UTILITY OF TRIAGE EARLY WARNING SCORES IN THE CARE OF CRITICALLY ILL SURGICAL PATIENTS AT KENYATTA NATIONAL HOSPITAL

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STUDENT'S DECLARATION

I hereby declare that, this thesis to be my original work and it has not been submitted to any institution for examination or otherwise.

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DEDICATION

To my late mother Teresia Wanjiru, for believing in me always, inspiring me to go beyond my comfort and limits. You got me to “eat the frog “.

To my father Benson Mutahi for the unending support and encouragement.

To my sister MaryAnn and brother Victor; you had my back, we went through it all together.

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LIST OF ABBREVIATIONS

KNH-	Kenyatta National Hospital
ICU-	Intensive Care Unit
CCU-	Critical Care Unit
HDU-	High Dependency Unit
A&E-	Accident and Emergency
SATS-	South African Triage Scale
TEWS-	Triage Early Warning Score
EWS-	Early Warning Score
MEWS-	Modified Early Warning Score
PARS-	Patient at Risk Score
BP-	Blood Pressure

DEFINITION OF OPERATIONAL TERMS

Critical events: In this study critical events were defined as unplanned ICU/HDU admission and cardiac arrest- with or without successful resuscitation.

Critical illness: A disease or state in which death is possible or imminent

Surgical patient: The American college of surgeons defines surgery as part of the practice of medicine that involves structurally altering the human body by incision and destruction of tissue, as well as diagnostic or therapeutic treatment of conditions or disease processes, by any instruments causing localized alteration or transportation of live human tissue, which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles.

Thus a surgical patient is one requiring any surgical intervention to investigate or treat a pathological condition such as disease or injury.

Paediatric patient: The children act of the Kenyan law defines a child as that who is under 18 years of age. The definition of paediatrics is the branch of medicine that deals with care of infants, children and adolescents. In this study, the cut-off age employed at KNH for paediatric patients is 12 years, thus surgical patients above 12 years are admitted to the adult surgical wards in KNH.

Polytrauma: Injuries to two or more organ systems that might be life threatening.

ABSTRACT

Background

Critical illness is a life-threatening condition involving one or more organ systems resulting in significant morbidity or mortality. Often, it is preceded by a period of physiological deterioration. Such early signs of critical illness are frequently missed, leading to late recognition by clinicians with consequent worsening morbidity and mortality. In such patients, ICU mortality has been estimated to be at 8-18%. Tools have been invented to capture such patients and prevent these outcomes by early intervention. Such tools include, Modified Early Warning Score, National Early Warning Score; and Triage Early Warning Score.

The general wards at KNH do not have a decision support tool to help identify and manage acutely deteriorating patients. Therefore, the ward care of patients with critical illness is suboptimal.

Objectives

The broad objective was to establish the appropriateness of care level of critically ill surgical patients using the triage early warning score in KNH. Specifically, the intentions were to: identify critically ill surgical patients using the triage early warning score tool in KNH A&E, establish a relationship between the triage early warning score and outcome of critically ill surgical patients after 72 hours of follow up; and determine the specificity and sensitivity of the cut off values of the triage early warning scores at KNH.

Methods

This was a prospective observational study involving 168 critically ill surgical patients who were followed up for 72 hours following recruitment. 4 hourly vitals, decisions regarding intervention, level of care and clinical outcomes were recorded. A relationship between the TEWS and clinical outcomes was established using logistic regression, while the specificity and the sensitivity of the cut-off score for the TEWS were established using the receivership operating characteristics curve.

Results

94 % of the cases presenting to KNH were due to trauma, while 6% were non traumatic cases. The most common score was 5 and the highest score recorded was 11. After 72 hours of follow up, 4.23% (7) had unplanned ICU admission and their average TEWS was 7.71, while 6.67% (11)

patients had died and their average TEWS was 7.55. The odds ratio for bad outcome (death and unplanned ICU admission) was 7.708 (95% CI 3.48-17.073). The TEWS was found to have good sensitivity at identifying patients at risk of adverse outcome, with cut off values of 6.5 and 7.5 for prediction of mortality and ICU admission respectively.

Conclusion

ICU strain and the burden of trauma pose a significant challenge at KNH. Based on our findings, the TEWS is a sensitive tool for predicting risk for unplanned ICU admission and death. Timely identification and action for patients at risk of deterioration using the TEWS may reduce adverse events and outcomes. However, since the TEWS is a modification of the Modified Early Warning Score, it may over-triage patients, due to addition of the immobility component.

1.0: INTRODUCTION

Data on burden of critical illness in Africa is quite limited. Studies from developed countries indicate that the ICU mortality was between 8-18%[1]. The reasons for this included; delay by clinicians in recognizing critical illness until organ dysfunction had occurred, the paucity of effective specific treatments for diverse critical illness syndromes and finally the variability in severity of critical illness as well as variability in comorbidities and baseline risk of mortality.

The ward care of critically ill patients is sub-optimal and failure to respond early to deteriorating patients leads to increased morbidity and mortality, as well as increased admission to ICU. According to Goldhill et al. 1999, as many as 80% of ward patients have physiological parameters outside normal ranges within the 24 hours preceding ICU admission.

Deaths occurring after the onset of physiological derangements have been attributed to lack of observations, deficiencies in documentation of observations, failure in recognition of early signs of deterioration and poor communication between healthcare providers.[2, 3]

Early recognition of the changes in the vital parameters would decrease the critical events, especially admission to critical care units in resource limited centers, whereby provision of optimum critical care is constrained.[4,5, 6]

1.1 Pattern of Deterioration among Acutely Ill Patients

Studies have shown that in the hours preceding critical events such as cardiac arrest and admission to critical care units, derangements occur in physiological parameters.

In 1990, Schein et al reviewed patients with pathological derangements in their physiological parameters in the hours preceding cardiac arrest in the general ward. They found that 84% of patients had documented observation of deterioration in physiological status up to 8 hours prior to cardiac arrest, with 70% of those patients having changes in respiratory rate as well as changes in neurological function.[7] Significant changes were also seen in metabolic parameters and cardiovascular system parameters (systolic and diastolic blood pressure and heart rate). However, routine laboratory parameters had no consistent changes.[8]

In 1999, Buist et al reviewed records of patients that had had critical events over a 12 month period. They found that 122 critical events had occurred in 112 patients, with more than half of the events involving unplanned ICU admission (79 events), while the remaining 43 events were cardiac arrests. The death rate in those patients with critical events was significantly higher (62%), as compared to a 2% death rate among other hospital admissions.[9]

Goldhill et al also studied a group of 433 patients in 2004 and found that the most common abnormal physiological reading among acutely deteriorating patients was respiratory rate and heart rate. Logistic regression further showed the odds ratio for mortality increased with further deterioration of the deranged physiological parameters.[10]

A follow up study demonstrated that mortality rate increased for patients with more than one abnormal physiological reading. [11]

An American study of 1 million patients was able to show that patients with three simultaneous critical vital signs reading during hospitalization had a mortality rate of 15% at 7 days and it increased to 35% by day 30.[12]

In Kenya, a retrospective study on characterization of in hospital cardiac arrests at a tertiary facility found that derangements in physiological parameters occurred up to 4 hours before cardiac arrest.[13]

1.2 Relationship between Physiological Parameters and Patient Outcome

The value of patient monitoring has been demonstrated, with evidence of increased risk for severe adverse events (unplanned ICU admission, cardiac arrest or death) among patients with derangements in their physiological parameters

In a 2006 study using the modified early warning score (MEWS), a review of 334 cases found that 17% of that population had triggered the call out algorithm for review, with 5% of them having unplanned ICU admission.[14]

In a similar study involving the MEWS in the USA, it was found that patients admitted to ICU had higher scores than those admitted to the general wards. Similarly, patients who died also had higher mean, maximum and median scores than those who survived.[15]

A prospective observational study of patients with suspected infection (as evidenced by fever) presenting through the emergency room was done. Vital signs were recorded every 30 minutes for the first 3 hours, and after 72 hours of follow up it was found that the patients with the most deranged vital signs (heart rate, mean arterial blood pressure and respiratory rate) either suffered; acute kidney injury, respiratory failure, unplanned ICU admission or death.[16]

By using the APCHE II score (acute physiology and chronic health evaluation) for emergency surgical patients, it was demonstrated that patients with a higher score at admission received timely intervention and the scores significantly reduced by the 7th and 10th day after treatment. However, patients with a much higher APACHE II score that ended up being admitted to ICU had poorer outcomes which were described as prolonged admission in the ICU and death. [17]

1.3 Prevention of Patient Deterioration

Dating as far back as world wars 1 and 2, a system known as triage was invented to classify the sick and wounded soldiers into categories depending on the severity of illness or injury. It was used to prioritise the soldiers and provide timely management in mass casualty situations. Various tools have since been invented and modified based on it.

Standard tools have been invented and implemented to monitor patients' physiological status, and to communicate accurately between different cadres attending to patients. The use of these tools coupled to clinical judgment has led to timely intervention with consequent reduction in severe adverse outcomes such as emergency admission to the ICU, or cardiac arrest. [18,19]

Such tools include but are not limited to: the modified early warning score (MEWS), the national early warning score (NEWS), BioSign, the south African triage scale (SATS) and the paediatric early warning score (PEWS).

2.0 : LITERATURE REVIEW

In the hours preceding critical events such as unplanned critical care admission and cardiac arrests, patients have deranged vital signs and abnormal laboratory findings.[8,20,9]

Deaths occurring after the onset of physiological derangements have been attributed to lack of observations, deficiencies in documentation of observations, failure in recognition of early signs of deterioration and poor communication between healthcare providers.[2, 3]

Early recognition of the changes in the vital parameters would decrease the critical events, especially admission to critical care units in resource limited centers, whereby provision of optimum critical care is constrained.[4,5, 6.]

2.1 Burden of Disease of Critical illness

Data describing the global burden of critical illness worldwide is scarce owing to the fact that it is not possible to diagnose critical illness syndromes using one single test, unlike other diseases like malaria and HIV whose global burden of disease are known.[1,21] Also, critical illness syndromes when compared to known chronic diseases like TB, have a short prodrome with high short term mortality rates in ICU resource limited facilities.

An estimate was done on global burden of critical illness, with deaths from critical illness in resource limited regions such as sub-Saharan Africa estimated to be 11,662,000 in a population of 749,269,000.[1] However, a follow up study found that data on critical illness burden was still scarce.[22]

2.1.1 Cost of Critical Care

On average, the cost of critical care is high. Few studies have been able to give rough estimates, mostly on the consumption of drugs used for sedation and analgesia, as well as neuromuscular blockers during mechanical ventilation. Cheng et a, 1995 found that drugs used in ICU accounted for 15% of the total cost, while Hariharan et al. in 2008 found that these drugs accounted for 50% of total drug costs.[23],[24]

In the developed countries, the cost of critical illness, with sepsis being the highest accounted for an incidence of 750, 000 cases per year in the united states, costing the healthcare system a total of US dollars 16.7 billion per annum. [25, 5]

A review on the economics of critical care in 2012 found that patients in the ICU on mechanical ventilation accrued the most bills, much higher than patients with sepsis and myocardial infarction. Of significance was the fact that mechanical ventilation was the greatest predictor of daily ICU costs. The average cost per patient on mechanical ventilation was approximately US Dollars 54,468, with costs reaching up to US dollars 200,000 for patients ventilated for 21 days or more, and further escalating up to $ 3.5 million for those surviving up to one year post mechanical ventilation.[26]

In 2004, Neil et al found that critical care medicine accounted for 4.2% of national health expenditure in the USA. Records from national health expenditure accounts (NHEA) of 2016 showed that health care expenditure was at 17.9%, reaching $ 3.3 trillion. Significantly, critical care costs were estimated at 0.56% of the gross domestic product (GDP) in the United states of America, which now stands at $ 20.41 trillion, meaning the extrapolated cost would be $ 11.4 billion per annum.[27,28]

An estimate of critical care costs was done in South Africa in 1995 and elucidated the high cost at approximately Rands 549,705 for approximately 30 days and a follow up study in Zambia in 2009 estimated the costs to be at around $ 1,000 per patient per day[29].

2.2 Tools Used for Monitoring Acute Deterioration

In 1961 during the cold war, an early warning system known as Ballistics missile early warning system (BMEWs) invented by the United States became functional and it served to warn the US forces of incoming Soviet nuclear attack.

Following the same suit, Professor Hillman et al. of Australia in 1989 introduced the concept of a team termed the Medical Emergency Team (MET) that comprised of doctors and nurses with advanced life support skills. The MET responded to a set of calling criteria based on abnormal physiological readings among acutely deteriorating patients. The aim of this team was to intervene early to prevent further deterioration as well as unplanned ICU admission or death, thus reducing hospital morbidity and mortality.

In 1997, Morgan , Williams et al. of the United Kingdom were the first to develop and publish an early warning score (EWS) comprising of 5 physiological parameters, where each parameter had cut-off points corresponding to a color banded trigger score whereby the colour bands indicated

the magnitude of deterioration from the normal range. The scores for each parameter ranged from 0 (normal) to upper and lower scores of 1, 2, and 3. The parameters included were: heart rate, systolic BP, respiration rate, temperature and level of consciousness. The total score after tabulation were used as a track and trigger system to identify early signs of clinical deterioration and prompt appropriate action. They found that patients with acute deterioration that were identified using this system had a lower APACHE ll score (acute physiological and chronic health evaluation score) compared to those that had standard ward care while critically ill.[30]

In 2008, it was found that the use of an early warning score (EWS) at admission was able to identify patients at risk of ICU admission and death, and subsequently, a higher EWS at admission correlated with increased ICU admission, death or longer hospital stay, while a decreasing serial EWS 4 hours post admission predicted an improvement in clinical outcomes.[31, 32]

Godhill et al. hypothesized that if a patient was identified early enough, action could be taken to prevent further physiological deterioration and improve outcome as well as prevent adverse outcome.[33] They therefore came up with the Patient at Risk (PAR) Score system that incorporated 5 - 6 physiological parameters; heart rate, systolic BP, respiration rete, level of consciousness, saturation of oxygen and urine output. A rapid response team (established by Lee et al. in 1995) was involved in reviewing ward patients who triggered a review based on physiological manifestations as per a protocol posted in the wards.

Since the invention of the EWS and PAR scores, various modifications have been done leading to derivation and validation of more track and trigger systems. They include: the **MEWS** (modified early warning score),**NEWS** (national early warning score – United Kingdom), **BioSIgn**, **ViEWS** (VitalPAC early warning score), **SATS** (south African triage score), **TEWS** (Triage early warning score) and **EDI** -early deterioration indicator among many more.[34]

Consequently, the number of tools used to capture early patient deterioration has increased and their classification is made based on the method the tools employ for risk stratification.[35] These include, but not limited to:

- **Aggregate weighted system** such as MEWS, ViEWS, CART (Cardiac Arrest Risk Triage Score) and BioSign.

They are considered among the most complex of the early warning scores. Vital signs and other variables are categorized into various degrees of physiological aberrancy and points are assigned values per category. Their ability to allow for risk stratification of patients and responses according to the degree of severity is an added advantage. However, when calculated manually, the degree of error increases.

- **Single parameter system** such as MERIT (Medical Early Intervention And Therapy)

They are based on a track and trigger system, whereby if a patient reaches a certain physiological criteria as given in a list, a response is triggered and action can be instituted. They do not however require calculation of a score, thus making them quite easy to implement.

- **Multiple parameter systems.**

These systems are based on a fusion of various physiological criteria to trigger a rapid response system.[12] Complex calculations are not a requirement while using these systems, and have the ability to allow for risk stratification while allowing graded responses.

2.2.1 The Modified Early Warning Score (MEWS)

The MEWS, an aggregate weighted system is a tool used to detect early patient deterioration based on physiological parameters that are measured during a patient's ward stay, where each parameter is given a score ranging from 0 to 3 and when a certain threshold is reached, appropriate action is taken (track and trigger).

The parameters are the vital signs which include heart rate, blood pressure, respiratory rate, oxygen saturation, temperature, level of consciousness as well as urine output (for catheterized patients).

The total score ranges from 0 for patients with no abnormalities to a maximum of 15. Various studies by Subbe et al showed the score of 5 and above was associated with a higher morbidity with prolonged ICU stay and mortality.[36,37]

The MEWS has been validated in different set ups and various modifications made to suit the needs of specific enters like the NEWS (national early warning score for the United Kingdom) which was accepted in 2012.

2.2.1.1 Validation of The MEWS

Various authors have been able to validate the ability to detect early patient deterioration.

Subbe et al. 2001, demonstrated that a cut-off score of 5 correlated with critical illness, with an increased risk of death, ICU admission, as well as prolonged hospital stay. [36] In 2005, it was found that mortality rate increased significantly in patients with a higher MEWS score, whereby mortality rates reached up to 33.7% and 51.9% for scores of 4 and above 5 respectively. The odds ratio for death (p value <0.0001) also increased significantly.[11]

In a risk stratification study, the sensitivity and specificity of various MEWS score for identifying IHCA(in hospital cardiac arrest) was done. It was found that for increasing MEWS score, the sensitivity gradually decreased while the specificity increased. [35]

The MEWS was validated in Uganda and the researchers demonstrated that in a population of 452 cases studied, 11.7% of ward patients had critical illness using the MEWS with a cutoff of 5. They also found that MEWS was an independent predictor of 7-day in-hospital mortality among mixed medical-surgical ward populations, with an overall 7-day in-hospital mortality of 5.5%. Mortality was higher among patients with a MEWS of 5 and above as compared to those with a MEWS of up to 4. In a multivariate analysis, MEWS and a medical admitting diagnosis were significantly associated with risk of death.[38]

In the Netherlands, the MEWS was modified to include nurses worry and urine output. It was found that in the surgical population studied with that modification, a score above 3 had a significantly higher specificity than sensitivity for outcomes of critical events and severe surgical complications.[39]

When compared to the EDI (early deterioration indicator), MEWS was less superior as a discriminator of deterioration in the 24 hours preceding deterioration- AUROC of 0.76 for EDI vs 0.64 for MEWS. However, the two tools had similar specificity for the likelihood of deterioration as compared to NEWS. However, MEWS had a higher specificity of 99.8% with a sensitivity of 4.4% at score of 5, compared to EDI sensitivity of 7.1% at that same threshold.[34]

In Kenya, a study done at The Aga Khan Hospital Nairobi used the MEWS records of ward patients who suffered cardiac arrests during their ward stay. It was found that a MEWS score of 5 or more was recorded up to 4 hours before these patients had an arrest.[13]

However, the **MERIT** study, a randomized controlled trial by Hillman and colleagues, failed to demonstrate benefit of MEWS partly because the sensitivity and specificity of the calling criteria

was below 50%. This meant that majority of 'deteriorating' patients were not detected until less than 15 minutes before they suffered a critical event- cardiac arrest or ICU admission.[40]

2.2.2 Early Deterioration Indicator (EDI)

Invented in 2017 and published in 2018, this is a system that uses the "log likelihood risk of vital signs to calculate continuous risk scores through an automated system".[34]

Its development involved using data collected retrospectively from general ward admissions using logistic regression and naïve- Bayesian classifier. It was validated by using calculated EDI scores of additional general ward stays in a second phase (validation cohort) that were compared to the MEWS and NEWS, and its discriminative ability calculated by using the AUROC (area under receivership operating curve).

"Mapping of the EDI to NEWS and MEWS was done by calculating the sensitivity and specificity of NEWS and MEWS at every value then calculating the EDI score that had the same specificity as each of the aggregate weighted systems."

Evaluation of the performance of the EDI, NEWS and MEWS at the last 24 hours of the patients' ward stay was done. Findings were exclusion of diastolic BP and level of consciousness as weak predictors of deterioration, with inclusion of heart rate (the strongest contributor), respiration rate, systolic BP, and oxygen saturation (weakest contributor).

The EDI was found to have a better discriminative power than MEWS and NEWS for the 24 hours preceding deterioration, where the NEWS and MEWS only were able to capture deterioration at only 7 hours prior.it also was able to consistently detect deterioration earlier than the two other scores with greater sensitivity and specificity.

The EDI was however not validated outside the study facility where it was invented, thus its performance would be different when applied to data collected from other countries. It was also found quite hard to calculate manually thus could not be used in places without the developed software package.

2.2.3 The Triage Early Warning Score (TEWS)

The TEWS is an aggregate weighted system that was modified by the Cape Triage Group (CTG), now known as the South African triage group in 2004. The CTG modified the MEWS by adding a

trauma and mobility component, increasing the parameters to 7 from 5 and the maximum score increasing to 17 from 14 as in the MEWS.

The two components were added because the MEWS was only able to capture medical patients, while missing out on patients with trauma who were critically ill. This was due to the fact that trauma patients may have previously been well, thus have more physiological reserve. This was reflected in a low MEWS score despite severe injuries.[41]

Upon its modification, the TEWS was found to have advantages of encompassing both trauma and medical patients since it demanded a comprehensive evaluation of the ill patient earlier on. Another advantage was the fact the TEWS had the ability to translate parameters that could be measured into easily interpretable triage scores. This further enabled medical staff, even the most basic trained, to classify patients similarly, hence promoting transparency in communication across all cadres.[41]

2.2.3.1 Validation of the TEWS

In 2014, the TEWS was validated in a retrospective observational study whereby 265 patients were studied and had their medical records reviewed. It was found that among the patients analyzed, 87.9% of them had a TEWS of < 7, of which 53.7% were discharged, while among the patients with score of above 7, 18.7% only were discharged. Of the patients with a score above 7, 59.4% of them were admitted to the wards, while 9.4% were admitted to the ICU. 4 of them (1.5%) died, with an average score among them of up to 9.5, while the average score of those admitted to ICU was 8.2. Higher TEWS were thus associated with morbidity and mortality with a p value of 0.032.[42]

2.2.4 The South African Triage Scale (SATS)

The Cape Triage Group (CTG) now known as South Africa Triage Group was convened in 2004 to produce a triage system suitable for local use, following need to properly prioritise the care of patients, in both the prehospital and emergency unit setting.[41] Their aim was to design and test a simple, effective triage tool, which would avoid discrepancies in patient classification. They reviewed existing triage instruments and developed a new combined CTG triage system and scoring sheet.The final scale was a 5 colour coded system that comprised of a TEWS and discriminators and three versions were rolled out: adult, child, and infant. The adult version is

intended for patients aged over 12 years, or taller than 150 cm. The infant version is for children under three years, or less than 95 cm, and the child version is for other children (three to 12 years, 95 to 150 cm).

2.2.4.1 Colour Coding Of SATS

The 5 colour coding system was introduced to deal with ambiguity associated with the 'stable red' and 'unstable yellow' patients, hence the colour orange was added into the SATS.

Red was used to denote a patient needing resuscitation and those with physiological instability, while orange denoted patients with potentially unstable physiology and/or potentially life/limb threatening pathology. Yellow was used to identify patients that were physiologically stable even though they had reasonably serious medical or trauma problems. The green label was for stable patients with minor injuries/illness, while the blue colour denoted a dead patient.

2.2.4.2 How The SATS Is Used

Patients upon presentation to the accidents and emergency area are triaged using a 5 step approach and flagged using the 5 colour code system as well as TEWS.

Patients with emergency signs such as obstructed airway, current seizure, facial and inhalational burns as well as cardiac arrest and hypoglycemia are triaged as color code RED and immediately taken to the emergency/ resuscitation room for immediate management. In paediatric population, the emergency signs are denoted **ABC-c-c-DO** for airway, breathing, circulation, convulsion, coma, dehydration and other. If there are no emergency signs, the triage personnel now look for very urgent signs such as abdominal trauma, high energy transfer injuries, reduced level of consciousness, uncontrolled haemorrhage, diabetics with hyperglycemia and ketonuria among others. If present they proceed to measure the vital signs and fill a TEWs chart and score the patient and management instituted within 10 minutes. After measuring the TEWS the patient can be color coded as RED with a score of 7 or more and ORANGE if score is 5 or 6.

A score of 7 and above mandates the patient be immediately transferred to the resuscitation room for management. After measurement of vital signs, additional information and investigation may be sought and this may be used to re-prioritise the patient from a lower color score to a higher one.

2.2.4.3 Validation of the SATS

The SATS was validated and implemented widely in public and private hospitals in South Africa as well as in other facilities outside south Africa such as Ghana and Kenya at Kenyatta national hospital casualty department.[43, 44]

In a retrospective cohort study carried out in Haiti, the SATS was found to be inferior when used alone to predict mortality in a resource limited emergency surgical Centre, than when used with a combined model (a prognostic model constructed and validated based on information available from the emergency department, that included reasons for admission as classified by the MSF-MEDICENS SANS FRONTIERE'- and combined with the SATS system). However, through a multivariate analysis, the SATS color code of red and orange were found to be independent factors associated with mortality (AUROC of 0.83), among other factors such as age 45-65years, age above 65 years and non-traumatic reasons for admission.[45]

Another retrospective cohort study was carried out in purely trauma centre and a mixed centre of trauma and non-trauma patients, to assess the validity of the SATS. Comparisons of patients' SATS rating with their final emergency department outcome in terms of admission, death or discharge were done. It was found that the SATS was able to predict an increase in mortality and hospitalization with increasing acuity levels, with a p value of <0.001 in both the trauma and mixed centres.[46]

2.2.5 Cardiac Arrest Risk Triage Score

This is also a form of aggregate weighted system that was published following a retrospective cohort study for 27 months of 47,427 patients' vital signs admitted during that study period. A regression model was employed to come up with a final model containing respiratory rate, heart rate, diastolic BP and age with aggregate scores for each range of physiological variables.[47]

Table 1 :Cardiac Arrest Triage Score

Vital Sign	Cardiac arrests, n (%)[a] [n=88]	Controls, n (%)[a] [n=44519]	Beta coefficient	Score
Respiratory rate				
<21	21 (24)	29997 (67)	Reference	0
21-23	19 (22)	8118 (18)	0.9	8
24-25	17 (19)	3688 (8)	1.4	12
26-29	12 (14)	1732 (4)	1.7	15
>29	19 (22)	984 (2)	2.4	22
Heart rate				
<110	41 (47)	33710 (76)	Reference	0
110-139	32 (36)	9911 (22)	0.5	4
>139	15 (17)	898 (2)	1.4	13
Diastolic BP				
>49	42 (48)	33783 (76)	Reference	0
40-49	28 (32)	8869 (20)	0.5	4
35-39	6 (7)	1007 (2)	0.6	6
<35	12 (14)	860 (2)	1.5	13
Age				
<55	22 (25)	21025 (47)	Reference	0
55-69	27 (31)	13962 (31)	0.5	4
>69	39 (44)	9532 (21)	1.0	9

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CART scores of >17 had a specificity of 89.9%, with a sensitivity of 53.4% for prediction of cardiac arrest, while a higher score of > 20 had a much higher specificity of 91.9%, but sensitivity remained the same.

It was validated for detection of ward to ICU transfers and Compared to the MEWS. The CART was found to be superior in terms of detection of critical events, of IHCA(in hospital cardiac arrest and unplanned ICU transfer. Also, the CART was able to identify cardiac arrest 6 hours earlier than the MEWS (median 48hours for CART vs 42 hours for MEWS).

The reasons for the CART's superiority over the MEWS were that the MEWS excluded significant predictors of critical events such as age and diastolic BP. Previous studies done had shown decreasing diastolic BP as a significant predictor of ward IHCA while increasing age was a significant independent predictor of IHCA.

Further comparison with other scores also found that the CART outperformed other aggregate weighted systems in predicting IHCA. Below is a snapshot of the comparison in terms of AUROC;

- CART VS ViEWS AUORC 0.83 vs 0.77
- CART VS SEWS AUROC 0.83 VS 0.76

However, CART perfumed similarly with other systems in terms of capturing ICU transfer and mortality .[35]

2.2.6 Biosign

This is an automated system that tracks information in real-time from the patients' vitals collected through ward monitors.[48] The parameters measured are heart rate, respiratory rate, BP, arterial oxygen saturation (SaO2) and skin temperature. These variables are evaluated every 5 seconds (except for the non-invasive BP which is taken every half hour) and the computers "learn" the patient's normal status and stores it as training data set Using the stored training data set, a model is employed to calculate the probability that the patients' data being evaluated falls within normal or is outside the learnt data. When the vital signs are abnormal enough to fall outside the training set, an alert is triggered for medical emergency team review (MET) or RRT (rapid response team).

An RCT was done in Oxford to validate the continuous monitoring of patients' vitals among those with a high risk of death form medical and surgical conditions. It was found that the rates of admission to the ICU for the mandatory monitoring group was similar to the standard care group, as well as review by the critical care outreach team, though mortality was higher in the monitoring group than the standard care group at 96 hours, but the rates equalized at 30days.

Patients in the monitoring group had more frequent acute changes in treatment compared to the standard care patients, where the interventions included fluid therapy, instigation of invasive monitoring as central venous pressure and changes in respiratory therapy. The length of stay for both groups was also similar.[49]

The study was therefore not able to demonstrate any benefit of mandatory monitoring among high risk surgical and medical patients.

3.0: STUDY JUSTIFICATION

Kenyatta national hospital is an 1800 bed tertiary care facility, the largest public hospital in East Africa. Statistics from 2016 and 2017 showed that patients presenting through the accidents and emergency department at KNH were between 31, 978- 61, 840, with admissions ranging between 20, 267 -21, 731 per annum.

A survey of critical care set up in Kenya showed Kenya had a total of 130 ICU beds for a population of 44 million, translating to an ICU strain 0.29 beds per 100,000 population. [50] According to the Society of Critical Care Medicine, critical care beds should form 20-40% of the total hospital capacity, while WHO recommends 10-20% of the total hospital capacity.

KNH has 36 ICU beds, which only accounts for 1.8% of the total hospital capacity. This falls far below the WHO recommendations, indicating a significant ICU strain at KNH.

Mortality rate was highest in the ICUs in comparison to a global estimated ICU mortality if 8-18%.[1] In PICU (paediatric ICU), the mortality rate for the years 2016 and 2017 varied between 49.6 -53.8% compared to general paediatric ward death rate of 13.2- 15.8%, while in the adult medical ICU, mortality rates ranged between 35.1 – 47.4% as compared to 11.0 – 28.4% in the general medical wards. In the main ICU that caters mostly to surgical cases, the death rate was 35.2 – 35.7 % compared to general surgical ward death rates of 0.7 – 8.0%,

The high mortality rates in the ICU may be attributed to late recognition of critical illness in the wards until end organ dysfunction has occurred, as well as poor communication between the health care staff since request for reviews for patients with critical illness (by ICU team) in the general wards are usually sent out late. This translates to admission to ICU of patients that have severe morbidity with high risk of mortality.

The A&E at KNH has a triage system that aids in early detection and prioritization of patients at risk of averse outcomes. The validated tools is the SATS which has a component called the TEWS that scores patients according to derangements in their physiological parameters. [51]

However, in the general wards, there exists no tool to identify patients at risk of deterioration hence delayed escalation of care for such patients. If the rapidly deteriorating patients are captured early, it would prevent adverse outcomes.

The findings of this study may form the basis for a decision support system as far as ward care of deteriorating critically ill surgical patients is concerned. Given the paucity of relevant data in our setup, this study aims at establishing knowledge and practice gaps related to care of the critically ill surgical patient

3.1 Study Question

Can the triage early warning score be a useful tool in the management of critically ill surgical patients who present to Kenyatta national hospital through the accident and emergency department?

3.2 Study Objectives

3.2.1 Broad objective

To establish the appropriateness of care of critically ill surgical patients using the triage early warning score (TEWS)

3.2.2 Specific Objectives

i) To identify using the TEWS tool, the surgical patients presenting as critically ill through the KNH A&E
ii) To determine the association between the triage early warning score (TEWS) and outcome of critically ill surgical patients after 72 hours of follow up
iii) To determine the specificity and sensitivity of the cut off values of the triage early warning scores (TEWS)

4.0 : METHODOLOGY

4.1 Study Design

The study was a prospective observational study involving the patients flagged as critically ill by scores of 5 and above using the Triage Early warning score (TEWS).

4.2 Study Location

Kenyatta national hospital is an 1800 bed tertiary care facility, the largest public hospital in east Africa. It has 50 wards, with 10 wards catering to surgical patients. KNH has 3 ICUs, 20 outpatient clinics, 24 operating theatres and 2 accident and emergency departments, with one being predominantly a paediatric medical emergency PFC (paediatric filter clinic) area and the other being a mixed trauma and medical emergency area.

KNH serves national catchment as well as the East African region.

The A&E receives between 31, 978- 61, 840 patients per year, with a monthly average of around 4,000 patients, of which 20, 267 -21, 731 are admitted to the wards per annum.

4.2.1 Study Site

The study was carried out at the KNH accident and emergency department where the patients were recruited after fulfilling the inclusion criteria and then followed up from the point of contact through their stay in either A&E itself (which includes a trauma theatre, resuscitation rooms-acute medical and surgical holding areas-, specialized review rooms for surgical patients) and the adult surgical wards (4^{th}, 5^{th} and 6^{th} floor wards).

4.2.2 Structure and Processes at A&E

The A&E comprises of a triage area manned by a SATS trained nurse and a team leader who is a medical officer, resuscitation rooms A and B (RRA, RRB), two trauma theatres (1 &2), acute rooms number 9 and specialized review rooms for surgical, obstetrics and gynaecology patients, as well as medical patients. It also has 4 consultation rooms for reviewing non emergent cases.

All patients presenting to A&E of KNH, apart from paediatric medical emergencies and maternity patients pass through the triage desk where they are classified using the SATS and TEWS. The

paediatric medical emergencies are directed to the PFC (paediatric filter clinic), while non-trauma maternity patients are taken to the labor ward on ground floor. After triage, the patients are attended to in order of the urgency as per the SATS flow chart. After being seen at the A&E, the patients may either be admitted to the ward, ICU or taken to emergency theatre or discharged.

4.3 Study Population

The study was carried out on critically ill surgical patients presenting to the KNH accident and emergency department who had the TEWS filled and had scored 5 and above.

4.4 Patient Recruitment

4.4.1 Inclusion Criteria

a) Critically ill surgical patients presenting at the KNH A&E

b) Consenting patients

4.4.2 Exclusion Criteria

a) Patients who decline to give consent.

b) Paediatric surgical patients- age below 12 years as this is the cut off for paediatric patients at KNH.

c) Patients without the TEWS chart in the file.

d) Patients with an incomplete TEWS

e) Stable adult surgical patients

f) Patients from maternity wards because they are referred through labor ward

g) Neurotrauma patients

4.5 Study Procedure

All patients presenting to the KNH A&E have the triage done and SATS/TEWS chart filled out by staff who have been trained to use the charts.

Once triaged, the patients who fulfilled the inclusion criteria were followed up from the point of triage for 72 hours. Their vitals were taken every 4 hours and the TEWS filled. 4 hours was chosen because a study at the Aga Khan hospital in Nairobi had found that patients at risk of in hospital cardiac arrest had changes in their vital signs up to 4 hours before cardiac arrest[13].

The follow up was done in terms of interventions the patients received, the time between intervention and the escalation of care for the critically ill surgical patient.

Measurable outcomes were adverse events, which included: unplanned ICU admission, resuscitation and death.

4.6 Sample Size Determination

Sample size was calculated using the (Daniel, 1999) formula;

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

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P = expected true proportion (estimated at 12.1%, from a retrospective observational study conducted by Naidoo D.K. et al (2014), at the Accident and Emergency Unit of Addington Hospital, KwaZulu Natal, South Africa; looking at assessing the effectiveness in identifying patients at risk of early deterioration to enable timely medical intervention using the TEWS, found 12.1% of patients had a TEWS category (high) ≥ 7.)

d = desired precision (0.05)

$$n_0 = \frac{1.96^2 x\ 0.121(1-0.121)}{0.05^2} \approx 165$$

A Sample size of **165** patients will be required for the study.

4.7 Sampling Procedure

The sampling was convenience sampling, in view of the fact that all patients presenting to KNH accidents and emergency (A&E) have been triaged using the TEWS and SATS and not all patients who are triaged will have critical illness. All critically ill surgical patients presenting through the triage area that fulfilled the inclusion criteria were recruited for the study until the desired sample size of 165 is reached. The number of patients recruited in this study were 168.

4.8 Data Analysis and Management Plan

4.8.1 Data Collection

Data was collected using serialized questionnaire which was filled out by trained research assistants. The vital signs were measured using an automatic oscillometric arm blood pressure machine, an automated clinical thermometer for temperature and a wrist watch timer was used to count the respiratory rate. The sternal rub was used to elicit response to pain in patients who are not responsive to verbal stimulation as well as touch.

Patients flagged as critically ill by scoring 5 and above using the TEWS were followed up and had the TEWS chart filled during the 72 hours of follow up. The highest recorded TEWS score was used for data tabulation.

The measurable outcomes were:

- Severe adverse events- cardiac arrest, successful resuscitations and death
- Unplanned admission to ICU/HDU

4.8.2 Data Management

The questionnaires were filled by trained research assistants who followed up the patients for the duration of 72 hours. Once each questionnaire was completed, they were collected and stored in a cabinet under lock and key where the statistician and primary investigator had access. The data was then cleaned, coded and entered into a Microsoft Excel spreadsheet. Another round of data cleaning was performed at the end of data entry and then stored under password protected file that would only be accessed by the primary investigator and statistician.

4.8.3 Data Analysis

Data was entered and analyzed with the use of IBM SPSS version 21.0. Continuous data was be analyzed and presented as means and standard deviation. Categorical data was also analyzed and presented as frequencies and proportions. Logistic regression was used to assess the relationship between the triage early warning score and patient outcomes at 72 hours, while the receivership operating characteristics curve were used to assess the sensitivity and specificity for the cut off values of the TEWS. The results were considered significant at $p < 0.05$. Where appropriate, tables and pie charts were used to display certain characteristics.

4.8.4 Data Storage

Data collected was stored in a computer under password protected folders in the form of soft copy, while hard copy data was stored in a cabinet under lock and key.

4.9 Ethical Consideration

4.9.1 Ethical Approval

Approval was sought from the Ethics and Research Committee KNH-UON prior to commencement of data collection. Authorisation was also sought from KNH administration to allow the study to be carried out in the accident and emergency department as well as the surgical wards.

4.9.2 Patient Recruitment and Consent

All surgical patients above 12 years presenting to the KNH A&E with a TEWS score of 5 and above were recruited after they gave their consent. For patients between 12 to 17 years, an assent form was used to obtain consent.

For the patients who were too sick to give consent, an application for waiver of consent and waiver of consent documentation was made and granted through the Ethics and Research Committee KNH-UON.

It was clarified to participants that participation was voluntary and they were allowed to withdraw at any time and that no penalties would befall them if they withdrew and they would continue receiving the ward care as prescribed by the health care teams involved.

The participants were assured of confidentiality whereby any information that identified the patient directly or indirectly would not be published. This was ensured by using serialised questionnaires which did not have patient name or registration numbers. Emphasis was also made on safekeeping of the collected data for at least 3 years. It was also be made clear to the participants that there was be no monetary benefits and theywould not incur any extra costs by participating.

4.10 Ethical Intervention

Where necessary, the surgical and medical teams in the wards as well as critical care team were asked to intervene to prevent further patient deterioration.

5.0: RESULTS

5.1 Study Period

Approval was granted by KNH-UON Ethics and Research committee in January 2019. Following the approval, patients that fulfilled the inclusion criteria were recruited from February 2019 to April 2019 and followed up for a duration of 72 hours.

5.2 Demographic Characterization

A total of 168 patients were recruited. There were more males than females. The males accounted for 77% of the total number of participants, while females accounted for 23% of the study population. Majority of the patients were young, ranging from 25-35 years and the mean age was 33.87 years with a median age of 31.0 and Interquartile range of 17.

Majority of the patients, accounting for 61.9% were referrals from other facilities while the rest were self-referred. In view of the reasons for presentation to the KNH A&E, majority of the cases were due to trauma (94%) while a small number were due to non-trauma (6%).

Table 2 : Patient Characteristics

Age	**Frequency(%)**
16-25	30.4
26-35	31.5
36-45	23.2
46-55	9.5
Above 55	5.4
Sex	
Male	77.4
Female	22.6
Referral	
Self	38.1
From health facility	61.9

Diagnosis	
Trauma	94.0
Non-Trauma	6.0

5.3 Breakdown of Cases by Diagnosis

Majority of the trauma cases were due to fractures involving the upper and lower limbs, as well as the pelvic and spinal vertebrae. This accounted in total for 68.98%. This was closely followed by patients with polytrauma who accounted for 13.29% of the population with trauma. The other categories of trauma were distributed between burns (5.69%), soft tissue injuries (7.59%), abdominal injuries (2.53%) and chest injuries (1.89%).

Among the patients with non-traumatic diagnoses, a significant number were due to cancer (30%), and the cancers were: lung cancer in two patients and metastatic cancer to the brain (primary site unknown). The second most frequent presentation was upper airway obstruction (20%), and one case was due to blockage of a tracheostomy tube in a patient on home care while the other was due to obstruction by a metastatic thyroid cancer.

Table 3:Breakdown of trauma cases

Trauma type	Frequency(%)
Fractures	68.98
Polytrauma	13.29
Burns	5.69
Soft tissue injury	7.59
Abdominal injury	2.53
Chest injuries	1.89
total	100%

Table 4: Breakdown of Non-Trauma Cases

Diagnosis	Frequency(%)
Abscess	10.0
Cancer	30.0
Intestinal obstruction	10.0
Intra-abdominal sepsis	10.0

Renal calculi	10.0
Soft tissue infection	10.0
Upper airway obstruction	20.0
Total	**100.0**

5.4 Triage Data

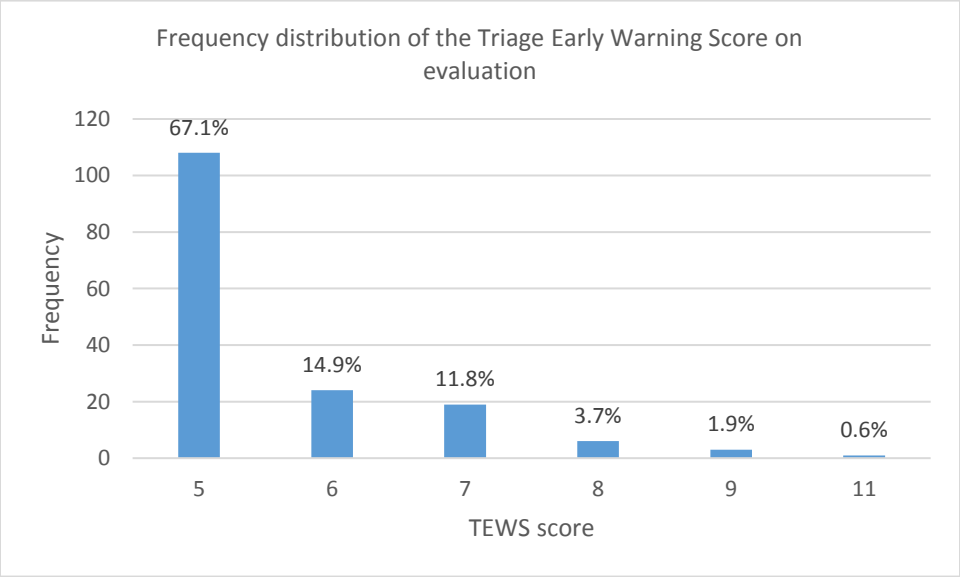
This section presents the results of using the TEWS tools in identifying the surgical patients presenting as critically ill through the KNH A&E.

The patients were categorized into two groups: those with score of 5 and 6 were considered low score, while those with score of 7 and above were considered high score.

Table 5 : Distribution of Patients by Triage Early Warning Score

Triage early warning score	frequency	percentage
TEWS category high (≥7)	22	13.1
TEWS category low (< 7)	146	86.9

Figure 1: Frequency Distribution of TEWS on Evaluation



The bar graph above presents the distribution of the scores on evaluation. Majority of the patients had a score of 5 (112 patients), followed by a score of 6 (25 patients), score of 7 (20

patients), score of 8 (7 patients), score of 9 (3 patients) and finally a score of 11 (1 patient). No patient had a score of 10.

5.5 Association between TEWS and Outcome

The table below represents the association between the TEWS and outcomes at 72 hours.

After the patients were categorized into high and low scores, their outcomes at 72 hours were compared to the highest recorded TEWS during the follow up. The patients were then put into four categories as: those discharged, those admitted to the ICU, those who died and those who continued the ward care as below.

Table 6 : TEWS and Outcome

	Outcome				**Total n (%)**
	Discharge n (%)	**Ward care n (%)**	**Admission to ICU n (%)**	**Death n (%)**	
TEWS category (low):<7	10 (6.06)	122 (73.93)	3 (1.81)	1 (0.61)	136 (82.4)
TEWS category (low):≥7	2 (1.21)	13 (7.87)	4 (2.42)	10 (6.06)	29 (17.5)
Total	**12**	**135**	**7**	**11**	**165**

5.5.1: Breakdown of the Highest Recorded TEWS and Outcomes

The table below represents a breakdown of individual TEWS and the outcomes at 72 hours as: patients who remained alive in the ward, those who died, those that had unplanned admission to ICU and those that were resuscitated. 1 patient was successfully resuscitated after having hypovolemic shock. They received fluids and blood products in the ward.

Table 7 : Highest Recorded TEWS and Outcome

Highest TEWS Recorded		Outcome				Total
		Alive	Dead	ICU	Resuscitated	
	5	109	1	0	0	109
	6	23	0	3	0	26
	7	14	4	0	1	19
	8	0	4	2	0	6
	9	0	2	1	0	3
	11	0	0	1	0	1
Total		146	11	7	1	165

Table 8: Mean TEWS per Category

	n	Mean TEWS	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
Ward care	135	5.30	0.683	.059	5.19	5.42	4	7
Discharge	12	5.50	0.798	.230	4.99	6.01	5	7
ICU	7	7.71	1.890	.714	5.97	9.46	6	11
Dead	11	7.55	1.128	.340	6.79	8.30	5	9
Total	165	5.57	1.072	.083	5.40	5.73	4	11

The average triage early warning score for the patients that continued ward care was 5.30, with a standard deviation of 0.63, while the average score for those who were discharged was 5.50, and the average score for the ones that were admitted to ICU and the ones that died were 7.71 and 7.55 respectively.

The table below represents the association between number of reviews and the highest recorded TEWS.

Table 9 : Association between Highest Recorded TEWS and Number of Reviews

No. of reviews		Outcome				Total
		Alive	Dead	ICU	Resuscitated	
	1	5	4	1	0	10
	2	10	1	0	0	11
	3	37	2	0	0	39
	4	49	1	0	0	50
	5	18	0	2	0	20
	6	16	2	0	0	18
	7	8	0	2	0	10
	8	3	0	0	1	4
	9	0	0	1	0	1
	10	0	0	1	0	1
	11	0	1	0	0	1
Total		146	11	7	1	165

Majority of patients had reviews ranging from 3 to 6 during the entire follow up period.

Table 10 : Mean TEWS in Relation To the Number of Reviews

Number of reviews	Mean TEWS per category			
	Ward care	Discharged	ICU	Died
1		6	6	7
2	6	5		8
3	5	5		6
4	5	6		9
5	5		8	
6	5			9
7	6		9	
8	6			
9			8	
10			8	
11				8

The table above represents the mean triage early warning scores in relation to the number of reviews and outcomes at 72 hours.

Of the patients who had 1 review, the average scores for the ones discharged were 6, average scores for those admitted to ICU were 6, and the average score for those who died was 7.

Among those that had 2 reviews, the average scores for those who continued with ward care , discharged, and those who died were 5, 6 and 8 respectively.

Patients who were admitted to the ICU and those who died seemed to have higher average TEWS as compared to the ones that were discharged and those who continued ward care.

Table 11:Direct Logistic Regression for Highest TEWS and Bad Outcome

	B	S.E.	Wald	P value	OR	OR 95% C.I.	
						Lower	Upper
TEWS	2.042	.406	25.337	<0.001	7.708	3.480	17.073
Constant	-14.861	2.732	29.582	<0.001	.000		

This table demonstrated that the odds of having a bad outcome is 7.7 times for each unit increase of the TEWS score.

5.6 Cut-off Values for TEWS and Outcome

This section represents the cut off values for the TEWS and unplanned ICU admission and mortality. Receiver operating characteristics (ROC) were used to establish the sensitivity and specificity.

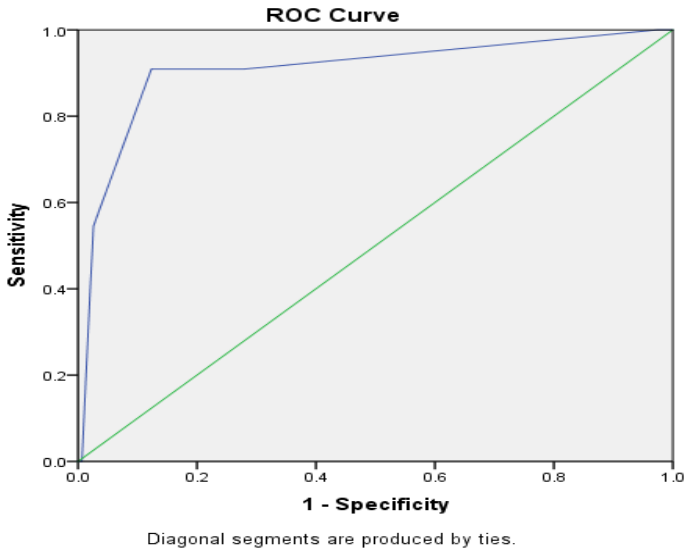


Figure 2 : ROC curve for highest TEWS and mortality

The figure above shows the receiver operative characteristics for the highest TEWS and mortality

Table 12 : Area under the curve for highest TEWS and mortality

Area Under the Curve					
Test Result Variable(s)	**Area**	**Std. Error**	**Asymptotic Sig.**	**Asymptotic 95% Confidence Interval**	
				Lower Bound	**Upper Bound**
TEWS	0.907	0.056	<0.001	0.797	1.000

	Cut off	Sensitivity	Specificity
TEWS	6.50	90.9%	12.3%

The area under the curve was 0.907, with a p value of <0.001, hence the cut off value was 6.50, with a 90.9% sensitivity and 12.3% specificity.

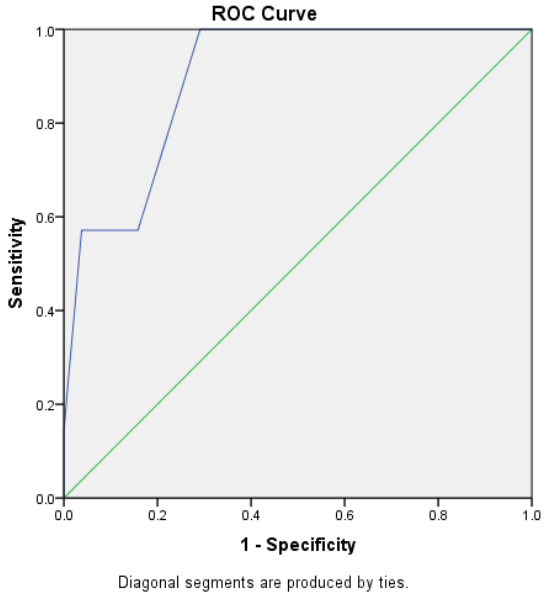


Figure 3: ROC Curve for Highest TEWS and Unplanned ICU Admission

This figure shows the receiver operating characteristics for highest TEWS and unplanned ICU admission.

Table 13: Area under The Curve for highest TEWS and unplanned ICU admission

Area Under the Curve					
Test Result Variable(s)	**Area**	**Std. Error**	**Asymptotic Sig.**	**Asymptotic 95% Confidence Interval**	
				Lower Bound	**Upper Bound**
TEWS	0.896	0.044	<0.001	0.810	0.981

	Cut off	**Sensitivity**	**Specificity**
TEWS	7.50	57.1%	3.8%

The area under the curve was 0.896 with a cut off value of 7.50 and a sensitivity of 57.1%, with a specificity of 3.8%. The p value was < 0.001

6.0: DISCUSSION

This study was done with the aim of finding out whether the triage early warning score could be used in the management of critically ill surgical patients at KNH. The patients were recruited from accident and emergency department and followed up for 72 hours.

Patients who present to KNH come through the accident and emergency area where they are triaged using the TEWS which is a component of the South African Triage Scale that was validated in KNH by Ali Wangura et al in 2017. [43] However, the ward where the patients are admitted lack a decision making tool to manage the patients once they leave the A&E.

Various studies have demonstrated that patients who have scores of 5 and above when triaged using the MEWS and TEWS are at increased risk for bad outcomes, such as critical illness, prolonged hospital stay with increased risk for death. This was the basis for using the baseline score of 5 and above in the recruitment process.

The TEWS is a modification of the MEWS, whereby trauma and mobility components were added to capture trauma patients who had been noted to have a large physiological reserve and by the time they had deteriorated, they had been missed out. The trauma component is given 1 point while immobility is given 2 points on the TEWS.

In this study, a TEWS of 5 and above was chosen as the baseline score while recruiting patients. The patients were further categorized as those with high score if they had scores of 7 and above and low score if below 7. This was done to cater for the mobility component of the TEWS that increased the score by 2 points if the patients arrived on a stretcher, which is how majority of patients present to KN A&E.

Majority of the cases presenting to KNH A&E were due to trauma, with fractures involving the limbs, spine and pelvis accounting for the larger proportion. These findings were similar to a study on epidemiology and outcomes of injuries in Kenya that found that the most commonly injured organs were the musculoskeletal system.[52] Most of the trauma were due to road traffic accidents and falls from height. This reflects on the burden of trauma, where according to WHO estimates that 90% of injury related deaths occur in low income countries, and a study at KNH showed that up to 48.8% of admissions through the casualty into surgical wards were due to trauma. The most

commonly affected age group in trauma is 15-44 years, and this was reflected in our study, whereby most of the patients were male, and the mean age was 33.87 years. According to the global burden of trauma and injuries, males are more than 3 times more likely to suffer non-intentional injuries such as road traffic accidents and falls.[53]

A large proportion of the patients had low scores, compared to the smaller proportion with high scores. Of these two categories, 6.06% in the low score and 1.21% in the high score category were discharged. This may have been attributable to the fact the TEWS considerably increases the score by 2 points if a patient comes on a stretcher, hence over-triaging them. This is true especially in KNH A&E where majority of patients arrive on a stretcher or wheelchair.

The patients that had adverse outcomes also had had more reviews as compared to those that were discharged or those that continued with ward care at the end of follow up. However, there was a slight discrepancy in the patients that had one review and ended up with adverse outcome. As shown in table 10, 5 patients had had 1 review done but ended up with adverse outcomes (4 died, 1 admitted to ICU). The average scores were however high at 7 (for those that died) and 6 for those that were admitted to ICU. This can be compared to average scores of patients who had 5-11 reviews, where their average scores ranged from 8-9 for those that had bad outcomes. This therefore reflects on the severe physiological derangements that these patients had, hence they could have been missed earlier on at their first presentation or they were already too sick to survive through the other reviews.

The average scores in the patients with adverse outcomes was higher than in those without adverse effects. For patients with unplanned ICU admission, the average score was 7.71, while the mean TEWS for those that died was 7.56. This was in contrast to mean scores of 5.3.and 5.5 for those continuing ward care and those discharged respectively. The average scores for patients that were admitted to ICU seemed higher because their number was slightly smaller (7) as compared to those that died (11).

A study done by Naidoo et al to evaluate the TEWS in an urban accident and emergency centre, showed that patients who had bad outcomes had significantly higher average TEWS than those that didn't. They found that the average TEWS for patients that died was 9.5 and 8.2 for those

that were admitted to ICU (p value 0.032).[42] This was also reflected in a study by Tian et al where they found that increasing scores significantly increased the mortality, in that among patients with TEWS of less than 9, the mortality rate was only 0.98% as compared to a high mortality rate of up to 80% among patients with TEWS of 14 and above. The average TEWS was significantly high at 7.05 ± 2.38 for those patients that were admitted to ICU.[54]In a Turkish study, Gorkhan et al demonstrated that average TEWS for patients that died were significantly higher at 10.6± 2.3 versus scores of 2.7 ± 2.3 for those that survived. [55]

In our setup however, no studies have been done in Kenya to test the value of TEWS in care of patients presenting through the emergency department. It can therefore be deduced that , based on the findings in our setup as compared to the studies above, higher TEWS are significantly associated with bad outcome, while lower scores may be associated with better outcomes.

Using direct logistic regression, we found that the odds for a bad outcome (death or unplanned ICU admission) was statistically significant at 7.7 times for each unit increase in the TEWS, which was higher than the findings by Tian et al that the odds ratio for death was 2.14 (95% CI 1.7-2.604) for each point increase in the TEWS. [54] This may be attributed to their large study population (456) versus 168 in our study. Since the TEWS is derived from the Modified Early Warning score (MEWS), Subbe et al found that a MEWS of 5 and above were associated with poor outcomes, with significant increased risk for mortality with an odds ratio of 5.4.[36,37]

We found that by using receiver operating characteristics, the TEWS was statistically significant at predicting patients at risk of adverse outcome at cut off values above 6.5 for mortality and 7.5 for unplanned ICU admission. These findings are comparable to those of Tian et al that found cut off values of 8 as significant for mortality prediction, while Gorkhan et al found that scores above 5 were significant. Since no studies have been done locally, and coupled to the significant ICU strain in our set up, the TEWS can be clinically applicable in identifying critically ill surgical patients at risk of deterioration, which may progress to adverse outcome.

We found that the cut off value for mortality prediction was lower than that of ICU admission. This was due to the fact that the number of patients that died was slightly higher than that of patients admitted to ICU.

7.0: CONCLUSION

Trauma still remains a significant burden in our set up as evidenced by the fact that majority of the patients in this study presented due to trauma.

The TEWS is a validated tool in use at the KNH A&E, but the surgical wards lack a decision making tool to help identify patients at risk of deterioration. The TEWS is therefore an easy to use tool that communicates information easily to all cadres of medical workers, and therefore clinically applicable in our set up.

Since the TEWS is a modification of the Modified Early Warning Score, it may over-triage patients, due to addition of the immobility component.

The TEWS is a track and trigger based tool, whereby once certain threshold points are crossed, appropriate action should be taken. In this study, we found that patients with scores of 6.5 and above were at increased risk for death or unplanned ICU admission, hence the TEWS can be used to identify patients at risk of deterioration.

ICU strain remains a significant challenge at KNH. Based on our findings, the TEWS is a sensitive tool for predicting risk for ICU admission and if patients can be identified early using the TEWS and action taken, it would prevent further deterioration hence reduce the need for unplanned ICU admission.

8.0: RECOMMENDATIONS

Patients with a score of 6 and above should be monitored closely once admitted in the wards.

A study with a longer duration of follow up and a larger sample size could be done to identify other risk factors for patient deterioration among surgical patients. Since majority of the patients had trauma, a study that excludes trauma cases should be done to further strengthen the identification of risk factors for patient deterioration.

A tool similar to TEWS can be implemented to easily identify the patients at risk of deterioration early. The tool should be easy to use and be able to communicate the same information across all cadre of medical staff.

KNH would benefit from implementation of a rapid response team that can do early reviews for patients that have been identified to be at risk of deterioration, hence help prevent further deterioration and aid in reducing ICU strain.

9.0: STUDY LIMITATIONS

The study involved the follow up of patients for only 72 hours, hence patients that developed adverse outcomes after the study period were missed out.

To obtain the number of reviews, the principal investigator had to retrospectively look through the patients' files, hence incomplete information was a challenge.

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APPENDICES

Appendix I: Questionnaire

Serial Number……

A: Demographic Data

1. Age…. ☐
2. Sex M ☐
   F ☐

3.Referral

I. Self ☐

II. From Health Facility ☐

Specify Facility Type……..

III. Reason For Referral……

……

IV. Cadre Of Referree

Nurse ☐

Clinical Officer ☐

Medical Officer ☐

Consultant Doctor ☐

Paramedic ☐

V. Intervention Prior To Referral……

……

……

VI. Mode Of Transport From Referring Centre

Ambulance ☐

Other Means ☐

4. Diagnosis……

   ……

5. Co-Morbidities…….

   ……..

B: Triage Data

1. Time Of Triage……..
2. Triage early warning score(TEWS)

Emergency (>7) ☐

Very Urgent (5 Or 6) ☐

Urgent (3 Or 4) ☐

Routine (0,1,2) ☐

3. First Intervention……

……

……

4. Outcome After Intervention……

……

……

5. Time Interval Between Triage And First Intervention

……

6. Triage early warning Score After Intervention

Emergency 7 and above ☐

Very Urgent 5-6 ☐

Urgent 3or 4 ☐

Routine 0,1,2 ☐

7. Dispatch Location After First Intervention

Surgical Ward ☐

ICU ☐

Resuscitation room A ☐

Resuscitation room B ☐

Theatre ☐

Other- Death ☐

Discharged ☐

8. Patient Status Prior To Dispatch (Triage early warning Score)

Emergency(7 and above) ☐

Very Urgent (5—6) ☐

Urgent (3 or 4) ☐

Routine ☐

9. Reason For Dispatch……

……

10. Baseline Investigations

Bloodworks investigations

Requested No ☐

Yes ☐

If Yes, List The Labs Requested……

……

……

Requested Investigations

Not Done ☐

Reason Not Done……

Findings of Done Investigations…….

……

……

…….

Ii Radiology Investigations

Requested No ☐

Yes ☐

If Yes, List The Radiology Investigation Requested……

……

……

.

Requested Investigations

Not Done ☐

Reason Not Done……..

Findings of Done Investigations……

……

……

C: 72 Hour Triage Early Warning Score TEWS(From The First Triage Score)

4th hour	8th Hour	16th Hour	20th Hour	24th Hour	28th Hour	32nd Hour	36th Hour	44th Hour	48th Hour
52nd Hour	56th Hour	60th Hour	64th Hour	68th Hour	72nd Hour				

Urine Output (Ml/Hour) For Catherised Patient

Highest Triage Early Warning Score Recorded……..

D: Ward Management

1. Patient Status On Arrival To Ward (triage early warning score)

Emergency (7 and above) ☐

Very Urgent (5 or 6) ☐

Urgent ☐

2. Patient Nutrition Status……

3. Investigations

I. Bloodworks

Requested No ☐

Yes ☐

If Yes, List The Labs Requested……..

……

……

Requested Investigations

Not Done ☐

Reason Not Done……

Findings Of Done Investigations……

……

……

ii. Radiology Investigations

Requested No ☐

Yes ☐

If Yes, List The Radiology Investigation Requested……..

……

……..

Requested Investigations

Not Done ☐

Reason Not Done……

Findings of Done Investigations……..

……

……

4.Ward Intervention Plan After Triage early warning Score

……..

……

……

……

……

……

5. Was Intervention Plan Carried Out

Yes ☐

No ☐

Reason Intervention Not Implemented…….

……

……

6. Patient Status After Intervention

Emergency (score 7 and above ☐

Very Urgent (5-6) ☐

Urgent (3 0r 4) ☐

E: Outcome After 24 Hour Follow Up

1: Escalation of care

ICU admission ☐

Theatre ☐

Resuscitation ☐

Outcome of Resuscitation……..

2: De-Escalation Of Care

Continue Ward Care ☐

Discharge ☐

F: Outcome after 48 Hours

1: Escalation of Care

ICU admission ☐

Theatre ☐

Resuscitation ☐

Outcome of Resuscitation……..

2: De-Escalation of Care

Continue Ward Care ☐

Discharge ☐

G**: Outcome After 72 Hours** ☐

1: Escalation of Care

ICU admission ☐

Theatre ☐

Resuscitation ☐

Outcome of Resuscitation……..

2: De-Escalation of Care

Continue Ward Care ☐

Discharge ☐

H. Total Number Of Reviews Done……

Appendix II (a): Consent Form (English)

Title of Study: Utility of Triage Early warning score in the care of critically ill surgical patients presenting through the KNH accident and emergency department

Informed Consent form for (patient serial number)……

The principal investigator is Dr Susan Mutahi under supervision from Dr Timothy Mwiti and Dr Idris Chikophe on a study looking at the utility of the triage early warning score in the care of critically ill surgical patients presenting through the KNH accident and emergency department. The study is being done under the department of Anaesthesia in the University of Nairobi.

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART 1

Introduction:

I am a student at the University of Nairobi undertaking a Masters degree in Anaesthesia. I am doing a study titled the clinical path of critically ill surgical patients presenting through the KNH accident and emergency department. I would like to explain what the study entails and I would like you to feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to

participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study is due for approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee.

Background of the study

Various studies around the world have been able to show that patients who are at risk of critical illness with poor outcomes such as unplanned admission to the intensive care unit or death usually have notable changes in their vital signs which are routinely recorded in the wards or at presentation to the hospital emergency room. Around the world, various monitoring tools have been developed to better capture such high risk patients, whereby the tools use a scoring system based on the patient's vital signs and when a certain score is reached, a special team is called to review such patients and appropriate action is taken.

Here at KNH, at the accident and emergency department, we have a specialized tool that is used to sort out the large number of patients presenting at the department. This process of sorting patients is called triage, whereby the patients who require the most urgent care are identified first and given the required care. The tool used at KNH A&E is called The South African Triage Scale, and it has a scale of 0 to 17 and patients are scored according to their summation in vital signs. Patients with a score of 7 and above are classified as emergency (colour code red) while those with score 5 or 6 are very urgent (colour code orange) while score of 3 or 4 are urgent (color code yellow) and score below 3 are routine (colour code green)

Once triaged, the patients are given care according to priority.

Purpose of the study ?

The monitoring of critically ill patients in the surgical wards remains an unexplored area in KNH. We wish to find out how the critically ill patients progress in the surgical wards once they present through the A&E. A component of the triage tool used at A&E called the triage early warning

score will be used to monitor these patients and aid in establishing the gaps in management of critically ill surgical patients and hopefully change these practices and implement the use of these monitoring tools.

Risks

The study poses no risk to the participant and all information given will be treated with utmost confidentiality.

Benefits

The study will improve patient management and follow up because with the implementation of this triage tool, categorization of patients according to the severity of their illness will help the ward staff prioritise care for the patients.

Participant selection

We invite all patients that have been triaged at the A&E and are classified as emergency and very urgent to participate in the study.

Voluntary Participation

Your participation in this research is entirely voluntary as such no remuneration or compensation will be offered to the participants of the study. Whether you choose to participate or not, all the services you receive at this hospital will continue and nothing will change. If you choose to participate in this research project, no extra cost will be incurred.

Procedures and protocol

Description of the process

In this study, we shall be recruiting the patients who have been categorized as 'emergency' and 'very urgent' which is done using the triage tool at the A&E. Once categorized, these patients' vital signs shall be taken every 4 hours and recorded and their general status shall be assessed as well for the 72 hours that the study shall be going on, these patients shall be followed up to where they shall be dispatched from the A&E department

This follow up shall be done by trained research assistants who shall be taking the vital signs of the participants and alerting the medical staff in the ward of any changes in the participant's condition that would warrant review by a senior medical staff such as the ward consultant or a specialized review team from the intensive care unit.

Confidentiality

This research will improve follow up and management of patients deemed as critically ill. We will not be sharing the identity of those participating in the research. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up. It will not be shared with or given to anyone except the department of Anaesthesia in the University of Nairobi.

Right to Refuse

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment in any way. You will still have all the benefits that you would otherwise have at KNH.

This proposal has been reviewed and approved by the department of Anaesthesia and the Ethics committee in Kenyatta National Hospital, which is a committee whose task it is to make sure that research participants are protected from any harm.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent **Serial Number: _____**

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it .Questions that I have asked have been answered to my satisfaction. I _____consent voluntarily to participate as a participant in this research.

Name of Participant (initials)_____ Signature of Participant_____

Researchers: Dr Susan Mutahi ……. Signature _____

Date _____

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

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Appendix II (b) Consent Form (Swahili)

IDHINI

Jina la utafiti: Matumizi ya cheti cha Triage Early warning score katika matibabu ya Wagonjwa Wa Upasuaji Walio Na Shida Dharura Wanapitia Katika Chumba Cha Ajali Na Dharura Katika Hospitali Kuu Ya Kenyatta

FOMU YA IDHINI YA (nambari ya siri ya mgonjwa)……

Mpelelezi mkuu ni Daktari Susan Mutahi chini ya usimamizi wa Daktari Timothy Mwiti na Daktari Idris Chikophe katika utafiti wa matumizi ya cheti cha Triage Early warning score katika matibabu ya wagonjwa wa upasuaji walio na shida dharura wanapitia katika chumba cha ajali na dharura katika hospitali kuu ya Kenyatta

. Utafiti utafanyika chini ya Idara ya Nusu Kaputi katika Chuo Kikuu cha Nairobi.

Hi fomu ya idhini ina sehemu mbili:

- Sehemu ya Maelezo (kukuelezea zaidi kuhusu utafiti)
- Shahada ya Idhini (sahihi ikiwa umekubali kujihusisha na utafiti huu)

SEHEMU YA 1

Maelezo

Mimi ni mwanafunzi katika chuo kikuu cha Nairobi, ninasomea shahada kuu kwenye Idara ya Nusu kaputi. Ningependa kukualika kushiriki katika utafiti wa matukio ambayo wagonjwa wa upasuaji walio na shida dharura wanapitia baada ya kuonekana katika chumba cha ajali na dharura katika hospitali Kuu ya Kenyatta. Tafadhali uliza maswali ukiwa na utata wowote kabla ya kushiriki katika utafiti huu.

Usuli wa utafiti

Utafiti uliofanywa katika taasisi mbalimbali za afya umeonyesha ya kwamba kabla ya wagonjwa kuwa katika hali mahututi, huwa kuna mabadiliko ya kifisiologia kadhaa katika mwili ambayo kulingana na utafiti yanaweza kupatikana mapema. Hospitali ya KNH ina vifaa vinavyotumika katika chumba cha dharura kupata wagonjwa hawa mapema kabla ya hali yao kuzorota. Wakati ambampo mgonjwa anawasisli katika chumba cha dharura pale KNH, wahudumu huwa wanapima ishara muhimu za kifisiologia kama vile shinikizo la damu, kiwango cha moyo kupiga na kiwango cha kupumua na kisha wagonjwa wanatengwa kando kulingana na hali yao. Wagonjwa walio na hali dharura kuliko wengine wanatibiwa kwanza kabla ya wengine. Utafiti huu utahusu waliopatikana kuwa wagonjwa wa dharura kulingana na vipimo vya kifisiologia.

Hatari

Hakuna hatari yoyote itakayotarajiwa utakaposhiriki utafiti huu.

Faida ya utafiti

Utafiti huu utasaidia kuboresha maisha yawagonjwa wanaolozwa kwenye wadi za upasuaji walio na hali dharura ama hali inayo hitaji uangalifu zaidi.

Waanaoalikwa kujihusisha na utafiti

Mtafiti anawakaribisha wagonjwa wote ambao watakuwa wamonekana katika chumba cha dharura na kupatikana kwamba hali yao ni dharura na wanahitaji uangalifu Zaidi.

Kushiriki

Kushiriki utafiti huu utakuwa kwa njia ya kujitolea na kwa hivyo hakuna malipo yoyote atakayolipwa mshiriki wa utafiti huu. Iwapo hungependa kushiriki ,uamuzi huu hautakuathiri kwa njia yoyote iwe matibabu yako au utakavyiohudumiwa.

Maelezo kuhusu mchakato

Iwapo utakubali kushiriki katika utafiti huu, wahudumu watapima ishara za muhimu baada ya kila masaa manne na kuandika katika cheti cha kufanyia utafiti. Kila baada ya kufanya vipimo, iwapo kutakuwa na shida yoyote, daktari aliye kwenye wadi ama daktari wa chumba cha uangalifu zaidi ataelezwa kuhusu halo yako na atakushughulikia kwa dharura.

Usiri

Matokeo ya utafiti huu yatawekwa siri wala hayatapatiwa mtu yeyote asiyehusika na utafiti huu. Zaidi ya hayo badala ya jina la mtoto, numbari zitatumiwa kutambulisha watoto hawa. Matokeo yatazungumziwa na idara ya Nusu kaputi pekee.

Haki ya kutoshiriki

Kushiriki utafiti huu ni kwa kujitolea na iwapo hungependa kushiriki, uamuzi wako utaheshimiwa na pia hautathiri kwa njia yoyote matibabu yako. Bali utaendelea kupokea matibabu na huduma ya hospitali hii kama hapo awali.

Pendekezo hili limeangaliwa na kuidhinishwa na Idara ya Nusu Kaputi ya Chuo kikuu cha Nairobi na kamiti ya maadili ya utafiti katika hospitali ya Kenyatta inayohakikisha kuwa haki za wanaoshiriki utafiti wowote inchini,zinazingatiwa **.** Iwapo utakuwa na swali lolote kumbuka una uhuru kuuliza.

Sehemu Ya II: Shahada ya Idhini

Nambari Maalum;……

Nimesoma maaelezo yote ya utafiti huu au nimesomewa maaelezo haya na nimekuwa na fursa ya kuuliza maswali .Maswali yangu yamejibiwa kadri na matarajio yangu kwa njia ya kuridhisha.Kwahio: _____ ningependa kupeana idhini yangu na pia kujitolea kushiriki kwa utafiti huu .

Kwa maelezo zaidi hata baada ya utafiti huu una uhuru wakuwasiliana na watu wafuatao kupitia anwani na numbari za simu silizoandikwa hapa chini.

Jina: Dkt Susan Mutahi (mpelelezi mkuu)

Nambari ya rununu: 0722 163 292

Barua pepe: suziemutahi@gmail.com

Dkt. Timothy Mwiti

Nambari ya rununu +254 722 366 294

Barua pepe: mtmwiti@gmail.com

Dkt Idris Chikophe

Nambari ya rununu+254 721436926
Barua pepe; idris6664@gmail.com
Nairobi, Kenya.

Kenyatta National Hospital/University of Nairobi Ethics and Research Committee
College of Health Sciences
P. O. Box 19676 00202 Nairobi
Nambari ya simu: (254-020) 2726300-9 Ext 44355
Barua pepe: uonknh erc@uonbi.ac.ke

Appendix III (a): Assent Form (English)

Utility of the Triage Early Warning Score in management of critically ill surgical patients presenting at KNH

Informed Assent Form for _____

This informed assent form is for children above 12 years of age who will be triaged using the triage early warning score at the KNH accident and emergency department and followed up for 72 hours in the surgical wards

The principal investigator is Dr Susan Mutahi under supervision from Dr Timothy Mwiti and Dr Idris Chikophe on a study looking at the utility of the triage early warning score in manafement of critically ill surgical patients at Kenyatta National Hospital. The study is being done under the department of Anaesthesia in the University of Nairobi.

This Informed Assent Form has two parts:

- **Information Sheet (gives you information about the study)**
- **Certificate of Assent (this is where you sign if you agree to participate)**

You will be given a copy of the full Informed Assent Form

Part I: Information Sheet

I am a Student currently doing my Masters in Anaesthesia at the University of Nairobi. I am doing a study looking at utility of the triage early warning score in management of critically ill surgical patients at KNH. Information will be given to you and you may feel free to ask questions before participating in the research.

There may be some words that you do not understand, Please ask me to explain as we go through the information. If you have questions later, you can ask them my contacts are available on this assent form.

Purpose: Why are you doing this research?

The management of critically ill surgical patients at KNH is an area that has not been explored well and it would be crucial to carry out the study that will shed some light on management currently and hopefully change in accordance to the results of the study.

Choice of participants: Why are you asking me?

We want to get some information from children who will be very sick and are at risk of further deterioration with possibility for admission to the critical care unit.

Participation is voluntary: Do I have to do this?

You don't have to be in this research if you don't want to be. It's up to you. If you decide not to be in the research, it is okay and nothing changes.

I have checked with the child and they understand that participation is voluntary _____ (signature)

Procedures: What is going to happen to me?

If you allow us we are going to be taking measurements of your vital signs every 4 hours and monitoring your progress through your stay in the surgical ward for the next 72 hours and noting it down in our charts and involving the medical care staff in the ward in case you need more treatment.

I have checked with the child and they understand the procedures _____(signature)

Risks: Is this bad or dangerous for me?

You will not be in any harm when you take part in this research.

I have checked with the child and they understand the risks and discomforts ____(signature)

Benefits: Is there anything good that happens to me?

Nothing might happen to you, but the information you give us might help us learn more about monitoring and escalation of care in the very sick patients with surgical conditions.

I have checked with the child and they understand the benefits_____ (Signature)

Reimbursements: Do I get anything for being in the research?

Unfortunately there will be no gifts if you choose to participate in the study.

Confidentiality: Is everybody going to know about this?

We will not tell other people that you are in this research and we won't share information about you to anyone who does not work in the research study.

Information about you that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone.

Sharing the Findings: Will you tell me the results?

When we are finished with the research we will not contact you personally to give you the results but you can come find out about the research at the Department of Anaesthesia, University of Nairobi. We will be telling more people, scientists and others, about the research and what we found. We will do this by writing and sharing reports.

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

You do not have to be in this research. No one will be mad or disappointed with you if you say no. It's your choice. You can think about it and tell us later if you want. You can say "yes" now and change your mind later and it will still be okay.

Who to Contact: Who can I talk to or ask questions to?

You can ask me questions now or later. I have written a number and address where you can reach us or, if you are nearby, you can come and see us. If you want to talk to someone else that you know like your teacher or doctor or auntie, that's okay too.

If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Assent **Serial Number……..**

I understand that this research is about finding out the utility of the triage early warning score in management of critically ill surgical patients at KNH and I will be asked a set of questions if I choose to participate in the research.

I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

OR

I do not wish to take part in the research and I have <u>NOT</u> signed the assent below._____ (initialled by child/minor)

<u>Only if child assents:</u>

Print name of child _____

Signature of child: _____ Date:_____

If illiterate:

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

Print name of witness (not a parent) _____ AND Thumb print of participant

Signature of witness _____

Date _____

I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Name of researcher: DR SUSAN MUTAHI

Signature of researcher_____ Date_____

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands the purpose and procedure of the study

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.

Name of Researcher: DR SUSAN MUTAHI

Signature of Researcher _____ Date _____

Copy provided to the participant _____(initialed by researcher)

Parent/Guardian has signed an informed consent: Yes_____ No_____

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Name: Dr Susan Mutahi (primary investigator)

Mobile number: 0722 163 292

Email address: suziemutahi@gmail.com

Dr. Timothy Mwiti
University of Nairobi, Kenya
Tel +254 722 366 294
Email address: mtmwiti@gmail.com

Dr Idris Chikophe
Kenyatta National Hospital
Tel +254 721436926
Email address: idris6664@gmail.com
Nairobi, Kenya.

Kenyatta National Hospital/University of Nairobi Ethics and Research Committee
College of Health Sciences
P. O. Box 19676 00202 Nairobi
Tel. (254-020) 2726300-9 Ext 44355
E-mail: uonknh_erc@uonbi.ac.ke

Appendix III (b): Assent Form (Swahili)

FOMU YA KUTIWA SAINI NA WATOTO

.**Utafiti wa Matumizi ya cheti cha Triage Early warning score katika matibabu ya Wagonjwa Wa Upasuaji Walio Na Shida Dharura Wanapitia Katika Chumba Cha Ajali Na Dharura Katika Hospitali Kuu Ya Kenyatta**

Fomu ya kutiwa saini na watoto _____

Fomu hii ni ya kutiwa saini na watoto wenye umri wa miaka saba na juu wanaopitia katika chumba cha ajali na dharura katika hospitali kuu ya Kenyatta. Mpelelezi mkuu ni Daktari Susan Mutahi chini ya usimamizi wa Daktari Timothy Mwiti na Daktari Idris Chikophe utafiti wa kuangalia kama cheti cha Triage early warning score kinaweza kutumika katika matibabu ya wagonjwa wa upasuaji walio na shida dharura . Utafiti utafanyika chini ya Idara ya Nusu Kaputi katika Chuo Kikuu cha Nairobi.

Hi fomu ya kutiwa saini na watoto ina sehemu mbili:

- **Sehemu ya Maelezo (kukuelezea zaidi kuhusu utafiti)**
- **Shahada ya Kutiwa saini na watoto (sahihi ikiwa umekubali kujihusisha na utafiti huu)**

Utapewa nakala ya maalezo ya utafiti huu.

SEHEMU YA I: Maelezo

Mimi ni mwanafunzi katika chuo kikuu cha Nairobi, ninasomea shahada kuu kwenye Idara ya Nusu kaputi. Ningependa pamoja na wasimamizi wangu kutafiti kama cheti cha Triage early warning score kinaweza kutumika katika matibabu ya wagonjwa wa upasuaji walio na shida dharura. Kando na haya utapewa maalezo zaidi kuhusu mada na pia una uhuru wa kuuliza maswali yoyote ili kuelewa uafiti huu zaidi.

Nia

Uangalifu wa wagonjwa walio na shida ya dharura au walnao elekea kuwa hali mahututi ni eneo ambalo utafiti wa kutosha haujafanywa. Kupitia utafiti wangu tutaweza kujua kama uangalifu

Zaidi wa ishara muhimu za kufisiologia unaweza kukinga kuzorota Zaidi kwa hali ya wagonjwa wa upasuaji walio na shida ya dharura umetosha ama kuna njia tunaweza tia bidii.

Hatari

Hakuna hatari yoyote itakayotarajiwa utakaposhiriki utafiti huu.

Nimethibitisha kuwa mtoto ameelewa ya kwamba hakuna hatari yoyote ile itayomkabili _____ (saini)

Faida ya utafiti

Utafiti huu utasaidia kuboresha maisha ya wagonjwa wetu wa shida za upasuaji na matibabu yao.

Nimethibitisha kuwa mtoto ameelewa faida ya utafiti _____ (saini)

Waanaoalikwa kujihusisha na utafiti

Mtafiti anawakaribisha wagonjwa wote wa upasuaji watakaopitia katika chumba cha ajali na dharura katika Hospitali ya Taifa Ya Kenyatta .

Kushiriki

Kushiriki utafiti huu utakuwa kwa njia ya kujitolea na kwa hivyo hakuna malipo yoyote atakayolipwa mshiriki wa utafiti huu. Iwapo hungependa kushiriki, uamuzi huu hautaathiri kwa njia yoyote matibabu yako au utakavyiohudumiwa.

Nimethibitisha kuwa mtoto ameelewa ya kwamba kujihusisha na hii utafiti ni kwa njia ya kujitolea _____ (saini)

Maelezo kuhusu mchakato

Iwapo utakubali kushiriki utapewa kama wapelelezi, tutapima ishara muhimu za mwili kama vile shindikizo la damu na kiwango cha moyo kudunda na joto la mwili kisha tutafuatilia hali yako katika wadi utakayo pelekwa..

Nimethibitisha kuwa mtoto ameelewa maelezo kuhusu mchakato_____ (saini)

Wakati utakaotumika

Kwa ujumla,utafiti huu utachukua siku tatu (masaa 72).Kwa wakati huu, tutapima ishara muhimu za mwili kwa kila masaa manne na kuona unavyo endelea katika wadi na iwapo unahitaji matibabu Zaidi, wahudumu wataelezwa wakushughulikie.

Usiri

Matokeo ya utafiti huu yatawekwa siri wala hayatapatiwa mtu yeyote asiyehusika na utafiti huu. zaidi ya hayo badala ya jina la mtoto, numbari zitatumiwa kutambuliwa watoto hawa.Matokeo yatazungumziwa na idara ya afya ya watoto pekee wala sio mtu mwingine.

Haki ya kutoshiriki

Kushiriki kwa utafiti huu ni kwa kujitolea na iwapo hungependa kushiriki,uoamuzi wako utaheshimiwa na pia hautathiri kwa njia yoyote matibabu yako. Bali utaendelea kupokea matibabu na huduma ya hospitali hii kama hapo awali.

Pendekezo hili limeangaliwa na kuidhinishwa na Idara ya nusu kaputi ya Chuo kikuu cha Nairobi na kamiti ya maadili ya utafiti katika hospitali ya Kenyatta inayohakikisha kuwa haki za wanaoshiriki utafiti wowote inchini,zinazingatiwa .

Iwapo utakuwa na swali lolote kumbuka una uhuru kuuliza.

SEHEMU YA II: Shahada ya Kutiwa Saini na Watoto Nambari Maalum:_____

Nimesoma maaelezo yote ya utafiti huu au nimesomewa maaelezo haya na nimekuwa na fursa ya kuuliza maswali ambayo yamejibiwa kadri na matarajio yangu kwa njia ya kuridhisha.Kwahio ningependa kupeana saini langu na pia kujitolea kushiriki kwa utafiti huu .

Nakubali kujihusisha na utafiti huu.

AMA

Si kubali kujuhusisha na utafiti huu na sijatia saini lolote._____ (alama ya mshiriki)

<u>Moto akikubali:</u>

Jina la mtoto: _____

Saini la mtoto: _____

Tarehe:_____

Iwapo mtato hawezi akasoma:

Nimeona na ninaweza thibitisha ya kwamba mtoto amesomewa yaliyo kwenye hii fomu ya kutiwa saini na mtoto, na mtoto mwenyewe ameweza kuuliza maswali atakayo. Na thibitisha ya kwamba mtoto amekubali kwa hiari yake kushirikiana na hii utafiti.

Jina la shahidi (isiwe mzazi): _____ NA Alama ya Kidole ya Mshiriki

Saini la shahidi:_____

Tarehe: _____

Nememsomea ama nimeona na ninaweza thibitisha ya kwamba mtoto amesomewa yaliyo kwenye hii fomu ya kutiwa saini na mtoto, na mtoto mwenyewe ameweza kuuliza maswali atakayo. Na thibitisha ya kwamba mtoto amekubali kwa hiari yake kushirikiana na hii utafiti.

Jina la mpelelezi: DR SUSAN MUTAHI

Saini ya mpelelezi: _____

Tarahe: _____

Nakala imepewa kwake mshiriki _____(alama ya mpelelezi)

Mzazi/Mgarini anaitia saini Shahada ya Idhini : Ndiyo_____ Hapana_____

Kwa maelezo Zaidi hata baada ya utafiti huu una uhuru wakuwasiliana na watu wafuatao kupitia anwani na numbari za simu silizoandikwa hapa chini.

Jina: Dkt Susan Mutahi (mpelelezi mkuu)

Nambari ya rununu: 0722 163 292

Barua pepe: suziemutahi@gmail.com

Dkt. Timothy Mwiti

Nambari ya rununu +254 722 366 294

Barua pepe: mtmwiti@gmail.com

Dkt Idris Chikophe

Nambari ya rununu+254 721436926

Barua pepe: idris6664@gmail.com

Nairobi, Kenya.

Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

College of Health Sciences

P. O. Box 19676 00202 Nairobi

Simu. (254-020) 2726300-9 Ext 44355

Barua pepe: uonknh_erc@uonbi.ac.ke

Appendix IV: Application for Waiver of Consent

APPLICATION FOR WAIVER OF CONSENT AND WAIVER OF DOCUMENTATION OF CONSENT

STUDY TITLE: UTILITY OF THE TRIAGE EARLY WARNING SCORE IN MANAGEMENT OF CRITICALLY ILL SURGICAL PATIENTS

PRINCIPAL INVESTIGATOR: DR SUSAN MUTAHI

INSTITUTION AFFILIATION: UNIVERSITY OF NAIROBI, DEPARTMENT OF ANAESTHESIA

I would like to apply for the waiver of consent and waiver of documentation of consent for the following reasons:

Critical illness is a life threatening condition that involves one or more organ systems with risk of significant mortality and morbidity. Such patients may present with a very low level of consciousness or severe confusion with inability to understand what is going on around them nor understand verbal instruction. . Patients with critical illness require to be attended to urgently, especially those with impending signs of deterioration to severe morbidity and cardiac arrest.

The urgency for the provision of life saving medical care for the critically ill surgical patient provides insufficient time and opportunity to locate and obtain consent from each subject's legally authorized representative.

In addition, the research will involve taking of patients' vital signs with escalation of care where necessary, hence posing no more than minimum risk of harm to the patient. The waiver of consent shall not adversely affect the rights and welfare of the participants. Participation in the research shall be beneficial in that it will help in the recommendation for a standardised decision making tool that shall be used in the care of critically ill surgical patients. Also, the research

involves no procedures for which written consent is normally required outside of the research context.

My responsibilities as the primary investigator will include:

i. To try and locate the patient's legally authorized representative (LAR) or family member or next of kin to determine whether they object to the subject's participation in the research.

ii. To avail detailed information about the research and obtain informed verbal consent from the legally authorized representative or family member or next of kin where possible. If the LAR or next of kin cannot be physically present, it shall be indicated that consent was obtained via the phone by the primary investigator.

iii. To ensure that the patient's confidentiality is maintained by protecting identifiers from improper use and disclosure.

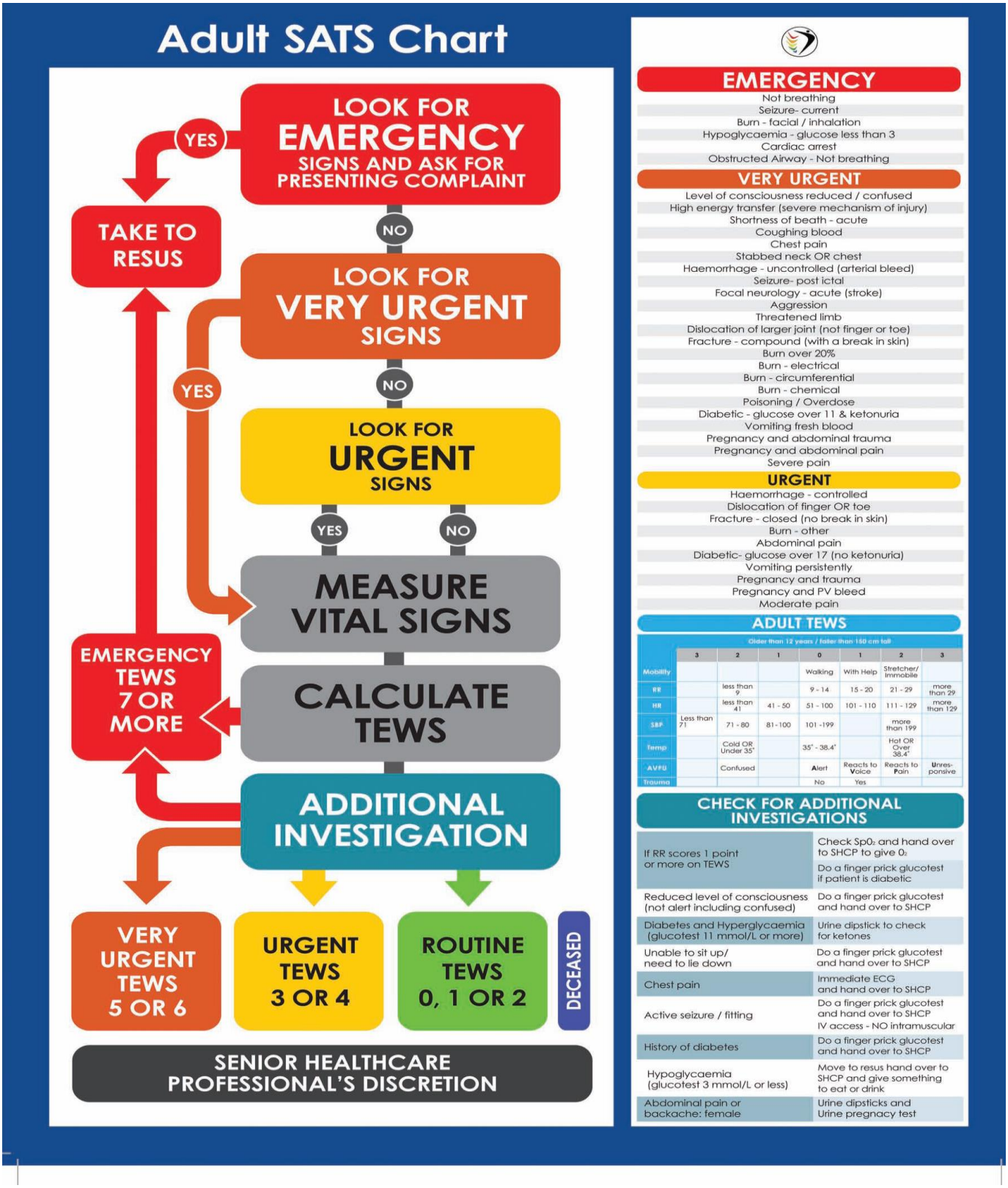
Appendix V: The Modified Early Warning Score

Physiological parameter	3	2	1	0	1	2	3
RR		Less than 9		9-14	15-20	21-29	>29
HR		<41	41-50	51-100	101-110	111-129	>129
SBP	<71	71-80	81-100	101-199		>199	
TEMP		below 35^{o}	$35.1-36^{o}$	$36.1-38.^{0}$	$38.1-38.5^{o}$	Above 38.6^{o}	
NEUROLOGICAL STATE				**A**lert	Reacts to **V**oice	Reacts to **P**ain	**U**nresponsive
TOTAL							

Appendix VI: The Triage Early Warning Score

	3	2	1	0	1	2	3
MOBILITY				walking	With help	Stretcher/immobile	
RR		Less than 9		9-14	15-20	21-29	>29
HR		<41	41-50	51-100	101-110	111-129	>129
SBP	<71	71-80	81-100	101-199		>199	
TEMP		Cold or below 35^{o}		35-38.4^{0}		Hot or over 38.4^{o}	
AVPU				**A**lert	Reacts to **V**oice	Reacts to **P**ain	**U**nresponsive
TRAUMA				NO	YES		
TOTAL							

Appendix VII: The Adult SATS Chart



Appendix VIII: Work Plan

Proposal development	Jan 2018
Proposal writing	Feb-March 2018
Discussion with supervisors	April –May 2018
Presentation to department	June 2018
Seeking ethical approval	July – October 2018
Data collection	February - April 2019
Data analysis	April - May 2019
Discussion of findings with supervisors	May 2019
Presentation of study findings	June 2019

Appendix IX: Budget

ITEM	COST
Statistician	40,000
Trained Research assistants (2)	80,000
Stationary	15,000
Bp machine (1 in number)@6,500	6,500
Thermometers (1 in number) @2500	2,500
Pulse oximeter(1 number)@3000	3,000
Printing and binding	10,000
KNH/UON ERC	2,000
SUBTOTAL	159,000
10% Contingency	15,900
GRAND TOTAL	**174,900**