PERFORMANCE OF PEDIATRIC EARLY WARNING SCORE AND PHYSICIAN GESTALT IN PREDICTING ADVERSE EVENTS AMONG PAEDIATRIC PATIENTS PRESENTING TO THE EMERGENCY MEDICINE DEPARTMENT OF A TERTIARY HOSPITAL IN TANZANIA

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By

Irene Aloyce Kindole

Dissertation Submitted in (Partial) Fulfillment of the Requirement for the Degree of Master of Medicine (Emergency Medicine) of

Muhimbili University of Health and Allied Sciences
October, 2024

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation titled; **"Performance of Pediatric Early Warning Score and Physician Gestalt in Predicting Adverse Events Among Paediatric Patients Presenting to the Emergency Medicine Department of a Tertiary Hospital in Tanzania",** in (partial) fulfillment as a requirement for the degree of Master of Medicine (Emergency Medicine) of Muhimbili University of Health and Allied Sciences.

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DECLARATION AND COPYRIGHT

I, Irene Aloyce Kindole, declare that this **dissertation** is my original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

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ABSTRACT

Background: Critically ill children are highly susceptible to adverse events if prompt interventions are not administered due to the variability of their vital signs. To anticipate such events, healthcare providers use a Pediatric Early Warning Score. In resource-limited countries, it is uncertain how accurately clinician gestalt predicts adverse events.

Aim: To evaluate the performance of the Pediatric Early Warning Score and clinician gestalt in predicting adverse events in pediatric patients who are triaged as emergency and priority.

Methodology: This prospective cohort study involved children aged 28 days to 14 years who presented to the Emergency Department at Muhimbili National Hospital from May to June 2024. Physicians estimated the likelihood of adverse events (e.g., intubation, ventilation, ICU admission, or death) using clinical gestalt, while the Pediatric Early Warning Score (PEWS) was recorded for all patients. Patients were monitored until their outcome was determined. A cut-off probability of ≥70% for clinician gestalt, based on Youden's index, and a PEWS score of ≥3 were used. Sensitivity, specificity, predictive values, and area under the curve (AUC) were calculated to assess the accuracy of both methods in predicting adverse events.

Results: A total of 250 children were enrolled. Physician gestalt had an area under the curve of 0.964 (95% CI, 0.936-0.992). An optimal cut-off probability of ≥70% predicted the occurrence of adverse events in 87.8% of patients and correctly identified those who did not have adverse events 94.8% of the time. Pediatric Early Warning Score could detect the occurrence of adverse events with a sensitivity of 80.0% and identify those who did not have adverse events in 79.5% of cases with area under the curve=0.869 (95% CI 0.809 to 0.930). A comparison of the two tests yielded a statistical significance in their specificity.

Conclusion: Physician gestalt was significantly associated with adverse events occurrence prediction than Pediatric Early Warning Score. However, a Pediatric Early Warning Score can also be used in the Emergency Department.

TABLE OF CONTENTS

CERTIFICATION i
ACKNOWLEDGEMENT iii
ABSTRACT iv
TABLE OF CONTENTS v
LIST OF TABLES viii
LIST OF FIGURES ix
LIST OF ABBREVIATIONS x
DEFINITION OF TERMS xi
CHAPTER ONE 1
1.0 INTRODUCTION 1
1.1 Background 1
1.2 Problem Statement 3
1.3 Conceptual Framework 3
1.4 Rationale 5
1.5 Research question 5
1.5.1 Specific Research Questions 5
1.6 Objectives 6
1.6.1 Broad objective 6
1.6.2 Specific Objectives 6
CHAPTER TWO 7
2.0 LITERATURE REVIEW 7
2.1 Scope of the problem 7
2.2 Predicting deterioration of critically ill children 8
2.3 PEWS score of the critically ill pediatrics 9
2.4 Physician likelihood of predicting adverse events 10
2.5 Comparison of clinical Gestalt and PEWS performance 11
CHAPTER THREE 13
3.0 METHODOLOGY 13

3.1 Study Design 13
3.2 Study Setting 13
3.3 Target population 14
3.4 Accessible population 14
3.5 Study population 14
3.6 Sampling design 14
3.7 Study Subject 14
3.7.1 Inclusion criteria 14
3.7.2 Exclusion criteria 14
3.8 Variable of interest 14
3.9 Outcome variables 15
3.10 Sample size estimate 15
3.11 Data Management 16
Screening and enrollment 16
3.12 Standardized data collection tool 16
3.13 Preliminary evaluation of the tool 16
3.14 Data Analysis 17
3.15 Ethical Consideration 17
CHAPTER FOUR 19
4.0 RESULTS 19
4.1 Social Demographic characteristics of pediatric patients triaged to resuscitation During the study period 19
4.2 Clinical characteristics of the pediatric patients triaged to resuscitation 21
4.3 Predictive ability of Physician Gestalt on the occurrence of adverse events among pediatric patients triaged to resuscitation 23
4.4 Physician gestalt prediction on the occurrence of an adverse event 24
4.5 PEWS prediction on the occurrence of adverse events among pediatric patients triaged to resuscitation 25
4.6 PEWS prediction on the occurrence of an adverse event pediatric patients triaged to

resuscitation 26
4.7 Comparisons of ROC between PEWS and physician gestalt to predict adverse events among pediatric patients triaged to resuscitation 27
4.8 Comparison of Physician Gestalt and PEWS on Predicting Adverse Events among pediatric patients triaged to resuscitation 28
CHAPTER FIVE 30
5.0 DISCUSSION 30
CHAPTER SIX 33
6.0 STRENGTH, LIMITATIONS, CONCLUSION AND RECOMMENDATIONS 33
6.1 Strength 33
6.2 Limitations 33
6.3 Conclusion 33
6.4 Recommendations 34
REFERENCES 35
APPENDICES 37
Appendix 1: Data Collection Tool 37
Appendix 2: Case Report Form 39
Appendix 3: Consent Form – English Version 42
Appendix 4: Consent Form – Swahili Version 44
Appendix 5: Form of Assent (Swahili) 46
Appendix 6: Approval for ethical clearance 48
Appendix 7: Introduction letter 50
Appendix 8: Permission to collect data at MNH 51

LIST OF TABLES

Table 1: Socio-demographic characteristics of the pediatric patients triaged to resuscitation..20

Table 2: Clinical characteristics of the pediatric patients triaged to resuscitation.....22

Table 3: Diagnostic performance of physician gestalt in predicting adverse events among pediatric patients triaged to resuscitation 23

Table 4: Diagnostic performance of physician gestalt in predicting adverse events among pediatric patients triaged to resuscitation 24

Table 5: Diagnostic performance of PEWS in predicting adverse events 25

Table 6: Diagnostic performance of PEWS in predicting adverse events among pediatric patients triaged to resuscitation 26

Table 7: Comparison of Physician Gestalt and PEWS among pediatric patients triaged to resuscitation.....28

Table 8: Comparisons of predictive values and diagnostic likelihood ratios between PEWS and physician gestalt to predict adverse events among pediatric patients triaged to resuscitation..28

Table 9: Adverse events occurrence.....29

LIST OF FIGURES

Figure 1: Conceptual framework....4

Figure 2: Flow diagram....19

Figure 3: Clinical characteristics of the pediatric patients triaged to resuscitation....21

Figure 4: ROC of Physician clinical gestalt of prediction of adverse events....25

Figure 5: ROC of PEWS for prediction of adverse events....27

Figure 6: ROC curve comparing physician gestalt and PEWS on prediction of occurrence of an adverse event....27

LIST OF ABBREVIATIONS

Citbi	clinically important for traumatic brain injury
CFR	Case Report form
ED	Emergency department
EMD	Emergency Medicine Department
ESI	Emergency Severity index
GCS	Glasgow coma scale
HDU	High dependent Unit
ICU	Intensive Care Unit
IRB	Institutional Review Board
MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Sciences
Npv	Negative predictive value
PEWS	Pediatric Early Warning score
PICU	Pediatric intensive care unit
Ppv	Positive predictive value
Redcap	Research and electronic data capture
SPSS	Statistical package for social sciences

DEFINITION OF TERMS

Critical illness is a condition characterized by malfunctioning of vital organs which can lead to death if care is not given in time.

Pediatric population -This included all patients aged twenty-eight days to fourteen years who attended the pediatric emergency medicine department of Muhimbili National Hospital.

Triage is a process of grouping patients according to the degree of their injuries and consequently providing treatment depending on the priority.

Critically ill pediatric patient- This included all pediatric patients triaged as priority and emergency who attended the emergency medicine department of Muhimbili National Hospital.

Clinical deterioration is the physiological decompensation that occurs when a patient experiences worsening conditions or an acute onset of a serious physiologic disturbance.

Adverse events are the negative outcomes that happen to the patient in the course of illness which can either be preventable or unpreventable**.**

Pediatric Early Warning Score identifies pediatric patients at risk for clinical deterioration. Originally developed to provide a practical and objective method to identify pediatric inpatients at risk for cardiac arrest.

The Pediatric Intensive Care Unit Is the unit of the hospital that provides the highest quality of care to pediatrics, It's the ICU designated for pediatrics only.

High-dependency Unit is the unit in the hospital where the care level of patients is between the levels found in the ICU and the general ward.

Clinical gestalt is the ability to use the clinical history facts combined with physical examination findings to make a clinical decision**.**

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

In low- middle income countries, where pediatric critical care is not well developed, the number of seriously ill children is substantial**.** Patients most frequently arrive at the hospital with any number of the following: breathing difficulties, central nervous system disturbances, respiratory failure, or metabolic disorders, which are usually associated with poor outcomes**.** A study that was done in Nigeria at the University College Hospital of Ibadan in 2016 found that 25.4% of all critically ill children admitted to hospitals in developing countries die within the first 48 hours. (1) These deaths can be prevented if there is early recognition of deterioration and interventions are done appropriately and at the right time.

Globally, failure to identify and intervene with the pediatric population experiencing clinical deterioration is a source of unintended harm, including prolonged hospital stays or readmissions, disability, and death. (2)

In the emergency department, the ability to identify deterioration or risk in the moment before an adverse event occurs is critical to avoiding this unintended harm. (2) However, early recognition of deterioration can be difficult in the pediatric population, especially in the emergency department. These challenges are due to age-related variations in normal vital sign parameters, modifications to physiological parameters resulting from causes other than disease or damage (medication, fear, pain, anxiety), and compensatory behaviors observed in critically ill pediatric patients that conceal the extent of the decline. (2)

A 5-component clinical severity score called the Pediatric Early Warning Score is used in inpatient settings for identifying patients who require intensive care and are at risk of deteriorating clinically. Its sensitivity and specificity have a wide range, depending on the settings applied. At the Emergency Department, PEWS has been accepted to be used because it supports early diagnosis, accurately estimates the severity of illness, and improves communication. On top of that, it might maximize early recognition of clinical deterioration and provide a structured approach to the reassessment and escalation of care in the

emergency department. (2) Recently conducted research from a Dutch pediatric emergency department assessed the reliability of several PEWS scores. Ten distinct established PEWS were examined by the authors in the ED, and it was found that each PEWS had a weak to medium discriminative ability for anticipating hospitalization and a medium to high discriminative ability for predicting ICU admission. (3) Bearing this in mind one cannot help but wonder if PEWS is at all the best tool to determine the clinical deterioration in ED settings or if clinical gestalt is more reliable.

Clinical gestalt is defined as an intuitive approach to making choices and is essentially pattern detection. As experienced physicians are better at recognizing patterns, the evidence currently implies that experience does favorably improve decision-making accuracy. (4) Lack of standardized evidence-based assessment tools in detecting patient deterioration at ED, most physicians in resource-limited settings use their clinical gestalt, which is subjective and at large affected by many factors including years of experience, past training, and workload at ED.

Therefore, when it comes to giving the best patient care, clinical gestalt alone may not be enough. Hence, the objective of this study is to compare the PEWS against physician clinical gestalt in the prediction of adverse event occurrence among critically ill pediatricians at the emergency department. Comparing these two entities will guide whether there is a need to introduce PEWS into the emergency department compared to relying on the current clinical framework to improve the care of critically ill pediatricians. It will also shine a light on the fact that the clinical decision rules and scores are not here to remove the capacity of the clinicians but rather serve to improve patient care.

1.2 Problem Statement

Generally, lengthy hospital stays, readmissions, disabilities, or even fatalities can result from a failure to recognize and treat pediatric patients who are undergoing clinical deterioration. A lack of standardization in the monitoring of critically ill pediatric patients and the diversity of provider expertise and experience can lead to disparities in care.

Worldwide, hospitals are increasingly using scoring algorithms to identify the sickest patients or those who could get worse as a standard of care. This has not been the case in most of the resource-limited settings, including Tanzania; hence, using PEWS in ED could help reduce cognitive influences, biases, and distractions that affect decision-making and hence improve outcomes. Alternatively, clinician gestalt is as good as or superior to PEWS in predicting the occurrence of adverse events in critically ill pediatrics, which would make a difference in the care of the patients. Therefore, this study compared the performance of PEWS versus clinician gestalt in predicting the occurrence of adverse events among pediatric patients presenting to the ED.

1.3 Conceptual Framework

Critical patients who come to the emergency department have a high risk of deterioration. Initially, triage helps categorize patients according to their acuity. However, their condition can change while in the ED. Identification of those patients that are starting to deteriorate to prevent the occurrence of adverse events can be done using either clinician gestalt or validated scores (PEWS) which can be widely influenced by the pre-morbid condition of the child.

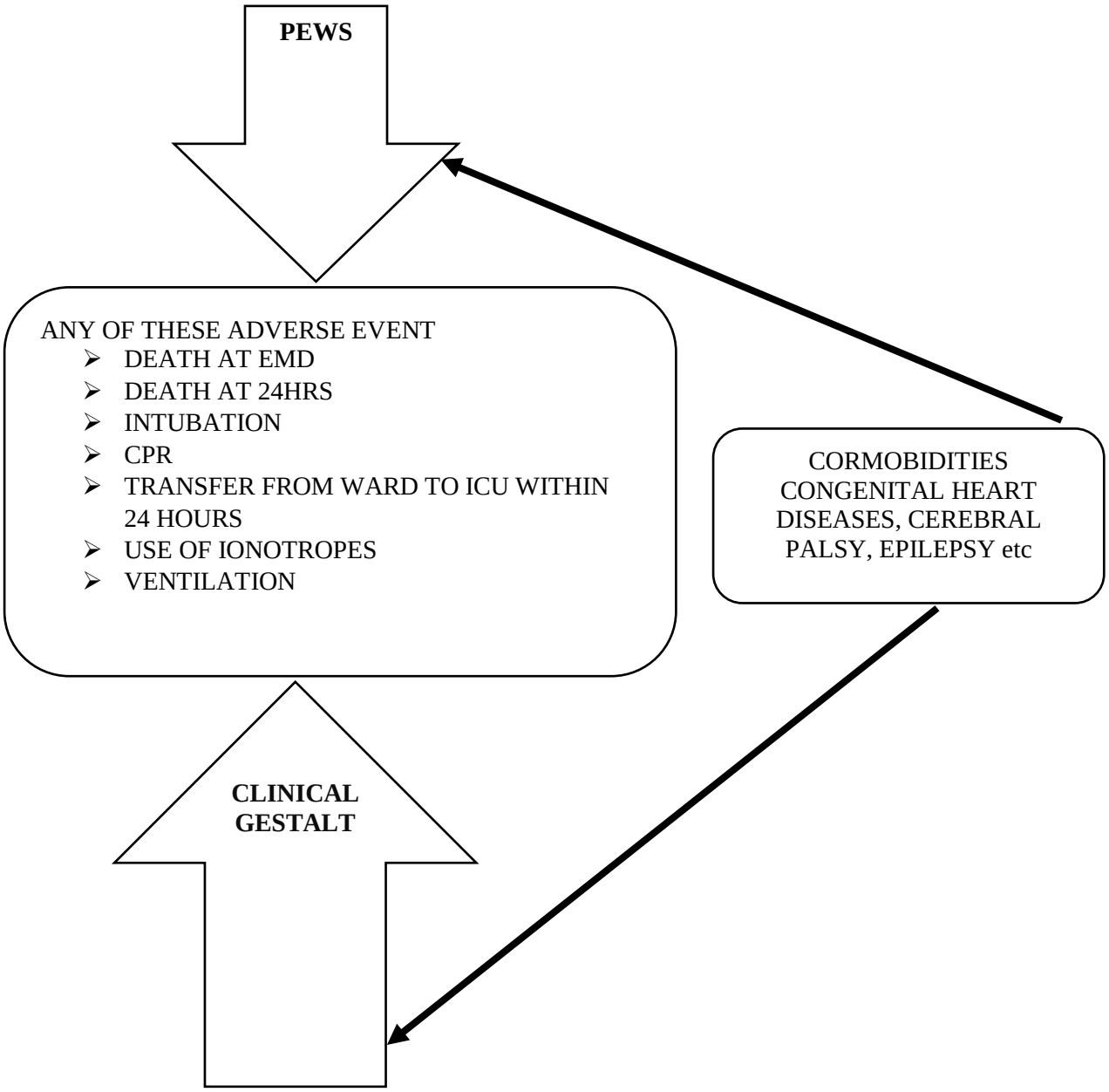


Figure 1: Conceptual framework

1.4 Rationale

Clinical deterioration in children is associated with increased risks of mortality and morbidity. If pediatric patients at risk of deterioration can be identified early, prompt assessment and action can improve survival and long-term outcomes.

Historically, identification of these high-risk patients can be achieved by either having a standardized assessment score that can be used to assess the patients over time or by having clinicians who are vigilant with a high suspicion index to detect even subtle changes that occur and act accordingly.

By comparing the performance of these two approaches, this study will help to identify which one is more reliable and hence provide a road map to the best method to be used in improving patient safety in the ED.

1.5 Research question

Among critically ill pediatric patients in the emergency department; What is the performance of PEWS and clinician gestalt in predicting 24-hours adverse events?

1.5.1 Specific Research Questions

1 Among pediatric patients triaged to resuscitation at ED MNH, what are their clinical profiles in 24 hours?
2 For pediatric patients at ED-MNH who have been triaged for resuscitation, what are their PEWS scores in 24 hours?
3 For each pediatric patient at ED-MNH who has been triaged to resuscitation, what is the doctor's estimate of the probability of adverse events in 24 hours?
4 In pediatric patients triaged to resuscitation at ED-MNH, what is the performance of PEWS in predicting adverse events in 24 hours?
5 In pediatric patients triaged to resuscitation at ED-MNH, how well do PEWS and clinician gestalt perform in terms of anticipating adverse events in 24 hours?

1.6 Objectives

1.6.1 Broad objective

To compare the performance of PEWS and clinician gestalt in predicting adverse events among pediatric patients triaged to resuscitation at ED-MNH in 24 hours

1.6.2 Specific Objectives

1. To describe the clinical profile of pediatric patients triaged to resuscitation at ED-MNH in 24 hours
2. To describe the PEWS, the score of pediatric patients triaged to resuscitation at ED-MNH in 24 hours
3. To determine physician estimate of the likelihood of adverse events for each pediatric patient triaged to resuscitation at ED-MNH in 24 hours
4. To determine the performance of PEWS in predicting adverse events of pediatric patients triaged to resuscitation at ED-MNH in 24 hours
5. To compare the performance of PEWS and clinician gestalt in predicting adverse events of pediatric patients triaged to resuscitation at ED-MNH in 24 hours

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Scope of the problem

Critical care remains in its early stages in many low-income countries, making the burden of the outcomes very high. Severe infections like pneumonia, malaria, and diarrhea are the primary causes of critical illness. (5)

An analysis conducted in the past at Thailand's Urban University Hospital emergency department found that among the children who were seen, 0.6% were categorized as critical, 37.6% as emergency, and 52.5% as acute. Symptoms of acute gastroenteritis, acute febrile sickness, and upper respiratory tract infections were prevalent. Typically, 44% of patients attended the ED in the evening, from 4 p.m. to midnight; the remaining 40% visited in the morning, from 8 a.m. to 4 p.m.; and 16% visited overnight, from midnight to 8 a.m. (6)

Sub-Saharan Africa was home to half of the world's under-five mortality cases in 2017. In Sub-Saharan Africa, 1 in 13 children died before the age of five, in contrast to high-income countries where 1 in 185 children died before the age of five. (7) . Compared to Europe, the risk of death for children is fifteen times higher. The majority of these children die from curable and preventable conditions such as neonatal sepsis, pneumonia, diarrhea, and other birth-related problems. This highlights the burden of critically ill pediatrics. (7)

Giving children who are seriously ill appropriate and timely care is essential for the best results. A prospective cohort study conducted at the pediatric emergency department in Swiss revealed that central nervous system illnesses (26.2%), trauma (25.1%), and respiratory problems (24.2%) were the most common presentations of critically ill patients. Most critically ill patients presented during the day and evening shifts (83%); the rest of them presented during the night. The distribution between the weekdays and weekends was even.(8)

In a study done in Nigeria at the University College of Ibadan to assess the needs of critically ill pediatric patients, it was found that of 391 pediatric medical emergencies admitted, 165 (42.4%) were classified as critically ill, with some having more deranged parameters than

others. (1) The majority of them had respiratory issues, followed by central nervous system issues, and lastly, cardiovascular issues. Of the critically ill, only 4% were admitted to the general ward.

This makes the burden of the critically ill intense, hence predisposing the pediatric population to experiencing adverse events in hospitals.

2.2 Predicting deterioration of critically ill children

It is commonly known that children who experience unexpected death or deterioration while in the hospital may exhibit distinguishable symptoms before the diagnosis of their illness. The most recent research on pediatric mortality in the UK found that almost one in five hospitalized children died from avoidable causes. According to the report's findings, "there should be ways of determining if something is wrong with a child as early as possible'', for example, an early warning scoring system. (9)

In inpatient settings, the 13-point Pediatric Early Warning Score is used to identify kids who are at risk of clinical deterioration and the need for intensive care. Each of the three components—cardiovascular, respiratory, and behavioral—has a score between 0 and 3, with extra points given for ongoing nebulization and persistent vomiting. (10) In this study, the PEWS score was preferred because of its ability to predict deterioration.

Other research has looked at the physiological and behavioral indicators of deterioration that could exist before a cardiac arrest and the possibility that hospital workers fail to notice or respond to these aspects promptly. (9)

The term "track and trigger" tools used at the bedside to notify professionals of children who are clinically worsening is commonly used to characterize early warning scores. These instruments are used to periodically monitor physiological parameters, generate a numerical score, and set up clear communication protocols with criteria for escalating urgent assistance. The objective of adopting these physiological track and trigger systems is to provide prompt identification of patients with prospective or existing critical illnesses and to assure prompt and appropriate staff action. (9)

A systematic review done to assess the effectiveness of PEWS in predicting clinical deterioration found that the components of PEWS ranged from clinical overview to resource allocation. These components are crucial to early warning scores because they provide a comprehensive safety system for patients who are clinically deteriorating, as well as those who are most likely to identify and manage patients at the highest risk for cardiac or respiratory arrest.

From this systematic review, the conclusion drawn on the ability of PEWS to predict clinical deterioration demonstrated a wide range of sensitivity and specificity due to different settings. (9)

2.3 PEWS score of the critically ill pediatrics

The PEWS is a rating scheme derived from clinical state and vital signs. It is calculated based on five parameters: behavior, cardiovascular status, respiratory status, frequent nebulizer use, and persistent vomiting. A higher PEWS score is associated with the severity of the illness and mortality. (11)

Based on the factors included in the score, PEWS is classified as low (0–2), intermediate (3-5), and high risk (6–9).

A study done by Shafi et al. proposed that a cut-off point of PEWS scores of >3 or more was implicated in the need for admission of the patient due to impending deterioration and severe illness. The sensitivity and specificity for this score point was 32% and 93%, respectively. However, in the same study, a low PEWS score of <2 had a sensitivity of 62% and a specificity of 68% for hospital admission. From this, it was determined that a low PEWS does not rule out a serious disease or hospital stay.(12)

In another study done in Guinea-Bissau, an LMIC to predict mortality at the PICU using the PEWS found that the risk of dying during hospitalization for critically ill children is higher when the PEWS score is higher. The risk increased as the PEWS score increased from 3-4 to 5-6, and again, where the rating was more than 7, there was a considerable danger of death. (11)

An increase of one point in PEWS increased the odds of admission to acute care by 48% when compared to the odds of discharge and 41% when it came to ICU care, according to a study conducted in a tertiary children's hospital to ascertain the relationship between the level of care at the ED and the PEWS score at the time of disposition. According to this, there is a greater chance of ICU admission when the PEWS is high. (10)

Hence, this highlights that pediatric patients who are critically ill have a higher PEWS score.

2.4 Physician likelihood of predicting adverse events

It has been shown in some studies that clinical decision rules do not perform any better than clinical gestalt.

A study comparing pediatric severity ratings and physician judgment was conducted retrospectively in a referral hospital to evaluate its possible application in pediatric intensive care triage in Utah, Idaho, Nevada, and Montana. The study found that physician judgment had a sensitivity of 98% and a specificity of 65%. (13) While Modified Sequential Organ Failure Assessment (MSOFA) had different sensitivity and specificity based on the cut-off points set, the low cut-off points correlated with high sensitivity but low specificity (93% and 34%, respectively), while higher cut-offs led to low sensitivity of 27% and specificity of 99% (13), making it ideal for use. Nevertheless, physician judgment outperformed the tools and was preferred.

The clinical gestalt of experienced doctors had a likelihood ratio of more than double that of inexperienced doctors who followed the decision rule for guidance, according to a study on clinical gestalt in the diagnosis of pulmonary embolism. The ability of the clinician to use the clinical gestalt depends on several factors, but the major one is experience, even though it has never been thoroughly studied. It also varies depending on the number of years of practice, which can impact the decision-making process. It was noted that the higher the experience, the better the chance of predicting pulmonary embolism occurrence and its complications. (14)

In another study done to compare clinician gestalt, Pediatric Emergency Care Applied Research Network (PECARN) found that the rule had a greater sensitivity in identifying clinically important TBI than clinician suspicion. However, the study also highlighted that the clinical decision rules can augment clinical suspicion and avoid unnecessary CT scans in pediatrics with minor brain injuries. (15)

Hence, the role of clinician gestalt is still of utmost importance, especially in a world where everything else is either computerized or programmed, as it allows rapid, global interpretation of clinical information within seconds of collection.

2.5 Comparison of clinical Gestalt and PEWS performance

It's highly recommended that clinical decision rules be compared to the clinician's gestalt before they are implemented.

In a commentary done by Ellen Weber and Carlton to see the side effects of decision rules, it was noted that there has been a significant shift in the value that has been placed on physician freedom over the last few decades due to the decision rules created by research to which clinicians are expected to adhere. The aim of these rules in the emergency department is to avoid a missed diagnosis, i.e., praising sensitivity at the expense of specificity, meaning that the majority will be tested for a particular condition, including even those who don't need it. (16)

A retrospective study in the PICU at a tertiary hospital comparing deterioration using PEWS vs. physician opinion found that the sensitivity of PEWS scores > 3 was 80% and the physician opinion was 43%, with a specificity of 94% and 93%, respectively. (17)

The PEWS score had a better chance of predicting adverse events than physician opinion, but both had a small margin of difference when it came to specificity. (17)

Few studies compare PEWS with physician opinion, but other clinical decision rules have been used.

A multicenter study that was done to compare the PECARN rule and clinician suspicion showed that the sensitivity of the PECARN prediction rules for pediatric ciTBI was significantly higher than a clinician's suspicion of 1%. This highlights the preference for specificity over sensitivity in clinical decision rules overall, even though the prognostic rule's specificity was lower than a doctor's hypothesis of TBI. (15)

Another study done by Babl to assess the accuracy of Nexus II in children, which also assessed clinician accuracy, found that the clinician gestalt had a higher specificity of 92% and sensitivity of 100% compared to the rule. This indicates that the clinician outperformed the rule, especially because at the end of it all, the clinician did fewer scans. (18)

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Design

This was a prospective descriptive cohort study on PEWS and clinician gestalt performance in predicting adverse events in critically ill children. It took place from May to June 2024 in the emergency department at MNH Upanga.

3.2 Study Setting

MNH is a national medical facility situated in Dar es Salaam, Tanzania with 1500 beds and 2000 outpatient visits each day. Most of the patients enter the hospital through the Emergency medicine department.

Approximately 300 children are seen per month at the emergency pediatric wing. Being a national referral hospital, in addition to self-referrals from homes, most patients who visit the ED do so after being referred by other district or regional healthcare services. These patients are seen in treatment and resuscitation rooms at the ED. All patients are categorized using a three-tier triage approach that was developed locally and adapted from the ESI. Patients who are seriously ill and arrive by ambulance or walk-in are brought to the resuscitation area, where they can get preliminary sorting either at the triage center or in the resuscitation sections. The MNH-ED comprises sections which are triage, treatment, wing c, resuscitation rooms, mass casualty, emergency theatre, and pediatric wing.

The ED Pediatric wing referred to as Wing D receives children from ages of more than 28 days to 14 years and 11 months. It has a treatment area, resuscitation area, and private area with a bed capacity of 15 beds;6 in the treatment area, 8 in resuscitation, and 1 in a private area. Triaging is continuous once the patient is in the wing. The equipment available includes airway equipment, cardiac monitors on each bed, a defibrillator, a ventilator machine, a bubble CPAP machine, a suction machine, a blood warmer, and an ENT kit. The available staff in the wing includes one pediatrician, an emergency physician, residents, registrars, and nurses.

3.3 Target population

All pediatric patients presenting to the emergency departments in LMIC.

3.4 Accessible population

Pediatric patients at ED-MNH

3.5 Study population

All children whose parents gave permission to participate and who were triaged to resuscitation in the ED-MNH within the predetermined data collecting time.

3.6 Sampling design

All pediatric triaged to resuscitation who presented to the MNH Emergency Department were conveniently recruited.

3.7 Study Subject

3.7.1 Inclusion criteria

Children who were 29 days old to less than 15 years triaged to resuscitation

3.7.2 Exclusion criteria

1. Pulseless on arrival
2. Children with no guardian

3.8 Variable of interest

Predictor variables

1. Clinician gestalt
2. From the components below PEWS will be calculated
    i. Behavior
    ii. Cardiovascular
    iii. Respiratory
    iv. Nebulization after every 15 minutes
    v. Persistent vomiting after surgery

3.9 Outcome variables

Primary Outcomes (any of these outcomes)

1. Adverse events (death at ED, death in 24 hours, intubation, transfer from ward to ICU within 24 hours, CPR, use of inotropes, ventilation)

Secondary outcomes

1. Clinical profile of critically ill pediatric patients
2. PEWS score of critically ill pediatric patients
3. Physician performance in predicting adverse events
4. PEWS performance in predicting adverse events
5. Comparison of pews and physician gestalt in predicting adverse events Composite outcome- adverse events

3.10 Sample size estimate

Burderer.wnarifin.github.io/ssc/sssnsp.html's method for determining the number of samples in prognostic research was used to calculate sample size by considering the sensitivity and specificity of PEWS.

Data on sensitivity and specificity was obtained from a study that was done in the Netherlands to validate the use of PEWS in the emergency department; the area under the curve for the study yielded sensitivity and specificity that range extensively from 36.4-85.7% and 27.1-90.5%, respectively. Based on these ranges, and the desire for sensitivity without too much loss of specificity given our setting, we chose 90% sensitivity and 60% specificity.

nSens >/= Z2. Sens (1- Sens)/(d2.Prev) nSps>/=Z2.Sps(1-Sps)/(d2.(1-Prev))

The resulting minimal sample size including 10% for loss to follow up will be 242 participants.

So, the total sample size for this study was a minimum of 252 participants.

3.11 Data Management

Screening and enrollment

Patient screening and enrollment were done by the principal investigator and/or research assistants. They were scheduled in the emergency department on alternate day and night shifts to guarantee that all participants who qualified were enrolled in the study. Both the principal investigator and/or research assistants screened each patient for inclusion and exclusion and consented to the patient. They then asked the treating physician for clinical gestalt probability without disclosing the initial PEWS of the patient and recorded their response. The number of patients excluded and reasons for exclusion were tallied.

3.12 Standardized data collection tool

Following the patient's consent to be enrolled in the study, the head researcher or research assistant completed an approved case report form to gather information from an electronic medical record (Well soft) and the treating physician. This occurred 15 minutes after the patient arrived at the emergency department (ED).

The enrolled patients were followed up to see whether any adverse events materialized within the next 24 hours.

3.13 Preliminary evaluation of the tool

Two research assistants were trained on the use of the Case Report Form; the training took 1 day to be completed and pretesting was done among 10 patients on the same day. There were no shortcomings that arose before the actual data collection began.

Three sections make up the authorized data-gathering form:

Section 1: Screening of participants: A questionnaire was utilized to assess participants for eligibility and exclusion requirements.

Section 2: Evaluation of Cases and Reporting: Data on clinical presentation, demographics, and details of the vital signs (blood pressure, heart rate, respiration rate, oxygen saturation, temperature, and level of consciousness, or AVPU) was collected for each patient included in the study. Each piece of information was included in a well-structured case report.

Section 3: Case follow-up. The main investigator or research assistant monitored the following for a whole day based on the following disposition: either the main ward, operating room, HDU, or ICU. For those who will be discharged, the patient or a relative was called to inquire about the patient's condition 24 hours following discharge. The estimated time of death for people who have passed away will be requested from families, and this information will be included in the data collection form.

3.14 Data Analysis

The statistical analyses were performed using the statistical package SPSS, version 23. Descriptive statistics for demographic variables- age, gender, referral status, clinical complaints, presence or absence of chronic disease, and as well as the qualification of the physician attending the patient are presented as either median (IQR) or frequency and percentage as appropriate.

The index tests were physician clinical gestalt and PEWS, and the reference standard was the occurrence of adverse events (any among the following; intubation, CPR, admission to ICU/HDU, cardiac arrest, death at ED). Sensitivity, specificity, positive and negative predictive values were calculated to evaluate each test's ability to predict adverse events. The discriminatory performance of physician clinical gestalt and PEWS in determining the adverse events was evaluated by comparing the area under the receiver operating characteristic curves (AUROC) using the DeLongs test.

Sensitivity, and specificity, positive and negative predictive values for physician gestalt for the probability of adverse events were calculated based on the optimum cut-off of the ROC curves (Youden's index). For PEWS cut-off value of >3 was used. The sensitivity and specificity of gestalt plus PEWS were determined. The continuous variable of physician's gestalt was used rather than the categorical variable as it was more precise.

3.15 Ethical Consideration

Study ethical approval was obtained from the MUHAS-Institutional Review Board (IRB) before the commencement of the study. Approvals were also sought from the relevant authorities of MNH to enable data collection from enrollment up to 24 hours. A numerical

code was assigned to participants to ensure data anonymization and the code and patient data were collected on REDCap which is password-protected. Written consent and assent were sought from patients' guardians before enrollment. A written informed consent form was administered in either English or Kiswahili, depending on the preference of the patient. One copy of the consent form was given to the patient while another copy was kept within a secured locker within MNH.

CHAPTER FOUR

4.0 RESULTS

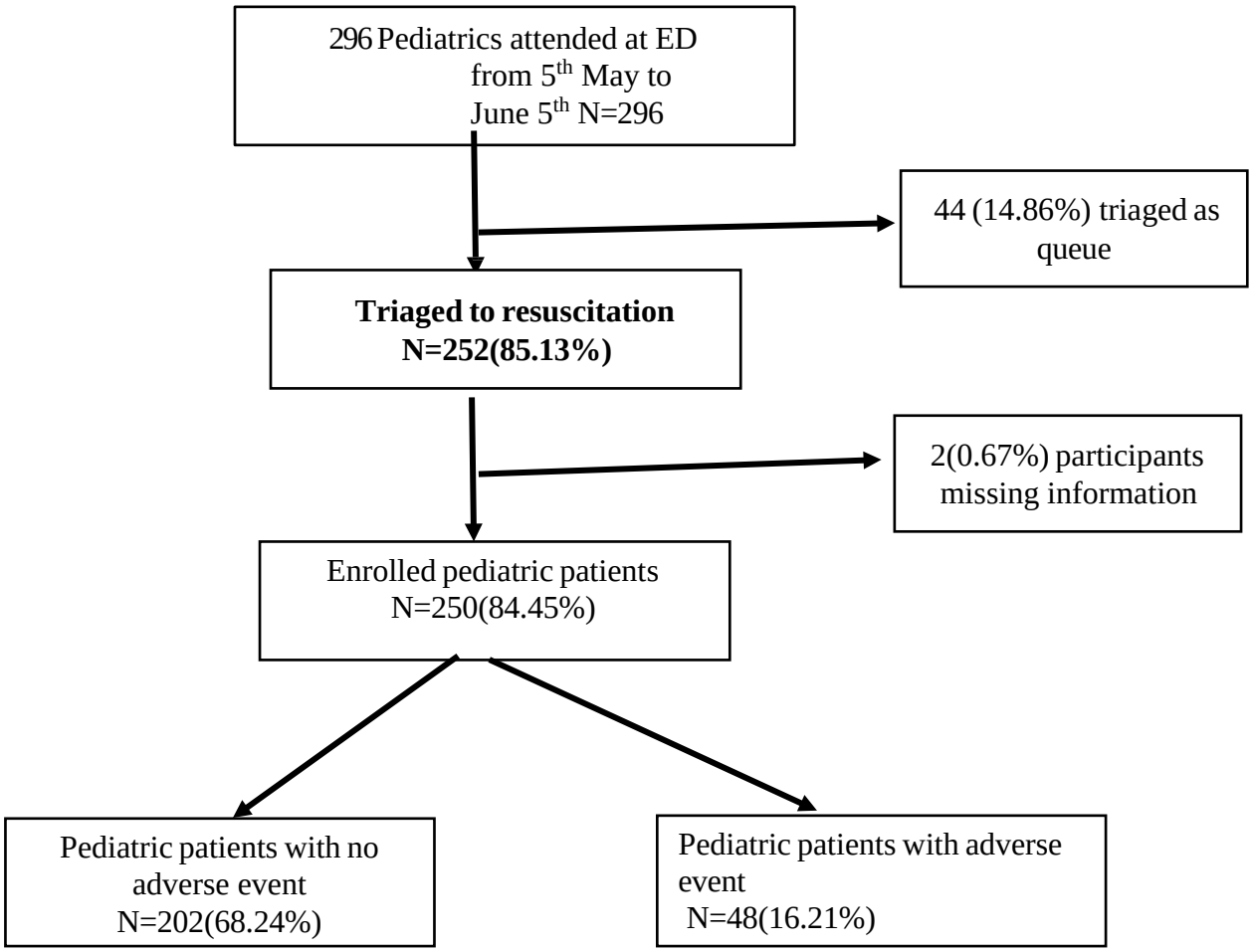


Figure 2: Flow diagram

4.1 Social Demographic characteristics of pediatric patients triaged to resuscitation

During the study period, 296 pediatric patients were attended at the Emergency department,252 (85.13%) were triaged to resuscitation but only 250(84.45%) were enrolled because 2 patients had missing information. Of the enrolled participants only 48(16.21%) sustained the adverse events.

The median age was 24 months with the largest distribution of pediatric patients falling above 60 months and below 12 months with a proportion of 38.4% and 24.4% respectively.

Gender analysis showed a slight predominance of male patients, who made up 54.8% of the study population. Regarding the type of visit, 58.0% of the patients were referred from other facilities, while 42.0% were self-referred.

Insurance status revealed that 77.6% of the patients were insured. In contrast, 22.4% were paying out of pocket. The qualifications of the treating doctors varied, with a notable concentration of patients being attended to by Resident year 3 doctors, who made up 47.6% of the treating physicians, and the least were specialists accounting for 2.4%. (Table 1)

Table 1: Socio-demographic characteristics of the pediatric patients triaged to resuscitation

Variable	Frequency (n)	Percent (%)
Age group (in months)		
< 12	61	24.4
12 – 23	40	16.2
24 – 59	53	21.5
≥ 60	96	38.4
Median age in months (IQR)	24 (12, 84)	
Gender		
Male	137	54.8
Female	113	45.2
Visit type		
Self -referral	105	42.0
Referred from other facilities	145	58.0
Medically insured		
Yes	194	77.6
No	56	22.4
Qualification of doctor who attended to patients		
Intern	25	10.0
Registrar	78	31.2
Resident year 1	8	3.2
Resident year 2	14	5.6
Resident year 3	119	47.6
Specialist	6	2.4

4.2 Clinical characteristics of the pediatric patients triaged to resuscitation

The most frequently reported complaint was fever, accounting for 37.2% of the patients. It was followed up by difficulty in breathing, accounting for 22.8%. Vomiting was also a prominent complaint, affecting 21.6% of the patients. Convulsions accounted for 12% and altered mental status 5.2% .(figure3)

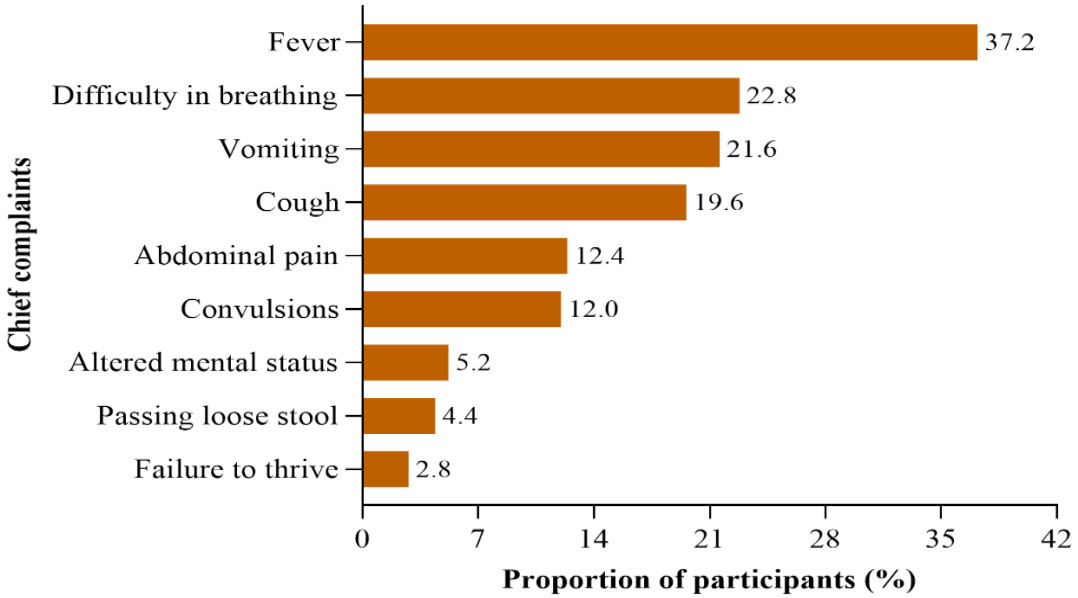


Figure 3: Clinical characteristics of the pediatric patients triaged to resuscitation

Critically ill children in this study had various comorbidities. Among them, congenital heart disease was the most common, affecting 23(9.2%) of patients in the studied population. Cerebral palsy was the second most common comorbidity, present in 19(7.6%) patients. Other significant comorbidities included malignancy, reported in 9(3.6%) patients, and diabetes mellitus, present in 3(1.2%) patients. The low prevalence of HIV only had 1(0.4%) patient. Nevertheless, 101(40.4%) patients in the cohort reported no comorbid conditions.

In PEWS score components, behavior was marked for alert pediatrics who were 143 while pain responsive were 35, cardiovascular- had 200 who had normal capillary refill <3sec, and 25 with tachycardia or bradycardia. Of the participants, 200 had normal respiratory rates, and 6 with below normal and grunting. The remaining components of nebulization after every 15 minutes and persistent vomiting had 217 and 230 participants respectively without it.

Table 2: Clinical characteristics of the pediatric patients triaged to resuscitation

Variable	Frequency (n)	Percent (%)
PEWS		
Behavior AVPU		
Alert	143	57.2
Sleeping	32	12.8
Irritable	40	16.0
Lethargic, Pain-responsive	35	14.0
Cardiovascular		
Pink/cap refill < 3sec	200	80.0
Pale/cap refill 3 sec	23	9.2
‘ Gray, cap refill > 3sec	2	0.8
Mottled, bradycardia, or techy >30 normal	25	10.0
Respiratory		
Normal	206	82.4
>10 above normal retractions	22	8.8
>20 above normal with retractions	16	6.4
Below normal with retractions and grunting	6	2.4
Nebulization every 15 minutes		
Yes	33	13.2
No	217	86.8
Persistent vomiting		
Yes	20	8.0
No	230	92.0
Comorbidities’		
Cerebral palsy	19	7.6
Congenital heart disease	23	9.2
Diabetes mellitus	3	1.2
Malignancy	9	3.6
HIV	1	0.4
Kidney diseases	2	0.8
Other comorbidities	44	17.6

4.3 Predictive ability of Physician Gestalt on the occurrence of adverse events among pediatric patients triaged to resuscitation

Using the physician gestalt estimate cut off- of 70%, 46 patients were thought likely to have an adverse event in the ED and 35 of them had an adverse event (true positives). Of 204 patients who were thought by physician's clinical gestalt to have less than a 70% likelihood of having an adverse event, five had an adverse event (false negative) and 199 did not have an adverse event (true negatives) (Table 3.)

Table 3: Diagnostic performance of physician gestalt in predicting adverse events among pediatric patients triaged to resuscitation

Presence of adverse events			
Physician Gestalt	**Yes (%)**	**No (%)**	**Total**
Event will occur	35	11	46
Event will not occur	5	199	204
Total	**40**	**210**	**250**

4.4 Physician gestalt prediction on the occurrence of an adverse event

Using occurrence of adverse events as the gold standard, the sensitivity and specificity of physician clinical gestalt on prediction of an adverse event among pediatric patients triaged to resuscitation were 87.5% (95% CI, 73.2-95.8) and 94.8% (95% CI, 90.8-97.4) respectively with a positive predictive value of 76.1% (95% CI, 61.2-87.4) and negative predictive value of 97.5% (95% CI, 94.4-99.2). Furthermore, physician clinical gestalt was found to have positive and negative likelihood ratios of 16.71 (95% CI, 9.29-30.05) and 0.13 (95% CI, 0.06-0.30) respectively with a diagnostic accuracy of 93.6% (95% CI, 89.8-96.3) as shown in (Table 4). The physician's clinical gestalt was found to have an area under the curve (AUC) of 0.964 (95% CI, 0.936-0.992), denoting an excellent discriminatory ability. (Figure 4)

Table 4: Diagnostic performance of physician gestalt in predicting adverse events among pediatric patients triaged to resuscitation

		95% Confidence Interval	
Decision Statistics	**Estimate**	**Lower**	**Upper**
Test sensitivity	87.5 %	73.2 %	95.8 %
Test specificity	94.8 %	90.8 %	97.4 %
Diagnostic accuracy	93.6 %	89.8 %	96.3 %
Positive predictive value	76.1 %	61.2 %	87.4 %
Negative predictive value	97.5 %	94.4 %	99.2 %
Likelihood ratio of a positive test	16.71	9.29	30.05
Likelihood ratio of a negative test	0.13	0.06	0.30

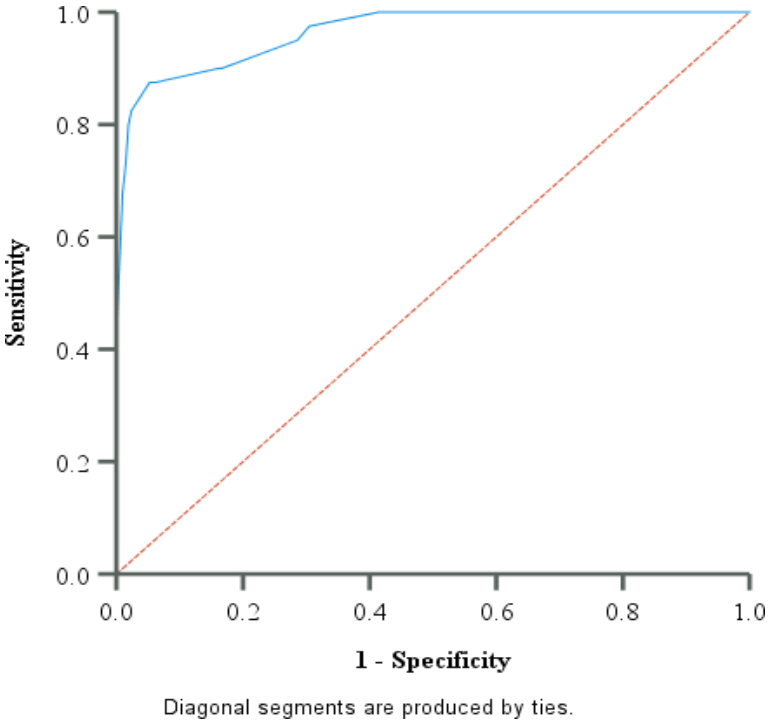


Figure 4: ROC of Physician clinical gestalt of prediction of adverse events

4.5 PEWS prediction on the occurrence of adverse events among pediatric patients triaged to resuscitation

Using the cut-off point of PEWS of 3, 75 patients were thought likely to have an adverse event in the ED and 32 among them had an adverse event. 175 patients who were thought less likely to have an adverse event as predicted by PEWS, 167 did not have an adverse event. (Table 5)

Table 5: Diagnostic performance of PEWS in predicting adverse events

Presence of adverse events			
PEWS	**Yes (%)**	**No (%)**	**Total**
More likely to experience adverse events	32	43	75
Less likely to experience adverse events	8	167	175
Total	**40**	**210**	**250**

4.6 PEWS prediction on the occurrence of an adverse event pediatric patients triaged to resuscitation

The sensitivity and specificity of the PEWS in predicting the occurrence of adverse events were 80% (95% CI, 64.4-90.9) and 79.5% (95% CI, 73.4-84.8) respectively with positive predictive value of 42% (95% CI, 31.3-54.6) and negative predictive value of 95.4% (95% CI, 91.2-98.0). PEWS>3 had positive likelihood ratio of 3.91(95% CI, 2.87-5.32) and negative likelihood ratio of 0.25(95% CI, 0.14-0.47). The AUC was 0.869 (95% CI 0.809 to 0.930). (Figure 5)

Table 6: Diagnostic performance of PEWS in predicting adverse events among pediatric patients triaged to resuscitation

	95% Confidence Interval		
Decision Statistics	**Estimate**	**Lower**	**Upper**
Test sensitivity	80.0 %	64.4 %	90.9 %
Test specificity	79.5 %	73.4 %	84.8 %
Diagnostic accuracy	79.6 %	74.1 %	84.4 %
Positive predictive value	42.7 %	31.3 %	54.6 %
Negative predictive value	95.4 %	91.2 %	98.0 %
Likelihood ratio of a positive test	3.91	2.87	5.32
Likelihood ratio of a negative test	0.25	0.14	0.47

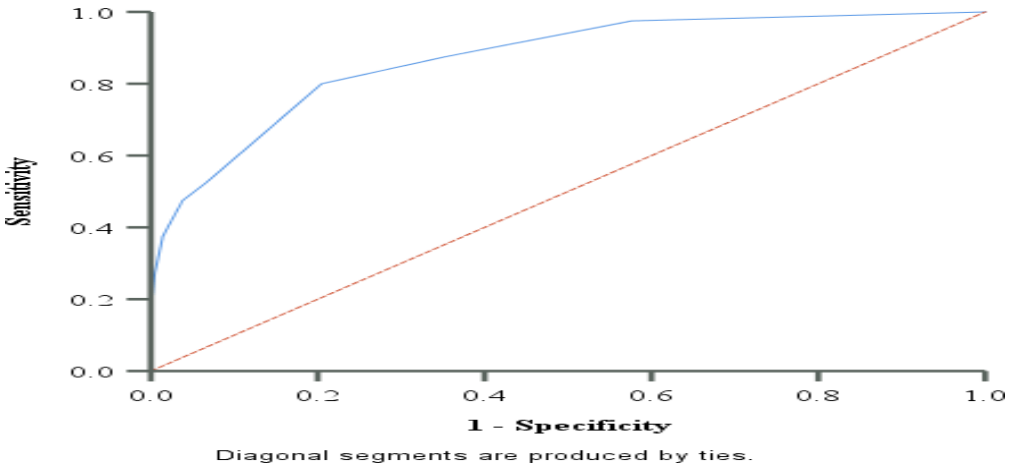


Figure 5: ROC of PEWS for prediction of adverse events

4.7 Comparisons of ROC between PEWS and physician gestalt to predict adverse events among pediatric patients triaged to resuscitation

Between the two index tests, physician gestalt had the highest area under the curve, AUC=0.964 (95% CI 0.936 to 0.922) which is considered to have an excellent discriminatory ability compared to the PEWS which had a lower AUC=0.869 (95% CI 0.809 to 0.930). (Figure 4)

ROC curve comparing physician gestalt and PEWS on prediction of occurrence of an adverse event

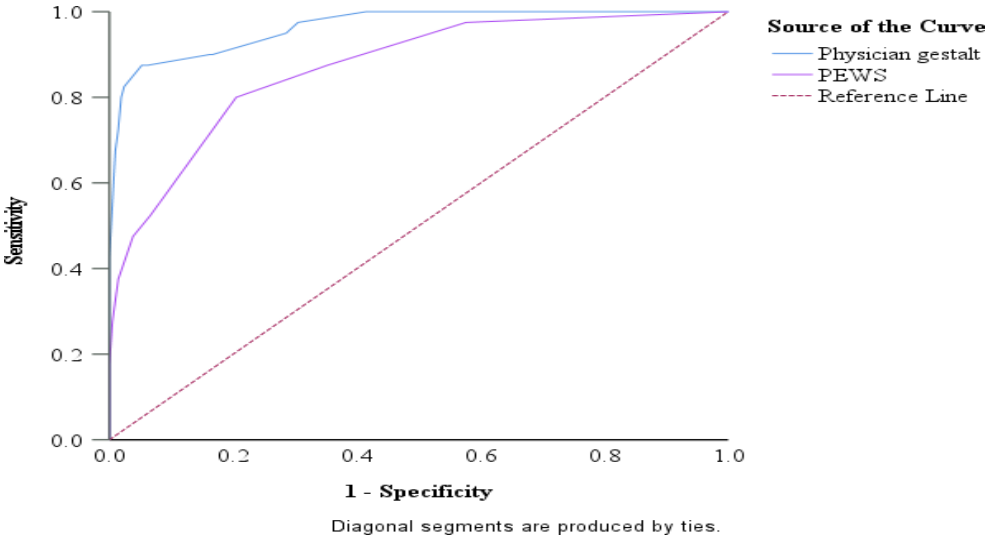


Figure 6: ROC curve comparing physician gestalt and PEWS on prediction of occurrence of an adverse event

4.8 Comparison of Physician Gestalt and PEWS on Predicting Adverse Events among pediatric patients triaged to resuscitation

Comparing clinical gestalt and PEWS on the occurrence of adverse events among pediatric patients, the sensitivity and specificity of physician clinical gestalt were 87.5% and 94.7% respectively and that of PEWS was 80% and 79.5% as seen in Table 8 below. The difference in specificity between the two was statistically significant. (Table 7)

Table 7: Comparison of Physician Gestalt and PEWS among pediatric patients triaged to resuscitation

	PEWs	Gestalt	Difference	Test statistics	P - value
Sensitivity	80.0%	87.5%	7.5%	1.2857	0.256
Specificity	79.5%	94.7%	15.2%	2.226	< 0.001

The physician clinical gestalt and PEWS were found to have a positive predictive value of 7.608 and 4.267 (95% CI 1.401-2.268) with a positive likelihood ratio of 16.70 and 3.91(95% CI 0.12-0.43) respectively which was statistically significant. (Table 8)

Table 8: Comparisons of predictive values and diagnostic likelihood ratios between PEWS and physician gestalt to predict adverse events among pediatric patients triaged to resuscitation

95% Confidence Interval						
	PEWs	Gestalt	Ratio	Lower CL	Upper CL	P - value
Positive predictive value	4.267	7.608	1.783	1.401	2.268	< 0.001
Negative predictive value	0.954	0.975	1.02	0.993	1.488	0.136
Positive diagnostic likelihood ratio	3.91	16.70	0.23	0.12	0.43	< 0.001
Negative diagnostic likelihood Ratio	0.25	0.13	1.90	0.83	4.34	0.124

Table 9: Adverse events occurrence

Type of Adverse Event	Frequency	Percentage
Admission to HDU	18	37.5%
Admission to ICU	20	41.7%
Cardiac arrest	8	16.7%
Death at EMD	2	4.1%

Among those who had adverse events, 37.5% were admitted to HDU and the least was death at EMD which was marked by 4.1%.

CHAPTER FIVE

5.0 DISCUSSION

Caring for critically unwell children in the emergency department takes a high level of assertiveness, and most physicians rely on their gestalt, or PEWS score to escalate management.

This prospective cohort study aimed at determining the performance of Pediatric Early Warning Score and Physician gestalt in predicting adverse events among critically ill pediatrics of a tertiary hospital in Tanzania. The Physician Gestalt was more sensitive than the Pediatric Early Warning Score.

Many of the patients in this study were males, with a median age of 24 months, and were referred from other hospitals. The majority of patients had a PEWS score of three or higher, which is indicative of a severe illness. This result was also observed in a prospective observational study among pediatrics conducted in the Muhimbili Emergency Department, except the median age, which was 12 months in this study. The similarity is due to the same setup and the difference could be because there is better access to healthcare which creates variation in age distribution stipulated by the high prevalence of the insured patients.(7) This was also consistent with a study that found that severely sick patients had a PEWS score of at least three.(12)These data highlight the vulnerability of these patients to adverse outcomes as well as the role of the referral system put in place in Tanzania.

The majority of critically ill pediatric patients in low- and middle-income nations present with infectious illness symptoms. In this research, we discovered that many patients presented with fever, difficulty in breathing, cough, altered mental status, and convulsions. This is consistent with a study conducted in Nigeria, which discovered that the most prevalent presentations were respiratory symptoms, infectious, and neurological.(1)It underlines the common challenges encountered in low- and middle-income countries, particularly in Africa, emphasizing the need for improved preventive measures.

PEWS was initially developed for use in in-patient escalation of care, however, it has been demonstrated to be beneficial in the emergency department in predicting clinical deterioration and admission. In our study, PEWS proved to be beneficial in anticipating adverse events and disposition, encouraging the caregiver to escalate management or not. It was also capable of accurately identifying people who were not at risk. These findings are consistent with a prospective descriptive study conducted in Thailand, which found high sensitivity in predicting ICU admissions. (19) On the other side, a study at ED-MNH discovered that PEWS can be utilized to determine the disposition strategy. This resemblance establishes the role of PEWS in the emergency department.

Physician clinical gestalt can be used in the emergency department to predict the clinical deterioration of pediatric patients as it has been reported in various studies. This particular study showed high sensitivity and acceptable AUC of physician gestalt thus making it a reliable tool to be used. It also had high specificity making it even better in ruling out the adverse events. A study on physician gestalt in the diagnosis of pulmonary embolism had similar findings, except the study done in PICU to compare PEWS and physician gestalt which reports PEWS to be better, the reasons for this can be because of the different settings.(14)(17) This showcases the dependability of the gestalt when different settings and diagnoses are considered.

In a fast-moving world clinician are subjected to following clinical decision rules which can impede their gestalt hence comparing the two is important. When comparing the physician clinical gestalt and PEWS, our study found that the gestalt was more sensitive and specific compared to PEWS. Their differences in specificity were statistically significant.

Contrary to the findings in a study done at PICU comparing the two showed PEWS to be better but the population and the setup were different. (17)

This means that gestalt is useful in regulating resources, especially in a limited resource setting by avoiding unnecessary interventions. However, PEWS can also be used by clinicians who are less experienced in decision-making since its sensitivity is good.

In this prospective study, it was discovered that both aforementioned methods can be used to predict adverse occurrences, with physician gestalt having a higher likelihood of recognizing adverse events than PEWS.

CHAPTER SIX

6.0 STRENGTH, LIMITATIONS, CONCLUSION AND RECOMMENDATIONS

6.1 Strength

This was a prospective observational study done at a tertiary hospital that caters for the variable of pediatric patients.

6.2 Limitations

1. The sampling method was based on convenient enrollment thus there was no 24/7 coverage: hence we may have missed some patients who might have met the inclusion criteria. The investigator and research assistant being available on alternate day and night shifts, should have resulted in a representative sample.
2. There was no literature providing a cut-off for gestalt probability, hence a cut-off for physician gestalt was chosen based on the receiver operating characteristics curve, while for the PEWS we used the standard cut-off values for increased risk reported in the literature. This would affect the sensitivity and specificity of the gestalt probability of the population to be used but would not affect the AUC.

6.3 Conclusion

Our study suggests that clinicians taking care of patients in ED can rely on their clinical judgment to determine which patients are likely to succumb to adverse events.

The comparison highlights that clinical gestalt, with its higher sensitivity and significantly higher specificity, appears to be a more reliable method for predicting adverse events in pediatric patients when used by ED clinicians.

6.4 Recommendations

1. The physician clinical gestalt should be highly used in our setting since it has high sensitivity and specificity in predicting adverse events. Thus, the patients should be monitored closely accordingly.
2. A study should be conducted to capture the findings in a place where triage system is absent so that findings can be generalized.
3. Despite the findings in this study, those who have adopted to using PEWS may continue using it because it has been shown to have good sensitivity as well.

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APPENDICES

Appendix 1: Data Collection Tool

A SCREENING FORM FOR ALL CRITICALLY ILL CHILDREN

To complete the form for each preselected study collection time Date…….

Time of collection……..

Include all children triaged as emergent and priority to the resuscitation room in the list.

SN	Time(24hrs)	MR NO	Date of birth (DD/MM/ YY)	Age	Sex	Meets inclusion criteria(yes/no)	Those meeting the inclusion criteria, consented(yes/no)
1							
2							
3							
4							

Inclusion Criteria.

All children meeting the below criteria should be screened to be enrolled as study participants.

SN		**YES**	**NO**
1.	Age <14 years		
2.	Triaged to the resuscitation area		
3.	Physician gestalt provided		

Exclusion Criteria

Children who meet any of the below criteria will not be included in the study.

SN		YES	NO
1.	Pulseless on arrival		
2.	Age <28days		
3.	Failure to obtain assent (those with no guardian)		

Form completed by: Date:

Site RA signature: Date:

Appendix 2: Case Report Form

PART I: PATIENT IDENTIFICATION AND DEMOGRAPHICS

MR Number: Doctor's code

QN1. How old is the child?

QN2.Gender 1.) male 2.) female

QN3.What type of visit 1.) self -referral 2.) Referred from other facilities

QN4. Are you insured? 1.) Yes 2.) No

QN5. Do you have any of the following comorbidity (Tick that applies)?

1). Cerebral palsy 2) Congenital heart disease 3) Diabetes Mellitus

5) Malignancy 6) HIV 7) Kidney diseases 8) None 9) Others…….

QN6.What is the qualification of the doctor seeing the patient?

1.) Medical Student 2.) Intern Dr 3.) Registrar 4.) Resident year 1 5.) Resident year 2 6.) Specialist

QN7.What is today's chief complaint (obtained from the medical record, patient, and physician in the room)

Chief complaint	YES	NO
Fever		
Altered mental status		
Convulsions		
Passing loose stool		
Abdominal pain		
Vomiting		
Passing loose stool		
Cough		
Difficulty in breathing		
Failure to thrive		
Others (explain here .....)		

QN8.Based on your clinical judgment, please estimate the likelihood of the patient experiencing any of the adverse events within 24 hours. Use the scale provided:

1. unlikely (0-40%) 2.) Likely (41-80%) 3.) very likely (81-100%) (answered by the treating physician)

QN9. What is the likelihood of an adverse event (admission to HDU/ICU, cardiac arrest, intubation, CPR) occurring to the patient? (answered by the treating physician)

1.) Low 2.) Moderate 3.) High

QN10. What parameters did you use to guide your gestalt? (Answered by the treating physician). Mention the component on each side selected

1.) Chief complaint 2.) Vital signs 3.) The general appearance of the patient 4.) Level of consciousness 5.) Others…….

QN11. What are the vital signs and the initial PEWS of the patient calculated within 30 minutes of the arrival? (Done by the research assistant and crosschecked in the medical record)

SBP	DBP	HR	RR	SPO2	Temperature	RBG	Behavior	Cardiovascular	Respiratory

QN11. What is the outcome of the patient at EMD?

Cardiac arrest	
Death at EMD before disposition	
Respiratory arrest	
Others …..(mention)	

QN12. What is the disposition of the patient? (As decided by the treating physician)

Disposition place
1.Home
2.General ward
3.Theatre
4.HDU
5.ICU

QN13. What adverse event led to transfer of patient from ward to ICU

Appendix 3: Consent Form – English Version

TITTLE: COMPARISON OF PEWS (PEDIATRIC EARLY WARNING SCORE) AND CLINICIAN GESTALT IN PREDICTING ADVERSE EVENTS OF PAEDIATRICS AT EMD-MNH

Introduction

Greetings, I Dr. Irene Aloyce Kindole a second-year resident taking Emergency medicine course at Muhimbili University of Health and Allied Sciences (MUHAS).

I am currently conducting a research study with above title and kindly requesting your participation and support in it when I or my research assistant approaches you. Your choice to participate or not will have no effect on your care or that of your patient. Please you may ask questions anytime pertaining this study if you do not understand.

The purpose of this study is to compare the performance pediatric early warning score and clinician gestalt in predicting adverse events of pediatrics.

Benefit.

No payment or any fringe benefits for your participation in this study, instead the results and its implications will be beneficial for the hospital and the general population using it.

Risks.

There is no risk in participating in this study.

What does this study involve?

This study involves the research assistant or the principal investigator asking a series of structured questions to you, the patient or relatives and the filling the responses in the prepared questionnaire. Also, the information about you will be obtained from the hospital file.

Assent

Your assent to be enrolled in this study is entirely voluntary and amenable by signing the assent form. You are free not to assent and this will not affect the care or management. You may also decide to stop and any moment to be in this study for any particular reason.

Confidentiality.

The information you provide is extremely respected and will be preserved strictly confidential. The study information will be stored in protected computer files and paper records stored in a locked filing cabinet. Only study staff will have access to the information.

Access to Information.

By signing this form, you allow the research team to use the information and give it to others involved in the research. The research team includes the researcher, facilitators, and others working on this study at MUHAS and EMD-MNH.

For further information questions, or queries, you can contact

1. The Principal Investigator, Irene A. Kindole

Department of Emergency Medicine, MUHAS,
P. O. Box 65001,

Dar es Salaam, Tanzania. Tel: +255 757898815
Email: kindoleirene@yahoo.com

2. Dr. Dr Nahya Salim

Director of Research and Publications, Research and Publications Committee,
Muhimbili University of Health and Allied Sciences,

P. O. Box 65001

Dar es Salaam, Tanzania. Tel: 2150302-6

Signature

I…….. have been informed of the content of this form, all queries have been answered, and I voluntarily agree to participate in this study.
Signature of the patient……

Signature of the caretaker/relative……Date ……

Appendix 4: Consent Form – Swahili Version FOMU YA RIDHAA YA USHIRIKI KWA TAFITI.

Mwanzo.

Naitwa Irene Aloyce Kindole, mwanafunzi wa Chuo Kikuu Cha Afya na Sayansi Shirikishi Muhimbili (MUHAS) katika idara ya madaktari bingwa wa magonjwa ya dharura (Emergency Medicine). Naomba ridhaa kutoka kwako na mgonjwa wako katika tafiti hii ikiwa mie au mwakilishi wangu atakufuata kupata taarifa za msingi za mgonjwa wako. Lengo la tafiti hii

Ushiriki katika tafiti:

Wagonjwa waliofika ambao ni mahututi na kupata huduma katika sehemu za magonjwa ya dharura.

Madhara:

Tuna tumaini kutokuwepo na madhara yatokanayo na uwepo wako katika tafiti hii..

Manufaa ya tafiti:

Kwa kutoa ridhaa ya mgonjwa wako kushiriki ndani ya tafiti hii, utasaidia kutumika kuimarisha maamuzi yatakayosaidia walio mahututi.

Usiri:

Yale yaliyopatikana katika tafiti hii ni siri, hivyo uwepo wako hautatambulika na asie kuwepo katika timu ya watafiti.

Malipo:

Hakutakua na malipo yeyote kwa uwepo wako katika tafiti hii.

Endapo una swali au shida yeyote, tafadhali wasiliana na wafuatao:

1. Irene Aloyce Kindole

Idara ya Magonjwa ya Dharura na Mahututi (Emergency Medicine), MUHAS,
S.L.P 65001,

Dar es Salaam, Tanzania.

Simu: +255 757898815
Barua pepe: kindoleirene@yahoo.com

2. **Dkt. Dr Nahya Salim**

Mkurugenzi wa Utafiti na Machapisho, Kamati ya Utafiti na Machapisho
Chuo Kikuu Cha Sayansi na Tiba Cha Muhimbili

S.L.P 65001,

Dar es Salaam, Tanzania. Namba ya Simu: 2150302-6

Kuweka sahihi ya makubaliano:

Mimi..... , nimesoma/nimesomewa maelezo katika jalada hili na nimeelewa.

Nipo tayari kushiriki kwani maswali niliyokuwa nayo yametolewa maelezo vizuri. Sahihi ya mshiriki …….
Sahihi ya ndugu wa mshiriki…….

Sahihi ya Mtafiti ……Tarehe ……

Appendix 5: Form of Assent (Swahili)

FOMU YA RIDHAA YA USHIRIKI KWA TAFITI

Mwanzo.

Jina langu naitwa Dkt. Irene A. Kindole, mwanafunzi katika Chuo Kikuu Cha Afya na Sayansi Shirikishi Muhimbili (MUHAS) katika idara ya madaktari bingwa wa magonjwa ya dharura (Emergency Medicine). Naomba uwepo wako au kwa ajili ya mgonjwa wako katika tafiti hii wakati mie ama mwakilishi wangu atakufuata kupata habariza msingi za mgonjwa.

Lengo la utafiti

Ushiriki katika utafiti:
Wagonjwa wakifika katika hali ya umahututi na kupata huduma katika vyumba vya magonjwa ya dharura

Hatari:
Hatutegemei kuwepo kwa madhara yeyote yatokanayo na uwepo katika tafiti hii.

Faida za tafiti:
Ridhaa ya mgonjwa wako kushiriki katika tafiti hii, utasaidia kuboresha maamuzi ya kasi kwa wagonjwa mahututi

Usiri:
Yale yatakayo patikana katika tafiti hii ni siri, hivyo ushiriki wako hautatambulika na asiekuwepo katika jopo la watafiti.

Malipo:
Kwa kushiriki kwenye utafiti huu, hautalipwa wala hautalipa ghrama yeote.

Endapo una swali au tatizo lolote, tafadhali wasiliana na wafuatao: Irene A. Kindole
Idara ya Magonjwa ya Dharura na Mahututi (Emergency Medicine), MUHAS,
S.L.P 65001,

Dar es Salaam, Tanzania. Simu: +255 687 369 722

Barua pepe: kindoleirene@yahoo.com

4.Dkt**. Dr Nahya Salim**

Mkurugenzi wa Utafiti na Machapisho, Kamati ya Utafiti na Machapisho
Chuo Kikuu Cha Sayansi na Tiba Cha Muhimbili

S.L.P 65001,

Dar es Salaam, Tanzania. Namba ya Simu: 2150302-6

Kuweka sahihi ya makubaliano:

Mimi, ……., nimesoma/nimesomewa maelezo katika jalada hili na kuelewa.Nipo tayari kushiriki na msawali yangu yameshajibiwa.
Sahihi ya mshiriki …….

Sahihi ya ndugu wa mshiriki ……
Sahihi ya Mtafiti ……. Tarehe ……

Appendix 6: Approval for ethical clearance

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA.282/298/01.C/2350 Date: 01/05/2024

MUHAS-REC-05-2024-2350
IRENE ALOYCE KINDOLE,
COLLEGE OF MEDICINE,
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: "PERFORMANCE OF PEDIATRIC EARLY WARNING SCORE AND PHYSICIAN GESTALT IN PREDICTING ADVERSE EVENTS AMONG PAEDIATRIC PATIENTS PRESENTING AT EMERGENCY MEDICINE DEPARTMENT OF A TERTIALLY HOSPITAL IN TANZANIA".

Reference is made to the above heading,

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 01/05/2024
EXPIRATION DATE OF APPROVAL: 01/05/2024

STUDY DESCRIPTION:
Purpose:
The purpose of this prospective observational cohort study is to compare the permeance of pediatric early warning score and clinician gestalt in predicting adverse events.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:
https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014532.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Nahya S. Masoud

For Chairperson, MUHAS Research and Ethics Committee



Appendix 7: Introduction letter

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

In reply quote;
Ref. No. HD/MUH/T.52/2021

01st May, 2024

Executive Director,
Muhimbili National Hospital,
P.O. BOX 65001,
DAR ES SALAAM.

Re: INTRODUCTION LETTER

The bearer of this letter is Irene Aloyce Kindole, with registration number HD/MUH/T.52/2021, a student at Muhimbili University of Health and Allied Sciences (MUHAS) pursuing MMed Emergency Medicine at the College of Medicine

As part of his studies he intends to do a study titled: **"Performance of Pediatrics early warning score and physician gestalt in predicting adverse events among pediatric patients presenting at Emergency medicine department of tertially Hospital in Tanzania".**

The research has been approved by the Chairman of University Senate.

Kindly provide her with the necessary assistance to facilitate the conduct of her research.

We thank you for your cooperation.

Ms. Victoria Mwanilwa.
For: DIRECTOR, POSTGRADUATE STUDIES

cc: Dean, School of Clinical Medicine, **MUHAS**
cc: Irene Aloyce Kindole.

Appendix 8: Permission to collect data at MNH

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL

In reply please quote:

Ref. No.: MNH/CRTCU/Perm/2024/286 Date: 04th May, 2024

Head of Department,
Emergency Medicine
Muhimbili National Hospital

RE: PERMISSION TO COLLECT DATA AT MNH

Name of Students	**Dr. Irene A. Kindole**
Title	**"Performance of Paediatric Early Warning Score and Physician Gestalt in Predicting Adverse Events Among Paediatric Patients Presenting at Emergency Medicine Department a Tertially Hospital in Tanzania "**
Institution	Muhimbili University of Health and Allied Sciences
Supervisors	Dr. Said Kilindimo (MUHAS)
Co – supervisor	Dr. Alphonce Simbila (MNH)
Period	6th May, 2024 to 30th July 2024

Approval has been granted to the above principal investigators to collect data at MNH. Dissemination of study findings at MNH shall be overseen by **Dr. Alphonce Simbila** (MNH) supervisor.

Kindly ensure the named principal investigator abide to the ethical principles and other conditions of the research approval.

Sincerely,

Dr. Charles K. Pallangyo
For: Head of Clinical Research, Training and Consultancy Unit

P. O. Box 65000
DAR-ES-SALAAM

C.c DMS
C.c Dr. Alphonce Simbila
C.c **Dr. Irene Kindole**

Upanga West, Kalenga Street, Plot No. 10480/3, P.O. BOX 65000, Dar es Salaam, Tanzania.
Telephone: +255-22-2151367-9, Telephone: +255-22-2151351-2
Email: info@mnh.or.tz, Website: www.mnh.or.tz