2004), calculated as follows:

$$n = \frac{Z^2 pq}{d^2}$$

Where:

n = desired sample size (where population >10,000).

Z = value representing area covering 95% of the population taken as 1.96.

p = since the level of validity of Glasgow coma scale and FOUR is not known, we will use 50% (0.5)

q= 0.5 (1-0.5)

d = margin of error of 5%

n = (1.96) 2 x 0.5 x 0.5

     (0.05)2

= 3.8416 x 0.5 x 0.5

    0.0025

=   0.9604

    0.0025   **= 384 Respondents**

Since the average admission number of patients in cardiac ICU, the multidisciplinary and medical ICU of Kenyatta national hospital is less than ten thousand (10,000). Yamane formula (1967) was used in sample adjustment.

nf =   n

1+ n/N

Defined as:

nf = the sample size for population <10,000

n= sample size when population is >10,000

N= estimated study population, in this study taken as 65 (Data from KNH Records Department)

nf = n/ (1+n/N)

= $\underline{384}$

  1+384/65

 nf = n/ (1+n/N)

= $\underline{384}$

  1+384/65

= **55 Respondents**

3.7 Sampling Technique

Census data collection method was employed to recruit a sample of 55 participants that met the inclusive criteria at the main, cardiac, and medical ICU in KNH. By involving all patients in the three ICUs, the study provided a true measure of the population with no sampling error. The census method was appropriate because the population was well defined and the number was manageable. The participants were recruited until the required sample size was attained.

3.8 Data Collection

3.8.1   Data collection instruments

A structured systematic observation checklist was adopted to obtain the required information. The observation checklist was organized into four sections: Part one had the demographic characteristics of patients. The second section contained the GCS

score to evaluate the level of consciousness of the participant according to the three components of the tool with a column of GCS scores on admission and the day of evaluation of outcomes if the patient was still alive.

The third section had the FOUR score tool with four parts, a column of FOUR scores on admission and the day of evaluation of outcomes if the patient was still alive. The fourth section had the patients' outcome at day fourteen, whether alive or dead, predicted outcome of the two scales and the length of ICU stay was noted.

3.8.2 Pretesting of the study instrument

Prior to conducting the study, the study tool was pretested to determine its validity. Pretesting of the tool involved five critically ill patients (10% of 55) at Gynecology CCU. This was done to ensure a proper flow of questions as well as correction of mistakes identified before the study commenced, to ascertain that the tool is accurate and reliable. There were no gaps were identified.

For validity; to ensure consistency and congruity to the identified gap, an observation checklist was designed to address the problem under investigation and presented to experts (research supervisor) in the Nursing department, critical care nurses, and a statistician who evaluated them for applicability in regards to the objective of the study. Their comments were assimilated accordingly to improve the efficacy of the tool.

The observation checklist was tested for consistency, accuracy, timing, and reliability. The results that were obtained from the tool ensured testability; the reliability of the instrument was estimated using Cronbach's Alpha Coefficient. A Cronbach's Alpha Coefficient of at least 0.70 was accepted.

3.9 Data Collection Procedures

An introduction was done to the head of department and unit in charges. The aim and objectives of the study were communicated. Recruitment of participants in the CCU commenced as soon as permission was granted.

3.9.1 Recruitment process

All participants meeting the inclusion criteria in the three units were recruited to attain a sample size of 55 participants by the researcher.

3.9.2 Consenting procedures

The researcher explained the aim of the study and the data collection process to the next of kin. Informed consent was then obtained from the next of kin, data then collected using the observation checklist.

3.10   Ethical Considerations

Approval to conduct this study was sought from KNH/UON ERC, the Kenyatta National Hospital Head of Department, and Unit in charges for ICU. Approval was granted on 30, July 2020 through a letter from KNH-UON ERC with a reference number of KNH-ERC/A/246.

Privacy and anonymity were observed, names and other means of identity were not used during the data collection process and analysis. The information obtained during the study was handled with high confidentiality, was only used for this study, and was accessible only to the researcher.

Beneficence; the next of kin was clearly informed that this study had no financial benefits and that the study intended to identify a tool that is reliable and beneficial to patients.

Non-maleficence; the researcher ensure that no damage was caused through omission of care and in case the next of kin opted out during the study. Their will was respected and no action whatsoever was taken against the respondent or the next of kin.

3.11   Data analysis and presentation

Data was analyzed using SPSS version 24. Categorical data was analyzed using percentages while continuous data was analyzed using standard deviation and mean. A chi-square test for association was conducted to determine the association between patient characteristics and outcomes. Chi- square test for association was also conducted to determine the association between the predicted GCS and FOUR score in relation to patient actual outcome at the end of evaluation.

The performance of the GCS and FOUR scores in predicting patient outcomes was analyzed using binary logistic regression. Survival analysis was performed using Kaplan Meier method. Sensitivity analysis was used to determine the reliability of GCS and FOUR scale in predicting actual outcome. The ROC curves were computed to assess the accuracy of GCS and FOUR scale based on area under the curve analysis. Calculation of cut off points was calculated and determination of overall accuracy of prediction of results, sensitivity, and specificity will be identified.

3.12 Quality Assurance

The principal investigator carried out the data collection exercise. In addition, a qualified statistician and critical care expert reviewed the questionnaire. The data collecting tool was adopted from standard tools used in the clinical area; the GCS and FOUR score. In addition, the questionnaire was detailed to ensure the collection of all relevant data. Pretesting of data collection tools was done before the actual data collection and there were no corrections made to the study tool. The respondent's next

of kin were assured of confidentiality and anonymity. Lastly, data was crosschecked for consistency and completeness before analysis.

3.13 Dissemination Plan

The researcher will disseminate the findings of the study to the college of health sciences, school of Nursing, University of Nairobi, and Kenyatta National Hospital. The results of this study will also be available at the University of Nairobi repository and will be published in a scientific peer-reviewed journal for reference.

3.14 Study Limitations

1. Because of the limited time to undertake the research, larger studies will be recommended to confirm these findings in Kenya.

2. Despite demonstrating high validity, the FOUR scale requires further prospective validation especially in different setups to confirm its predictive validity and its clinical effectiveness across various ICUs before it can replace GCS in Kenya.

3. Prior to endorsing the FOUR scale, both inter-rater and intra-rater reliabilities should be established across several contexts in Kenya.

CHAPTER FOUR: RESULTS

4.1 Introduction

This study was a prospective study, which sought to compare the performance of GCS with FOUR score in predicting patient outcomes in Intensive Care Unit (ICU) at Kenyatta National Hospital. Fifty-five respondents were observed and included in the analysis having been assessed and determined to include correct data thus representing a 100% response rate. Data was collected on the level of consciousness of the respondents using the GCS and FOUR scales. The survival and mortality rate as well as the reliability of the two scales was calculated in correctly predicting respondent's outcome. A pretest was done at the Gynecology ICU on five respondents, and no changes were made to the assessment tool.

4.2 Demographic characteristics of the Respondents

Assessment of the respondent's demographic characteristics showed that, 37 (67%) were male. The average age was 41±18 years, 29 (52.7%) of the respondents had secondary level education, 29 (52.7%) were self-employed as shown in Table 2.

Table 2: Demographic characteristics of the respondents

Variable		Frequency (n)	Percentage (%)
Gender	Male	37	67
	Female	18	33
Age	≤18 years	7	12.7
	19 – 30 years	10	18.2
	31 – 50 years	18	32.7
	>50 years	20	36.4
	Mean ±SD	41.2±18.8	
	Median (IQR)	38(25 – 55 years)	
Level of education	No formal education	7	12.7
	Primary education	6	10.9
	Secondary education	29	52.7
	Tertiary education	13	23.6
Occupation	Formal employment	5	9.1
	Self-employment	29	52.7
	Unemployed	12	21.8
	Student	8	14.5
	Others	1	1.8

4.3 Patient Medical Characteristics

The medical characteristics of the respondents were assessed. These included patient admission ward to ICU, time from referral to KNH, diagnosis, length of stay in ICU, whether the respondent was sedated or intubated. The findings revealed that, 30 (54.5%) of the respondents were admitted to the ICU from other facilities. Among the respondents who were referred to KNH, the median time was 24 hours while ranging within 17 and 48 hours. 28 (51%) respondents had head injuries while 15 (27.2%) had spinal cord injuries. The average length of stay was 10 days with an SD of ± 6 days, as shown in Table 3.

Table 3: Respondent's medical characteristics

Variable		Frequency (n)	Percentage (%)
Source of admission	A&E	15	27.3
	Referral from another facility	30	54.5
Time taken for referral cases to reach KNH	≤10 Hours	6	20.0
	11 - 24 Hours	9	30.0
	≥ 24 Hours	15	50.0
Diagnosis	Head injuries	28	51
	Hemorrhages	12	21.8
	Spinal cord injuries	2	3.6
	Others	13	23.6
Length of stay in ICU	≤2 Days	5	9.1
	3 - 14 Days	41	74.5
	>14 Days	9	16.4
	Mean ±SD	10±6	
Patient sedated	Yes	20	36
	No	35	64
Sedation duration	Median (IQR)	15 (8 – 24 hours)	
Patient intubated	Yes	27	49
	No	28	51

4.4 The Level of Consciousness obtained from the GCS and Four Score in the prediction of patient outcomes in ICU, KNH

The respondent's level of consciousness using both GCS and FOUR were assessed at admission, after 48 hours and after 14 days. The assessment was based on a cut-off of 6 for GCS and 9 for FOUR scale. A score of six and below for GCS is associated with a poor outcome while a score of 12 and above predicts a good outcome. While a score of nine and below for FOUR score predicts a poor outcome and a score of twelve and above predicts a good outcome.

Based on GCS scale, at admission, 22 (40%) of the respondents had a low level of consciousness less than 6, at 48 hours 21 (39%) and at 14 days, 14 (30%) had a low level of consciousness of less than 6. While at 14 days, respondents with a score of 12 and above were 18 (40%). In assessing the FOUR scale, at admission, 26 (47%) of the

respondents had a lower level of consciousness of 9 and below. At 48 hours 24 (45%) and at 14 days, 13 (28%) had a score of nine and below. While those with higher levels of consciousness of 12 and above at 14 days were, 24 (52%) as shown in Table 4.

Table 4: Level of consciousness among respondents using GCS and FOUR scales

Scale	Measurement Score	Level Consciousness at Admission (n =55) n (%)	Level Consciousness after 48 hours (n =53) n (%)	Level Consciousness after 14 days (n =46) n (%)
GCS	<6	22 (40)	21 (39)	14 (30%)
	6 – 12	19 (35)	18 (34)	14 (30)
	>12	14(25)	14 (27)	18 (40)
FOUR	< 9	26 (47)	24 (45)	13 (28)
	9 -12	11 (20)	13 (25)	9 (20)
	> 12	18 (33)	16 (30)	24 (52)

4.4.1 Predicted outcome at Admission and Actual Outcome at the end of Evaluation (14 Days)

The study also sought to compare predicted outcome at admission and actual outcome at the end of evaluation (14 days). The findings revealed that, FOUR score predicted 29 (53%) to die by the end of evaluation while GCS predicted, 33(60%) to die by the end of evaluation. The actual outcome at the end of evaluation found as shown in Table 5.

Table 5: Actual and predicted outcomes at the end of evaluation

Predicted Outcome at Admission	Alive n (%)	Died n (%)
FOUR score	26 (47%)	29(53%)
GCS	22(40%)	33(60%)
Actual outcome at the end of evaluation	19(35%)	36(65%)

4.4.2 Association between patient characteristics and outcome at the end of evaluation

The study also sought to determine the association between patient characteristics and outcome at the end of evaluation as shown in Table 6. The results found that length of stay, $x^2(2) = 10.583$, p =0.005, and patient intubation $x^2(1) = 10.354$, p =0.001 were significantly associated with patient outcome at the end of evaluation.

Table 6: Association between patient characteristics and outcome at the end of evaluation

| | | Patient Outcome | | | | | | |
		Death	Alive	Total	chi-square	df	p-	value
Age group of patients	<18 Years	3 (43%)	4(57%)	7				
	19 - 30 Years	4(40%)	6(60%)	10	1.302	3		1
	31 - 50 Years	7(39%)	11(61%)	18				
	>50 years	5(25%)	15(75%)	20				
Gender	Male	14(38%)	23(62%)	37	0.542	1		0.336
	Female	5(28%)	13(72%)	18				
Education	No formal education	2(29%)	5(71%)	7				
	Primary education	2(33%)	4(67%)	6	0.343	3		1
	Secondary education	11(38%)	18(62%)	29				
	Tertiary education	4(31%)	9(69%)	13				
Occupation	Formal employment	2(40%)	3(60%)	5				
	Self-employment	10(35%)	19(65%)	29	0.632	4		1
	Unemployed	4(33%)	8(67%)	12				
	Student	3(38%)	5(62%)	8				
	Others	0	1(100%)	1				
Source of admission	Other wards in KNH	2(13%)	13(87%)	15				
	A&E	13(43%)	17(57%)	30	4.141	2		0
	Referral from another facility	4(40%)	6(60%)	10				
Length of stay within the ICU	<2 Days	5(100%)	0	5				
	3 - 14 Days	12(29%)	29(71%)	41	10.583	2		0
	Above 14 Days	2(22%)	7(78%)	9				
Sedated	Yes	10(50%)	10(50%)	20	3.32	1		0.064
	No	9(26%)	26(74%)	35				
Patient intubated	Yes	15(56%)	12(44%)	27	10.354			0.001
	No	4(14%)	24(86%)	28				

4.4.3 Association between the predicted scale outcomes and actual patient outcomes at the end of evaluation.

A chi square test was conducted to determine the association between predicted scale outcomes and actual patient outcomes at the end of evaluation as shown in Table 7. The findings showed that there was association between predicted FOUR score at admission and actual patient outcome, $x^2(1) = 5.209$, p =0.022. However, there was no significant association between predicted GCS outcome at admission and actual patient outcome, $x^2(1) = 3.684$, p =0.055.

Table 7: Association between the predicted scale outcomes and actual patient outcomes at the end of evaluation

| | | Patient Outcome | | Total | chi square | df | p-value |
		Death	Alive				
Predicted	Died	9(52.9%)	8(47%)	17	3.684	1	0.055
Outcome at	Alive	10(26%)	28(74%)	38			
admission							
by GCS							
Predicted	Died	13 (50%)	13(50%)	26	5.209	1	0.022
FOUR	Alive	6(21%)	23(79%)	29			
outcomes at							
admission							

4.4.4. The relationship between predicted GCS outcome at admission and actual patient outcome

A binary logistic regression was conducted to determine whether predicted GCS outcome significantly predicts actual patient outcome. The model was not significant ($x^2(1) = 3.595$, $p = 0.058$,) yielding a small effect size (r = 0.063). Thus, thus the outcome as predicted by GCS at admission was not a significant predictor of actual patient outcome at the end of evaluation (after 14 days) as shown in Table 8.

Table 8: Relationship between predicted GCS outcome at admission and actual patient outcome

Omnibus Tests of Model Coefficients					Model Summary			
		Chi-square	df	Sig.	Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
Step 1	Step	3.595	1	0.058	1	67.310[a]	0.063	0.087
	Block	3.595	1	0.058	a. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.			
	Model	3.595	1	0.058				

Variables in the Equation								95% C.I.for OR	
		B	S.E.	Wald	df	P-value	OR	Lower	Upper
Step 1[a]	Predicted Outcome at admission by GCS	1.147	0.610	3.541	1	0.060	3.150	0.953	10.408
	Constant	-1.265	1.039	1.482	1	0.223	0.282		

a. Variable(s) entered on step 1: Predicted Outcome at admission by GCS.

4.4.5 The relationship between predicted FOUR score outcome at admission and actual patient outcome

A binary logistic regression was conducted to determine whether FOUR score predicted outcome at admission was a significant predictor of actual patient outcome at the end of evaluation as shown in Table 9. The model was significant ($x^2(1) = 5.292, p = 0.021,$) yielding a small effect size (r = 0.092). FOUR score at admission was found to be a significant predictor of actual patient outcome ($p = 0.026$, *OR*= 3.8, 95%*CI* [1.12.51]. The findings show that FOUR score at admission was 3.8 times more likely to predict an accurate actual outcome at the end of evaluation.

Table 9: Relationship between predicted FOUR score outcome at admission and actual patient outcome

Omnibus Tests of Model Coefficients					**Model Summary**			
		Chi-square	df	Sig.				
Step 1	Step	5.292	1	0.021	Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
	Block	5.292	1	0.021	1	65.613[a]	0.092	0.127
	Model	5.292	1	0.021	a. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.			

Variables in the Equation								
							95% C.I.for OR	
		B	S.E.	Wald	df	P-value	OR	Lower	Upper
Step 1[a]	Predicted FOUR outcomes at admission	1.344	0.603	4.961	1	0.026	3.833	1.175	12.506
	Constant	-1.344	0.909	2.187	1	0.139	0.261		

a. Variable(s) entered on step 1: Predicted FOUR outcomes at admission.

4.5 Survival Analysis

4.5.1 Mean and Median Survival Time

Kaplan Meier survival analysis was performed to determine the survival rate among patients who were included in the study within the study period (14 days). The mean estimate survival time was 13.98, 95% CI (12.82 – 15.14 days) median was 14 days, 95%CI (13.68 – 14.32 days) as shown in Table 10.

Table 10: Means and Medians for Survival Time

Mean[a]				Median			
		95% Confidence Interval				95% Confidence Interval	
Estimate	Std. Error	Lower Bound	Upper Bound	Estimate	Std. Error	Lower Bound	Upper Bound
13.976	.592	12.816	15.136	14.000	.164	13.678	14.322

4.5.2 Survival analysis curve

The results as shown in Figure 1 shows that, at admission (Zero days) all patients were alive, after 48 hours the results show that 100% of the patients were alive. The average median length of stay in the ICU was 14 days. At 14 days, the probability of survival was 50%. The analysis also shows that by the end of evaluation on day 14 approximately 65% of the respondents were alive.
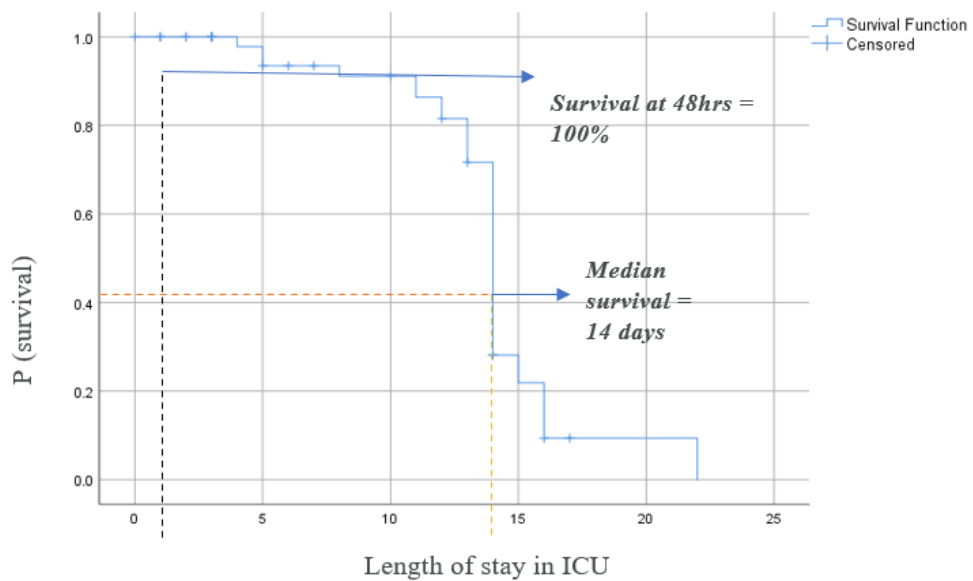
4.1 Figure 1: Respondents survival analysis

4.6 Reliability of the GCS and Four score in the prediction of patient outcomes

4.6.1. Receiver operating curve (ROC)

Receiver operating curves were constructed to help in assessing the accuracy of GCS and FOUR scale in predicting accurate outcome as shown in Figure 2. The ROC curves show that there was no significant difference in the predictive value between FOUR score and GCS in predicting patient outcome.
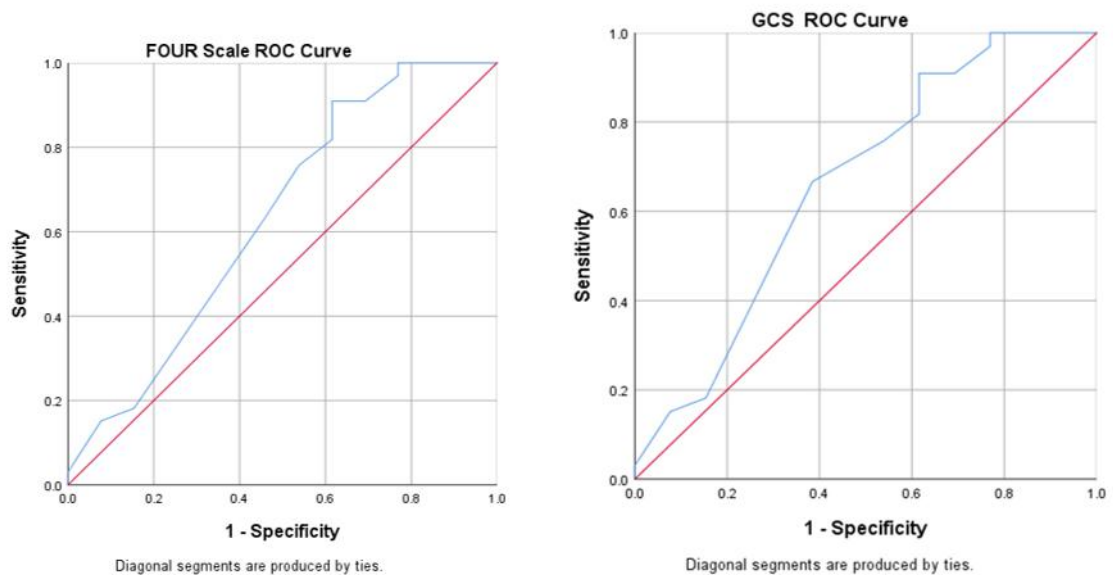
Figure 4.2: ROC curves for GCS and FOUR scales

4.6.2 Area under the curve

In assessing the predictive accuracy of the two scales, area under the curve (AUC) was identified as shown in Table 11. Thus, based on the findings, the predictive accuracy of FOUR scale was higher than GCS considering that the AUC for FOUR score was significantly higher (AUC= 0.761, 95%CI (0.439 – 0.827) than GCS (AUC = 0.633, 95% CI (0.471 – 0.850).

Table 11:Area under the curve for FOUR and GCS scales in the prediction of outcome

Area Under the Curve

	Test Result Variable(s): Length of stay in the ICU				
				Asymptotic 95% Confidence Interval	
	Area	Std. Error[s]	Asymptotic Sig.[b]	Lower Bound	Upper Bound
Scale					
FOUR	0.761	0.099	0.164	0.439	0.827
GCS	0.633	0.097	0.092	0.471	0.85
a. Under the nonparametric assumption					
b. Null hypothesis: true area = 0.5					

4.6.3 Sensitivity analysis

To determine the reliability of the two scales in effectively predicting outcomes, sensitivity analysis was conducted as shown in Table 5. The results show that both scales did not effectively predict the outcome at admission with FOUR score having a higher sensitivity of 68.4% while GCS had 47.8%. At 48 hours of admission, FOUR score was able to effectively and correctly predict patient outcomes with a sensitivity of 100% compared to the sensitivity of 58.8% shown by GCS scale. The FOUR score was also able to successfully predict a survival outcome at 14 days with a sensitivity of 100% compared to 98% obtained by GCS scale. This means that at 48 hours and 14 days of admission to the ICU, FOUR score was able to accurately predict a survival patient outcome, while the GCS predicting correctly at 14 days as shown in Table 12.

Table 12: Diagnostic values of GCS and FOUR scales for prediction of death

Scale	Cut-off	Period	Sensitivity	Specificity	PPV	NPV
GCS		At admission	47.4%	77.8%	52.9%	73.7%
	6.0		58.8%	91.7%	76.9%	82.5%
		After 48 hours	98%	91.7%	76.9%	100%
		After 14 days				
FOUR		At admission	68.4%	63.9%	50%	79.3%
	9.0		100%	80.6%	70.8%	100%
		After 48 hours	100%	91.7%	76.9%	78.3%
		After 14 days				

PPV – Positive predictive value, NPV – Negative predictive value, GCS – Glasgow Coma Scale

CHAPTER FIVE: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

In this chapter, there is a discussion of findings of this study while relating it to the overall aim of the study, which is to compare the performance of GCS and FOUR score scales in the prediction of patient outcomes in the Critical care units at KNH. Determination of the survival and mortality rates of critically ill patients and the reliability of the GCS and FOUR scales in prediction of patient outcomes. The findings of this study were discussed further, comparing them to other studies carried out elsewhere to identify the similarity and differences associated with the neurological scales.

5.2 Demographic Characteristics of the Patients

The research was conducted to compare the performance of GCS with FOUR score in the prediction of patient outcomes, on admission, at 48 hours and after 14 days. The findings revealed that more than half of the clients were male. This is related to their lifestyle which is likely to associate them with high risk of accidents or violence. In Kenya a large percentage of motorcyclists are men below the age of 40 years, who have an increased risk of injuries and crashes. From a study done in Naivasha, some factors increasing this risk are; interaction with traffic system since they ride together with motor vehicles and poor traffic law enforcement mechanisms in Kenya (Wilberforce et al, 2015).

A study on trauma in rural, Kenya done at Kijabe mission hospital, stated that the mean patient age was 31, with 77% being males. Mechanisms of injury included road traffic

accidents 52%, fall 22%, assaults 13% and burns 6%. The major injuries were fractures of the limbs, soft tissue injuries, injury to the head and hemothorax and pneumothorax.

The average age among the patients in the study was 41 years with an interquartile range of between 25 and 55 years. A study on the incidence and characteristics of injuries in Eldoret, Kenya revealed that of the total 1304 casualties registered, males were 71%, while females were 29%. The groups with the greatest risk were males and young adults of ages between 20 and 30 years. A retrospective analysis of 209 patients admitted at Consolata Hospital and diagnosed with head injury between January 2009 and December 2012. The median age was 30 years. Road traffic accidents, assault, and falls were the leading causes of head injury. Mean and standard deviation of patients' age was thirty nine years.

Half of the patients had secondary education as their highest level of education. This is explained by the fact that in Kenya, majority of the population has secondary level as the highest level of education attained. In a study by Cheloboi, 2018, almost all patients had secondary school level of education and below. While those that were unemployed were 38 %. This is the reason that most of the young male population ride motor cycles, hence are commonly involved in road traffic accidents, and end up as admissions in the critical care units. As this was the case with respondents in this study.

More than half of the patients, included in the study were mainly referral cases. This is mainly because Kenyatta national hospital is the biggest referral facility in Kenya. The hospital receives patients who need critical care services from the whole country as well as east African region. A study on Interhospital transfer of critically ill and injured patients into KNH indicated that most ICU admissions to the facility were transferred from other hospitals and had neurosurgical issues. (Kochi, 2013). In another study

majority of the patients were referrals and most of them had a low GCS at admission (Cheloboi, 2018).

The average length of stay in the ICU among patients included in the study was 10 days with a standard deviation of six days. The results also show that seventy four percent of the patients spent between three and fourteen days in the ICU. Mehmet T, Sengul, Samanci, Akkoc, (2018) study revealed that the average length of stay in ICU is ten days. The mean length of stay was not associated with mortality and survival of the respondents.

The results further show that thirty six percent of the patients were sedated with an average duration of sedation between eight to 24 hours. Forty nine percent of the patients included in the study were intubated. In a study by Aliakbar on sedation in trauma clients revealed that it can lead to a decrease in the scores of GCS and FOUR scales. However, the decrease was higher in the GCS than the FOUR score. The study also indicated that the withdrawal of the sedatives caused great changes in the scores on the level of consciousness in the clients in both scales although the changes were higher in the mean GCS score than the mean FOUR score. In accordance to the findings, the FOUR score is better than the GCS in measure the level of consciousness in patients receiving sedation. (Aliakbar , Hasan , & Ali, 2016).

Most patients had a diagnosis related to trauma with half of the patients with head injury and brain hemorrhages accounted for twenty-one percent while other conditions accounting for twenty three percent. Oduor, 2015 revealed that the common mechanisms of trauma were motorbike and motor vehicle accidents and falls from heights of 3 meters and above. Other diagnosis identified in the study were,

hypertension, diabetes, neurological and cardiovascular conditions (Wilberforce et al, 2015).

5.3. The level of consciousness of patients from GCS and FOUR score

The assessment of level of consciousness was performed comparing GCS and FOUR scales. The findings were assessed on three levels that included on admission, after 48 hours and after 14 days. At admission, the average GCS score was nine with a standard deviation of four, after 48 hours the average score was still nine with a standard deviation of four. However, at the end of evaluation, the average score was 10 with a standard deviation of five. Several studies The GCS scores are decreased by the inability to evaluate the client's verbal response, respiratory pattern and brainstem reflexes. This leads to inappropriate interpretation of the client's status. An alternative scale the FOUR score was developed to cater for the mishaps of the GCS and the findings of this study revealed that it is more reliable and simple to implement.(Aliakbar et al 2016).

The average score for FOUR scale at admission was 10 having a standard deviation of four, at 48 hours, the average score was 10.7 with a standard deviation of 4.5. The level of consciousness at 14 days was 11.3 score with a standard deviation of five. In Akavipat, 2011, study, ninety-six percent of patients with a FOUR score of ten and above survived till discharge. The cut-off points for a poor outcome were 14 and in hospital mortality was 10. Respondents with a FOUR score of below eleven had twice the chance of death in a comparison to compared to those with the score of twelve and above. Those with a GCS score of below eight had a two point seven chance for dying in a month in comparison to of nine and above (Abdallah, 2019).

5.4 Survival analysis

Survival and mortality rate were assessed at the end of the study; majority of the respondents were still alive at the end of evaluation. When comparing the findings to the GCS and FOUR scale findings, GCS predicted a sixty percent mortality rate and forty percent survival rate. The FOUR scale at the end of intervention predicted equal deaths and survival with GCS score.

At admission, the two scales could not predict accurately the outcome, although FOUR scale had a higher degree of success with sixty eight percent sensitivity in predicting survival compared to forty eight percent on GCS score. This hence showed that the FOUR score is more reliable than the GCS.

After 48 hours, FOUR scale had one hundred percent sensitivity in predicting survival compared to fifty eight percent shown by GCS scale. At the end of evaluation, FOUR score had 100% sensitivity in predicting survival compared to GCS, which had 98% sensitivity in predicting survival. Hence, the two scales are reliable for prediction of patient outcomes, with the FOUR score having a higher sensitivity and more reliable for ICU patients.

When comparing this to other studies; Rostam and Mansour's (2014) study on 104 patients revealed the sensitivity of the two scales being 68.4%, the specificity of GCS as 63.6% and FOUR score as 77.3%, while the positive predictive power of GCS and FOUR score were 52% and 63.4% respectively. In line with this study, within the first forty eight hours of admission the tools did not predict the correct outcome. This could be associated to the fact that some of the patients were sedated and on analgesics that affected their response to the assessment.

The results of Gujjar et al. 2018 study revealed that FOUR score is superior to GCS in assessment of changes of changes in level of consciousness of patients in the hospital wards. Nair et al. (2017) revealed that a statistically difference existed between FOUR score and GCS in evaluating the severity of head injuries. Similarly, a study by Gujjar et al. (2013) evaluating FOUR score and GCS on patients in the course of the first three days of admission concluded that there is no notable difference in the scale's mean scores on the second and third day between the dead and live patients. However, a notable difference existed on the first day of assessment (Ghelichkhani et al., 2018). The two tools have almost similar predictive power and are both useful tools in neurological assessment of critically ill patients.

Though most studies have shown the higher sensitivity of the FOUR score, a few studies dispute these findings. Atahar et al. (2017) study showed that there is a similar prediction rate for in-hospital mortality of the GCS and FOUR scales. Similarly, to the findings of this study, some other studies like the Temiz et al. (2016) study, over a period of one year on forty-seven clients showed that the GCS and FOUR score have the same prediction value of the level of consciousness evaluation and follow up of client's status in neurosurgical CCU.

5.5 Conclusion

The study revealed that both scales were able to predict patient outcome with different accuracy and sensitivity rates. The GCS had a low predicting power especially in the early hours of admission but sensitivity increased as time went by. The FOUR score has proved to be a more reliable tool in patient assessment because of its high sensitivity and prediction power. In summary, most of the studies have revealed that both GCS and FOUR scores are significant in the prediction of outcomes in patients, but the

FOUR is more reliable, superior and convenient for prediction of outcomes of ICU patients.

The FOUR scale is easy to apply with fewer requirements on the assessment of the nervous system in checking mental status and most importantly identifies some unconscious states. The new scoring system classifies coma and identifies relevant conditions in patients with altered level of consciousness, which allows additional distinction of in-CCU mortality prediction for clients on admission with a low GCS. Since patients in ICU are on intubation and sedation, the FOUR is therefore important and reliable to apply it in assessing the comatose clients. The two tools were able to predict the survival analysis of the respondents fairly well with a small difference between the predicted and actual survival status. This hence shows that the GCS and FOUR score good predictors of patient outcomes in ICU patients.

5.6 Recommendations

The following recommendations were made based on the results:

1. Using larger sample sizes and studying different centers may yield more reliable and valuable results.

2. Different members of the healthcare team should do follow up studies to improve the inter rater reliability.

3. A larger study should be done and all patients followed up until discharge or death for more reliable results. Though the GCS and FOUR scales were both able to predict patient outcomes, further studies are necessary to ascertain which tool is more reliable and specific for use in critically ill patients in ICU.

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APPENDICES

APPENDIX I: OBSERVATION CHECKLIST

A COMPARISON OF THE GLASGOW COMA SCALE WITH FULL OUTLINE OF UNRESPONSIVENESS SCALE IN PREDICTION OF PATIENT OUTCOMES IN THE CRITICAL CARE UNIT AT KNH

[FILL ALL SECTIONS]

Department   Main ICU ☐   Medical ICU ☐   Cardiac ICU ☐

Study number……………………   Date of study …………………….

Diagnosis……………………………………………………………………………….

Date of admission……………….   Date of discharge/death……………

SECTION I: DEMOGRAPHIC AND MEDICAL CHARACTERISTICS

1. Age in years………………………..

2. Gender (Tick one)

    a. Male   ☐

    b. Female   ☐

3. Education (tick one)

    a. No formal education ☐

    b. Primary   ☐

    c. Secondary   ☐

    d. Tertiary   ☐

4. Occupation (tick one)

      a. Formal employment   ☐

      b. Self-employment   ☐

      c. Unemployed   ☐

      d. Student   ☐

      e. Others   ☐

5. Admitted to ICU from (Tick one)

      a. Other wards in KNH   ☐

      b. A&E   ☐

      c. Referral from another facility   ☐

6. Time in hours from referral to KNH Casualty……………..

7. Duration in hours spent in Casualty/ Ward…………............

8. Length of stay in ICU in days……………………………

9. Is the patient sedated (Tick one)

    Yes   ☐

    No   ☐

10. If yes for how long (number of hours)_____

11. Is the patient intubated (Tick one)

    Yes   ☐

    No   ☐

SECTION II: <u>GLASGOW COMA SCALE</u>

Glasgow Coma Scale	Score on admission	Score at 48 hours	Score on day of evaluation (If alive)
Eye-opening			
4 = spontaneous			
3 = to speech			
2 = to pain 1 = none			
Best motor response			
6 = Obeying commands			
5 = Localizing to pain			
4 = Withdrawal from pain			
3 = Abnormal flexion response to pain			
2 = Extension response to pain			
1 = None			
Best Verbal response			
5 = Oriented			
4 = Confused			
3 = Inappropriate words			
2 = Incomprehensible sounds			
1 = None			
GCS SCORE			

SECTION III: <u>FULL OUTLINE OF UNRESPONSIVENESS</u>

FULL OUTLINE OF UNRESPONSIVENESS SCALE			
	Scores on admission	**At 48 hours**	**Score on day of evaluation (If alive)**
Eye response 4 = Eyelids open or opened, tracking, or blinking to command 3 = Eyelids open but not tracking 2 = Eyelids closed, but open to a loud voice 1 = Eyelids closed, but open to pain 0 = Eyelids remain closed with pain			
Motor response 4 = Thumbs-up, fist, or peace sign 3 = Localizing to pain 2 = Flexion response to pain 1 = Extension response to pain 0 = No response to pain or generalized myoclonus status			
Brainstem reflexes 4 = Pupil and corneal reflexes present 3 = One pupil wide and fixed 2 = Pupil or corneal reflexes absent 1 = Pupil and corneal reflexes absent 0 = Absent pupil, corneal and cough reflex			
Respiration 4 = Not intubated, regular breathing pattern 3 = Not intubated, Cheyne-Stokes breathing pattern 2 = Not intubated, irregular breathing 1 = Breathes above the ventilator rate 0 = Breathes at ventilator rate or apnea			
FOUR score			

SECTION IV: PATIENT OUTCOMES

Patient outcome (tick one)

        a. Alive ☐   b. Death ☐

Predicted outcome by **GCS**   (Tick one)

        a. Alive ☐   b. Death ☐

Predicted outcome by **FOUR scale** (Tick one)

        a. Alive ☐   b. Death ☐

APPENDIX II: CONSENT FORM

STUDY TITLE: A COMPARISON OF THE GLASGOW COMA SCALE WITH FULL OUTLINE OF UNRESPONSIVENESS SCALE IN PREDICTION OF PATIENT OUTCOMES IN THE CRITICAL CARE UNIT AT KENYATTA NATIONAL HOSPITAL

Introduction to study and researcher

My name is Abira Delilah, a student at the University of Nairobi pursuing a Master of Science degree in Critical care nursing. I'm conducting a study to compare the Glasgow coma scale with a Full outline of unresponsiveness scale in the prediction of patient outcome in ICU, KNH.

To complete this study, I request your permission to collect data from your relative through observation and assessment of her/him. The patient's level of consciousness will be assessed by the two tools and their scores filled in a checklist and evaluation of the outcome will be done on the fourteenth day of their admission.

Confidentiality

All the information retrieved from the patient will be highly confidential and will not be shared with anyone. No name will be indicated on any observation checklist to ensure the information remains anonymous. An identification number only known to the researcher will be allocated for the accountability of the observation checklist administered.

Your Rights

You have a right to voluntarily agree without coercion for your relative to participate in this study or withdraw at any point in the study without any penalization. The provision of services in the unit will not be affected in case you decide your next of kin

not to participate in this study. Kindly note that no monetary benefits will be availed for participating in this study.

Benefits and risks of the study

Identification of the difference between the reliability and validity of the Glasgow coma scale and FOUR score in predicting patient outcomes. The policymakers will be informed of the results of this study to consider having training programs on the use of FOUR score in the assessment of critically ill patients in ICU. The study findings will also be referred to in future research in related studies. This study does not involve any invasive procedures and may not have any physical risks.

Duration of the study

The assessment will take approximately 20 minutes and the researcher and research assistants will be performing the study. There will be follow up on the fourteenth day to observe the patient outcome and compare it with the predicted outcome on the day of study.

Contact information

For any clarifications concerning this study, feel free to contact:

Principal researcher: Delilah Abira   Mobile number: 0726546752

Email address: dellabira@gmail.com

Supervisor: Dr. Maina,   Mobile number: 0724440843

Email address: mainad@uonbi.ac.ke

OR

KNH-UON ERC: Tel number, +254-020-2726300   Extension   44355

Email address: uonknh_erc@uonbi.ac.ke

Consent form

This is a declaration that the details of this study have been explained to me and I agree that my relative participate in the study. I hereby give my consent to allow my relative to be examined.

Participants' next of kin signature/ thumb mark

_____Date_____

Researchers' signature _____Date

_____

APPENDIX III: FOMU YA IDHINI

TITI YA KUJIFUNZA: ULINGANISHAJI WA GLASGOW COMA SCALE NA FULL OUTLINE OF UNRESPONSIVENESS SCALE KWA UCHAMBUZI WA MATOKEO YA WAGONJWA KATIKA SEHEMU YA UTUNZAJI MKUBWA KATIKA HOSPITALI KUU YA KENYATTA.

Utangulizi wa utafiti wa masomo

Jina langu ni Abira Delilah, mwanafunzi katika chuo kikuu cha Nairobi kufuatilia shahada ya sayansi katika uuguzi wa utunzaji muhimu. Ninafanya utafiti kulinganisha Glasgow coma scale na Full outline of unresponsiveness scale katika utabiri wa matokeo ya mgonjwa huku ICU, KNH. Kukamilisha utafiti huu, naomba ruhusayako kukusanya data kutoka kwa jamaa yako kupitia uchunguzi na tathmini yake. Kiwango cha ufahamu wa mgonjwa kitapimwa na vifaa hivyo viwili na alama zao zitajazwa katika orodha ya ukaguzi na tathmini ya matokeo itafanywa siku ya kumi na nne baada ya kuandikishwa kwao.

Usiri

Habari yote iliyohifadhiwa kutoka kwa mgonjwa itakuwa ya siri sana na haitashirikiwa na mtu yeyote. Hakuna jina litaonyeshwa kwenye orodha yoyote ya uchunguzi ili kuhakikisha kuwa habari hiyo haijulikani. Nambari ya utambulisho inayojulikana tu na mtafiti itatengwa kwa uwajibikaji wa orodha ya ukaguzi itakayopeanwa.

Haki zako

Una haki ya kukubaliana kwa hiari bila kulazimishwa kwa jamaa yako kushiriki kwenye utafitihuu au kujiondoa katika hatua yoyote ya utafiti huu bila adhabu yoyote. Utoaji wa huduma kwa jamaa yako haitaathiriwa ikiwa utaamua hatashiriki katika

utafiti huu. Kumbuka hakuna faida za kifedha zitakazopeanwa kwa kushiriki katika utafiti huu.

Faida na hatari za utafiti

Utambulisho wa tofauti kati ya uegemezi na uhalali kati ya of Glasgow coma scale na FOUR score katika utabiri wa matokeo ya mgonjwa utafanywa. Watunga sera wataarifiwa kuhusu matokeo ya utafiti huu kuzingatia kuwa na ratibu za mafunzo juu ya matumizi ya FOUR score katika tathmini ya wagonjwa wanaougua sana katika sehemu kubwa ya utunzaji. Matokeo ya utafiti huu pia yatatajwa katika tafiti zijazo zatafiti zinazohusiana. Utafiti huu hauhusiani na mifumo yoyote ya uvamizi na haina hatari zozote za kimwili.

Muda wa utafiti

Tathmini nii itachukua takriban dakika ishirini na mimi kama mpelelezi mkuu nitakuwa nikifanya uchunguzi huo. Kutakuwa na ufuatiliaji siku ya kumi na nne ili kuona matokeo ya mgonjwa na kulinganisha na matokeo yaliyotabiriwa siku ya masomo.

Nambari ya mawasiliano

 Kwa ufafanuzi wowote kuhusu utafiti huu, jisikie huru kuwasiliana na:

Mtafiti mkuu: Delilah Abira, Nambari ya rununu: 0726546752

                                        Barua pepe: dellabira@gmail.com

                              AU

Msimamizi wa utafiti: Dk. Maina,   Nambari ya rununu 0724440843

                    Barua pepe: mainad@uonbi.ac.ke

                              AU

KNH-UON ERC: Nambari ya simu, +254-020-2726300   Ugani wa simu   44355

                    Barua pepe: uonknh_erc@uonbi.ac.ke

Idhini

Hii ni tamko kwamba maelezo ya utafiti huu nimeelezewa na ninakubali kwamba jamaa yangu ashiriki katika utafiti huu. Kwa hivyo ninatoa idhini yangu kumruhusu jamaa yangu achunguzwe.

Saini ya ndugu au jamaa wa mshiriki / alama ya

kidole_____   Tarehe_____

Saini ya

mtatifi_____Tarehe_____

APPENDIX IV: WORK PLAN

ACTIVITY	DECEMBER 2019 TO FEBRUARY 2020		MARCH TO JUNE 2020	JULY-SEP 2020	OCT TO DEC 2020
PROPOSAL WRITE UP	███	███			
APPROVAL OF PROPOSAL			███		
DATA COLLECTION				███	
DATA ANALYSIS				███	
FINAL WRITE UP, PRINTING & DISSEMINATION OF FINDINGS					███

APPENDIX V: BUDGET

ITEM	QUANTITY	UNIT PRICE	AMOUNT
STATIONERY			
Laptop	1	44,000	44,000
Printing papers	4 Reams	500	2,000
Printer	1	10,000	10,000
Pencils	2	20	40
Rubber	1	20	20
Ball pens	3	20	60
PERSONNEL			
Typing and data entry	3 days	2,000	6,000
Research assistants	14 days	1000	14000
Statistical fee		15,000	15,000
PRODUCTION COST			
Binding & printing			4,000
Ethical review fee	1	500	500
Subtotal			95,620
Contingency (10% of the total cost.)			9,562
TOTAL			**105,182**

APPENDIX VI: KNH-UON APPROVAL LETTER

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/246

30th   July   2020

Delilah Kwamboka Abira
Reg. No.H56/11310/2018
School of Nursing Sciences
College of Health Sciences
University of Nairobi

APPROVED
3 0 JUL 2020
KNH/UoN-ERC

Dear Delilah

RESEARCH PROPOSAL – A COMPARATIVE OF THE GLASGOW COMA SCALE WITH FULL OUTLINE OF UNRESPONSIVENESS SCALE IN PREDICTION OF PATIENT OUTCOMES IN THE CRITICAL CARE UNIT AT KENYATTA NATIONAL HOSPITAL (P93/02/2020)

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 30th July 2020 – 29th July 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. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study.
   This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Protect to discover

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APPENDIX VII: STUDY REGISTRATION CERTIFICATE

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
   ABIGA KWAMBOKA DELILAH

2. Email address: ...delilahawg@gmail.com...   Tel No. ...0736 546 752...

3. Contact person (if different from PI)..........N/A

4. Email address: ....N/A...............   Tel No. ....

5. Study Title
   A COMPARATIVE OF THE GLASGOW COMA SCORE & THE FULL OUTLINE OF
   UNRESPONSIVENESS SCALE IN PREDICTION OF PATIENT OUTCOMES IN
   THE CRITICAL CARE UNIT AT KENYATTA NATIONAL HOSPITAL

6. Department where the study will be conducted ......CRITICAL CARE UNIT..........
   (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. Momanyi............... Signature .... Date 07/09/2020

9. KNH UoN Ethics Research Committee approved study number __P93/02/2020__
   (Please attach copy of ERC approval)

10. I __ABIGA KWAMBOKA DELILAH__ commit to submit a report of my study
    findings to the Department where the study will be conducted and to the Department of Medical
    Research.

    Signature................................. Date ....

11. Study Registration number (Dept/Number/Year)__KNH CCU__ / 131 / 2020
    (To be completed by Medical Research Department)

12. Research and Program Stamp _____
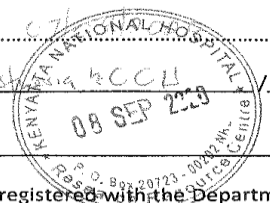
All studies conducted at Kenyatta National Hospital **must** be registered with the Department of Medical
Research and investigators **must commit** to share results with the hospital.

Version 2: August 2014

APPENDIX VIII: KNH CCU STATISTICS FROM RECORDS OFFICE

WARD CCU IN-PATIENT STATISTICS - JAN TO DEC 2019

	Admissions	Discharges	Deaths	% Occupancy	ALOS	Death Rate
JAN	76	40	35	97.2	8.4	46.7
FEB	84	59	29	90.3	6.0	33.0
MAR	83	36	50	90.5	6.8	58.1
APRIL	81	44	38	95.2	7.3	46.3
MAY	67	37	28	95.5	9.6	43.1
JUNE	65	43	24	96.2	9.0	35.8
JULY	56	37	23	95.2	10.3	38.3
AUG	55	27	28	97.2	11.5	50.9
SEPT	44	26	18	97.8	14.0	40.9
OCT	55	30	23	97.5	12.0	43.4
NOV	70	37	35	96.5	8.4	48.6
DEC	54	29	24	95.2	11.7	45.3
TOTAL	790	445	355	95.4	9.0	44.3

KEY
ALOS - Average Length of Stay
For % Bed Occupancy ; ALOS and Death Rates the figures in the total column are averages for
the entire duration.
Prepared by Health Information Services
02/01/2020