Evaluating level of practice, knowledge and attitudes to optimal alarm management, the burden and the predictors of alarm fatigue among health care workers (HCWs) in acute care settings of Kenyatta National Hospital: A Cross-sectional study design

RESEARCH PROPOSAL

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ABBREVIATIONS

RN- Registered Nurse

ED – Emergency Department

ICU – Intensive Care Unit

AF – Alarm Fatigue

TMSC – Transactional Model of Stress and Coping

PICU – Paediatric Intensive Care Unit

ERC – Ethics and Research Committee

CCU - Critical Care Unit

ACCE – American College of Clinical Engineering

A&E – Accidents and Emergency

OPERATIONAL DEFINITIONS

Alarm fatigue (AF) – occurs when health workers experience high exposure to medical alarms leading to desensitization and non-responsiveness to clinical alarms.(Deb & Claudio, 2015)

Alarm management practice: involves adhering to set standards and protocol in setting clinical alarms parameters and responding to audio and visual alerts of the alarms(Meng'anyi, Omondi, & Muiva, 2017).

Alarm safety: refers to enhanced care of patients, health outcomes and reduced monitoring based on optimal recognition and response for life-threatening, and crisis alarm conditions

Patient safety culture - the perceived extent to which collective institutions' daily operations supports and promotes patient safety and wellbeing (Lee, Lee, Seo, & Son, 2021)

Perceived workload – measure of the amount of activity and effort required to complete a task: in this study, the tasks of alarm management(Tubbs-Cooley, Mara, Carle, & Gurses, 2018).

Burn out: refers to emotional and physical exhaustion , cynicism and negative feelings among professionals serving people which leads to deterioration of their performance ,service to clients and the larger institution of work (Maslach & Jackson, 1981).

ABSTRACT

Introduction*: Alarm fatigue (AF) among clinicians in acute care settings resulting from excessive and non-actionable clinical alarms, is associated with sentinel patient events and harm. However, evidence on the burden of alarm fatigue (AF) and its contributing factors remain scarce in the Kenyan hospital settings. Therefore, the purpose of this stud is to apply empirical methods to establish predictors of AF and its prevalence in select acute care settings with the aim informing strategies for alleviating alarm fatigue among clinicians and for optimizing alarm management for patient safety.*

Methods*: The study applies a cross sectional design utilizing quantitative survey and observational data collection method to establish the prevalence of AF and its predictors. A literature-based structured and interviewer-administered questionnaire shall be used to gather data from a sample of 157 health workers comprising of nurses and doctors proportionately and randomly sampled from three acute care departments. Levels of knowledge, attitude, practice, patient safety culture, burn out, alarm-related mental workload, and alarm fatigue (AF) shall be assessed. Non-participant observations for alarm frequency and counts shall be conducted on hourly blocks for two hours per 6 hour-shift across 7 day shifts and 7 night shifts distributed randomly across the 1 month of the study period. Alarm frequency will be reported in proportions for different categories while alarm load results reported in alarm count per unit, per patient and per hour. Prevalence of AF will be computed as a proportion. Multilevel and multi-linear regression methods will be applied to control collinearity and confounding and identify predictors of alarm fatigue at 95% Confidence Interval.*

Utility*: Knowledge on alarm frequency, typology, the burden and predictors of alarm fatigue will inform policy guidelines and strategies to reduce alarm fatigue and optimize clinical alarm response among health care workers which will ultimately enhance patient safety.*

CHAPTER 1: INTRODUCTION

1.1 Background

Hospital alarms-also known as clinical alarms- are critical in signaling patients in need in life-saving health interventions. However, excessive clinical alarms and failure to respond appropriately to clinical alarms has been associated with adverse patient outcome and harm (The Joint Commission, 2013). Therefore, hospital organizations should ensure that no patient dies because of untimely response to critical alarm signals and from adverse events related to suboptimal alarm response. When health care workers get used to excessive alarms and consistently fail to take action or feel overwhelmed by the clinical alarm noise, this is referred to as alarm fatigue and has been associated with patient harm (Ruskin & Hueske-Kraus, 2015). Between 2009 and 2012, out of the 98 alarm-related events, 80 of them resulted to deaths as reported in The Joint Commission Sentinel Database(The Joint Commission, 2013). Therefore, Joint Commission National Patient Safety Goal recognizes alarm hazards as a top patient safety issue(The Joint Commission, 2013). The health care organizations should therefore utilize evidence-based approaches to manage alarm systems with the goal of safeguarding the safety of patients in high-risk areas, such as critical care units and emergency departments, from alarm-related medical errors including improper alarm response and in protecting health care workers from alarm fatigue. For example, an international compendium of clinical alarm management guidelines and solutions based on multidisciplinary expert consultations and existing empirical evidence from developed regions such as United States on alarm safety published and sponsored by the Association of the Advancement of Medical Instrumentation (AAMI), provides specific institutional measures for ensuring that “no patient should be harmed from adverse alarm systems events”. Despite the pressing burden of clinical alarms, the authors of the compendium observe research gaps in evidence-based rationale for alarm configurations and sounds and lack of documentation and alarm data to inform alarm management in many hospital institutions(AAMI, 2020). In line with health systems goal of responsiveness(Mirzoev & Kane, 2017), clinical alarms should enhance health workers’ attention and responsiveness to patient’s changing needs and expectations for quality and safe health care. Therefore, there is need to expand research based on the previous but scarce literature to improve responsiveness of acute care and critical care health providers to clinical alarms. Lack of contextual tools and methods for systematic alarm data

collection and review stands in the way of evidence-based alarm safety policies and guidelines and help bring alarm safety issue as a priority within hospital organizations. Therefore, the study aims to apply literature-based scientific research methods of gathering and reviewing clinical alarm data to establish the burden of alarm fatigue and its predictors as well as its effects on patent safety and on health workers' clinical workflows in the Kenyan hospital setting.

1. 2 Statement of the research problem

Alarm systems are purposed to help the nurses in timely recognition of patients' change in condition, prompt early lifesaving intervention and enhance quality of patient care and better patient outcomes. However, non-actionable clinical and excessive preventable technical alarms can be a source of extreme stress on the health care providers including nurses and doctors. As a result, health workers may be unnecessarily interrupted in their primary tasks (leading to distress and performance impairment) or miss alarms due to crying wolf scenario (May contribute to alarm-related medical errors). This has been elucidated in literature; such as an non-participant observational study in an ICU setting in Brazil showed more than 10 minutes delay in response to clinical alarms with more than 60% of alarms without any response(Oliveira, Machado, Santos, & Almeida, 2018),alarm fatigue burden among clinicians in critical and acute care settings(Ruskin & Hueske-Kraus, 2015), staff performance deterioration from the interplay of alarm fatigue, work conditions and staff individual characteristics(Deb & Claudio, 2015). Previous literature has also validated audit tools for alarm data collection, alarm frequency and alarm fatigue assessment in emergency and critical care hospital departments where alarm safety is a safety issue(Torabizadeh, Yousefinya, Zand, Rakhshan, & Fararooei, 2017)(Ashrafi, Najafi Mehri, & Nehrir, 2017)(Baillargeon, 2013). However, addressing safety issues around clinical alarms remains a challenge , first, due to under-utilization of alarm data, as well as suboptimal configuration of alarm devices(Sowan, Reed, & Staggers, 2016), second, due to limited context-specific data and evidence for clinical alarm optimization(AAMI, 2020), and third, alarm safety has not received adequate public health attention and research efforts in low-middle income hospital and health delivery settings as indicated by scarcity of relevant scientific articles. Limitation of published evidence on alarm safety and related fatigue is exemplified in the low-middle income countries where few relevant studies can be traced such as in Ghana(Nyarko, Yin, Chai, & Yue, 2023) and Kenya(Meng'anyi et al., 2017) for the African region. In Ghana, Nyarko et al applied a cross-

sectional design to investigate the burden and predictors of alarm fatigue among ICU nurses. The authors found a positive relationship between alarm fatigue and specific dimensions of burn out using Maslach Burnout Inventory (MBI) in addition to other significant predictors of alarm fatigue such as existence of policies on alarm safety, type of ICU and staff work experience at ICU. The authors called for future research to improve generalizability of findings, establish association between alarm fatigue and burnout and explore other unstudied factors contributing to the burden of AF(Nyarko et al., 2023). The evidence from a Kenyan hospital settings applied a cross sectional design to examine alarm management practices among CCU nurses. The authors observed that the age of the nurse was associated with alarm management performance. In addition, the study site was cited to be lacking in alarm checklists and alarm management protocols with authors calling for more research efforts to gather more data and generate more knowledge on alarm management especially using multi-cadre study population and departments owing to methodological limitations(non-random sampling methods, only nurse-cadre and ICU department included, and lack of quantitative measurement of alarm fatigue) (Meng'anyi et al., 2017).

CHAPTER 2: REVIEW OF LITERATURE

2.1 Alarm safety and typology

The Joint Commission National Patient Safety Goals January 2021 for the Hospital Program requires hospitals to establish alarm safety as a priority. This begins with identifying context specific alarm data to guide which alarms are of safety concern. The commission also recommends development of policies on alarm management and staff in service training on alarm safety(The Joint Commission, 2021) Unnecessary and excessive medical alarms have been cited as hazardous to patients using health technology devices (ECRI Institute, 2012). Data on the type and frequency of clinical alarms within a given hospital setting is the foundation of alarm risk and hazard minimization and mitigation strategies(Vockley, Howard, Flack, & Blair, 2015).

Ruskin et al classify alarms into either clinical or technical alarms. Clinical alarms (false, true and nuisance) indicate a change in patient condition that correctly or incorrectly require attention. Nuisance clinical alarms are true in nature however no attention and action is required for the health worker, for example, an alarm of a heart rate of 59 beats per minute in a patient whose normal heart rate is 64. Technical (true technical, false technical and avoidable technical alarms) alarms indicate the need to check the equipment. For example, if the device is malfunctioning such as having a faulty oximetry cable, a technical alarm will be generated and hence attention for the device will be needed. False technical alarms indicate artifacts and no true change in clinical state of patient such as motion artifacts. Avoidable technical alarms indicate true alarms that can be eliminated by proper application of equipment such as proper electrocardiogram electrode application and optimal device functionality. Further literature elucidates alarm categories based on alarm priority(high, low and medium) and need for alarm intervention (need intervention or does not need clinical intervention) (Johnson, Hagadorn, & Sink, 2017).

Using alarm data collection tool as proposed by Baillargeon's, the first column identifies an alarm as false, valid or technical. Then the alarm is described to justify the classification in first column. Then response column is filled to record duration of the alarm condition, and response to the alarm condition. Describe column was for name of the alarm as it appeared on the monitor, individual column was yes or no as to whether there was individualization of the alarm parameter per patient or not, while repeated alarms for the patient were tallied in the repeat column as well. Comments were tallied for further analysis or reevaluation by the researcher/observer. The tool was

administered by an experienced critical care nurse knowledgeable about alarms, selected monitors were studied, there was an institutional review board (IRB) approved plan not to share observation data with unit managers but the plan also required the observer to notify the registered nurse (RN) on duty when a critical condition of a patient was noted for appropriate care to the patient. No demographic data was taken.

2.2 Access to alarm data

Observational methods and retrospective data review (device audit logs) methods have been applied in literature to elucidating baseline information on clinical alarms in different hospital and clinical settings. For example, Fleischman et al's study classified alarms in terms of whether they lead to clinical change for patient care or not using a prospective quantitative observational design (direct observation method) that sought data in a busy Emergency Department. From this study, it was observed that only 3.4% of the patient alarms resulted to clinical changes in patient care while 65% of all observed alarms were not responded to while 34% of the alarms were silenced. An emergency department (ED) physician undertook 53 hours of observations within the ED on patients on monitors and staff responses to alarms. The authors conclude that selective monitoring of patient based on patient profile and risk as per clinician's assessment has the potential to reduce excessive and unnecessary alarms and recommend future research aiming for higher specificity and low false positives for clinical alarms devices (Fleischman, Ciliberto, Rozanski, Parwani, & Bernstein, 2020). Structured tools for data collection on alarm frequency and typology exists in literature (Baillargeon, 2013).

Debs applied observational methods to study work environment and performance impact of alarm fatigue across 4 day shifts and 4 night shifts of random observations on clinical alarms and work environments (Deb & Claudio, 2015).

Alarms can also be studied retrospectively using audit log alarm data in the clinical monitors**.** For example, Sowan et al utilized audit log to study 20 cardiac physiological monitors. Audit logs can provide a consistent, objective and less costly way of tracking trends on alarm data. Reporting of alarm data from audit logs should have information on enhance or basic modes, automatic detection modes, alarms delays, alarms (not) amenable to clinical actions, pausing or silencing alarm responses, and priority display for alarm types configurations. Understandable nomenclature

for alarms between vendors is a challenge to overcome with standardization of reporting and presentation of alarm data from the audit log (Sowan et al., 2016).

2.3 Alarm fatigue (AF)

Bliss & Dunn define alarm fatigue as a situation where by clinical staff habituate to ignoring alarms to alleviate sensory overload and cognitive demand as a result of perpetually unreliable alarms. In simulated real complex-task environment comparing workers' response to alarms with degree of unreliability, workers ignore alarms and concentrate on primary tasks. This observation supports alarm fatigue related to excessive non-actionable and nuisance alarms within busy clinical environments where clinicians ignore the alarms, or silence the alarms(Bliss & Dunn, 2000)(Sowan et al., 2016). Where alarm fatigue is prevalent, lack of specific and reliability of alarms bundles renders all alarms the same regardless of their specific urgency signals and attention to important primary tasks can be diminished. Therefore, knowledge on alarm fatigue can inform coping mechanisms on clinical workload.

Primary drivers of alarm fatigue include operator staff, environment, device, alarm settings, patient profile. Measures for alarm burden include alarm count (alarms per day) derived from time-stamped alarm history (can also study alarm per patient per day and devices have limited data capacity so frequent extraction is necessary), nonactionable alarm count (either nuisance or false alarms-false alarms are system malfunction when there is no issue with patient while nuisance are reflective of clinical changes that do not require any action), alarm priority level(high ,medium, low-high priority alarm needs immediate attention while medium and low sounds when it is not immediate-thus reducing the latter two can reduce alarm fatigue without increasing risk to the patient, alarm response time (device information on alarm duration can be a surrogate measure, clinician perceptions on alarm burden and balancing risk and gains in alarm burden alleviation. Sources of data for alarm quality improvement (QI) initiatives include the monitors with storage configurations and export of data capacity, third-party middle ware systems for data collection and manual data collection for assignment of action ability of the alarms. Sustainability should be seen and considered as a culture change strategy(Johnson et al., 2017).

Torabizadeh et al. proposed a validated and reliable tool for assessing nurses' perception and practices on clinical alarms within intensive care unit (ICU) setups. The authors utilized a 19 item psychometric tools from literature to develop a set of 13 questions with acceptable validity and

reliability measured by Cron-bach alpha scores (0.91) and test-retest reliability scores (0.99). The scale is scored from Never (0), Rarely (1) Sometimes (2), Often (3), Always (4). The total scores range between a minimum of 8 and maximum of 44 scores showing level of alarm fatigue impact on staff performance(Torabizadeh et al., 2017).

Another study by Claudio et al described a Framework for alarm Fatigue assessment among critical care staff which included measuring personality types by use of big Five Personality Model (measures conscientiousness, neuroticism, extroversion, agreeableness, openness) and work-related stressors (staffing ratio, sound levels in decibels, time since shift started, task priority and alarm criticality) and alarm fatigue by use of Subjective work assessment test (SWAT) for assessing overwhelming sensation and affect (distrust, boredom and apathy). The authors observed that work stressors; staff ratio, priority levels and shift lengths were associated with AF while personality types that are goal-oriented, proactive, assertive and high intellectual curiosity are better placed and less prone to AF. Work stressors and personality types require attention to reduce staff alarm fatigue. This model applied for assessing AF is comprehensive, in essence that, personality factors, and other work related factors apart from alarm load were studied as contributors to AF(Claudio, Deb, & Diegel, 2021). To refine the understanding of AF and its impact on clinical staff performance, Debs et al, de-linked AF from staff performance measures (response time and alarm response interventions) and studied it as measurement of mental workload and affect by use of validated tools. The authors observed that a combination of AF, working conditions and staff individuality had strong explicative statistical value for staff performance rather than AF alone. In conclusion, performance on alarm management is determined by other factors apart from alarm fatigue(Deb & Claudio, 2015). Alarm fatigue has also been significantly associated with dimensions of burnout among health providers however methodological limitation and scarcity of evidence makes this observation ungeneralizable in different settings (Nyarko et al., 2023) Lwiza et al's analytical cross sectional study assessing burnout among health workers in a hospital in Uganda established a 62% prevalence of burnout with work-related issues such as longer working hours being burnout predictors. The authors utilized modified Maslach Burnout Inventory tool(Maslach & Jackson, 1981) to examine the three aspects of the burn out, namely, emotional exhaustion, depersonalization and personal achievement(Lwiza & Lugazia, 2023). Despite the high burnout burden in sub-Saharan Africa

clinical settings(Dubale et al., 2019), scant evidence exists on its association with alarm fatigue as well as its specific impact on alarm management practices(Nyarko et al., 2023).

2.4 Study Rationale

Despite availability of international evidence on the burden of alarm fatigue and its negative effects on clinical workflows and its significance as an emotional, physical and cognitive burden on health care workers, little empirical effort has gone into establishing alarm fatigue burden and its effects among the health providers working in acute care settings in the Kenyan tertiary hospital. Moreover, literature-based alarm data gathering tools and methods remains under-utilized for systematic alarm data collection and review. Therefore, findings from this study will inform future quality improvement initiatives for optimizing collection and utilization of alarm data and improvement in alarm management protocols and policies for alarm safety and patient safety culture within clinical environment as proven in other contexts (Lee et al., 2021).

2.5 Theoretical Framework (Lazarus & Folkman, 1987)

Transactional Model of Stress and Coping (TMSC) by Lazarus et al posits that stress is caused by the transaction or relationship between personal characteristics and environmental factors. Under this framework, stress is defined as a mismatch between the demand to solve a problem and the resources and the existing capacity to respond to the problem at hand. Based on this mismatch, a person primarily makes a judgement on the stakes involved when a stressor occurs such as threat or harm to perform under stressing circumstances. This initial mediating processes is called primary appraisal and is followed by evaluation of the coping options available to address the stressors, called secondary appraisal. Secondary appraisal includes evaluating resources for response including skills and knowledge, consultation, or just ignoring or silence. This is followed by actual coping strategies based on the cognitive process of appraisals on the stressor. Coping strategies include problem-focused (such as confrontive coping, accepting responsibility, planful problem-solving) and emotion-focused strategies (such as positive re-appraisal, escape-avoidance, distancing). Coping to stress is related to contextual factors including perceived stakes and options for coping. Based on this cognitive and coping processes, a person is affected in the short term or in the long terms. The short-term effects include fatigue, apathy, negative or positive feelings depending on the outcome. The longer term effects could be social performance , physical health effects and subjective wellbeing(Lazarus & Folkman, 1987).

Application of Transaction Model of Stress and Coping Theory

Acute care settings have been cited to be very stressful environments for nurses and physicians owing to competing tasks and the required fast tempo of accomplishing tasks, such as taking and recording observations from cardiac monitors, drug administration and turning of patients. In the midst of these clinical roles, clinical alarms has been cited as stressors when they are excessive and non-actionable thus being regarded as nuisance alarms which can get ignored by the clinicians if they interfere with other primary tasks(Deb & Claudio, 2015). The clinicians have been cited to respond to the alarm in proportion of the probability of the validity of the alarm, which means that when clinicians perceive alarms to have high false positives, the alarm is ignored and distrusted as a coping mechanism for excessive and nuisance clinical alarms(Ruskin & Hueske-Kraus, 2015).

The TMSC model has been successfully applied and proven in previous studies seeking to understand causes of distress and exploring coping strategies among women (Quine & Pahl, 1991). Sensory overload from exposure to excessive clinical alarms has been hypothesized as the contributing factor to AF, however, this association can be modified and confounded by other clinical, socio-demographic and institutional characteristics.

Under the TMSC framework, first, in the primary appraisal the clinician cognitively evaluates the clinical alarm stressors in the working environment including personal capacity and expertise in responding to clinical alarms such as cadre, age, sex, professional experiences and training and the clinical environment including patient safety culture, clinical workload and staffing levels, existing protocols or support for alarm management. Second, in the secondary appraisal, the clinician forms a perception on the impact of a particular stressor and his or her ability as well as capacity of the multidisciplinary team to meet the demands of stressor. In the case of an alarm condition that is perceived not to present any threat, harm or challenge, it will be regarded as irrelevant and hence the secondary appraisals will not find apt and active coping strategies. Passive coping strategies such as habitually ignoring the alarm condition are elicited if a clinicians feels the alarm condition cannot be trusted. Otherwise, the clinicians would consider active coping strategies such as silencing the alarm, changing monitor parameters or attending to the patient if the condition warrants. Third, short term and long term outcomes of the causal outcomes and mediating stress mechanisms results to enduring effects on the clinicians including apathy, distrust, subjective feeling of fatigue in the short term and a culture of ignoring alarms and patient effects such as

avoidable threats to patient harms are habitually left unattended. It is this habitual detachment, unresponsiveness and apathy and exhaustion from clinical alarms that manifests alarm fatigue (AF). By the application of the TMSC theoretical model, personal factors and clinical work conditions that influence coping strategies such as patient culture safety and training have been deductively identified as potential predictors of AF among the clinicians. The personal and environmental (work conditions) factors of the study interest are shown in the conceptual framework in figure 2.

2.6 Broad Objective

Evaluating level of practice, knowledge and attitudes to optimal alarm management, the burden and predictors of alarm fatigue among health care workers (HCWs) in acute care settings(ICU and A/E) of Kenyatta National Hospital

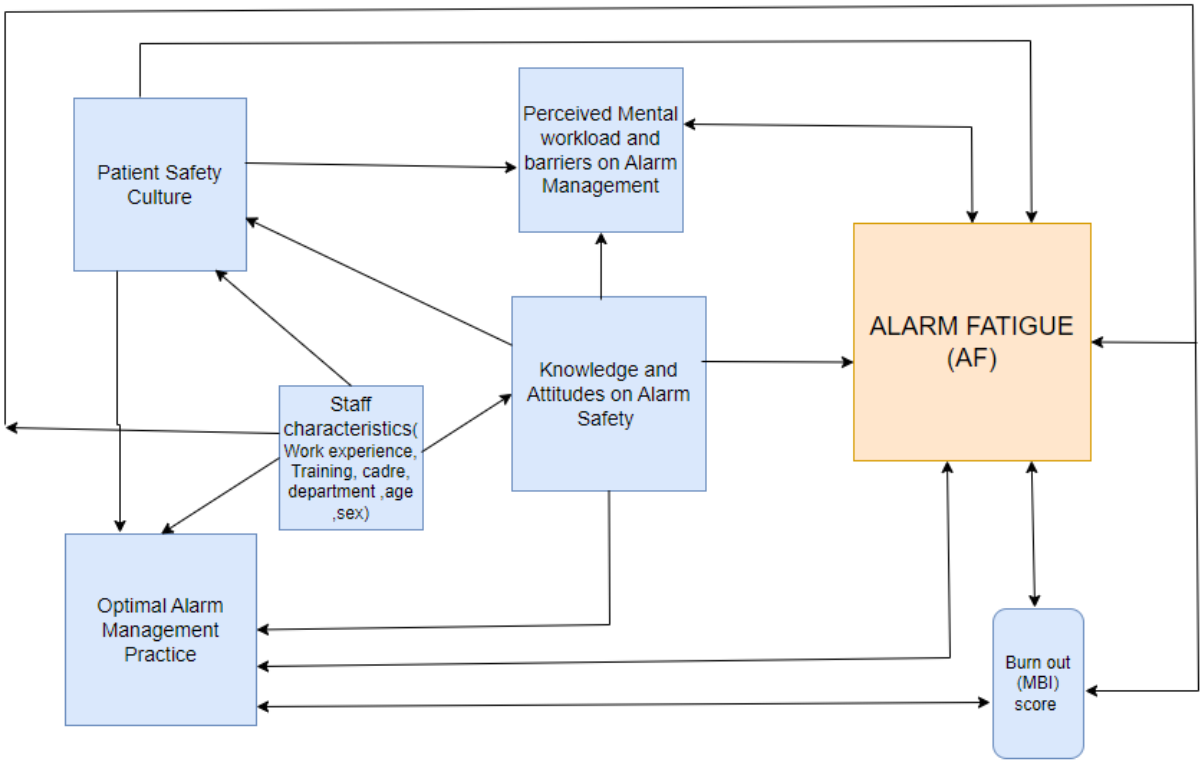
Specific Objectives

1. To establish the level of practice, attitudes, knowledge on optimal alarm management at acute care hospital settings.
2. To establish the prevalence of alarm fatigue among nurses and physicians at acute care hospital settings.
3. To establish the predictors (patient safety culture, burn out, sociodemographic characteristics of the provider) of alarm fatigue among nurses and physicians at acute care settings.
4. To determine the frequency of clinical alarms within acute care settings (total alarm load per patient, per hour, per unit and the proportion of false, valid ,nuisance, leads off , actionable and non-actionable alarms).

2.7 Conceptual Framework

Conceptual framework (figure 1) on the causes of Alarm Fatigue, adapted from Debs and Claudio conceptual model for Alarm fatigue(Claudio et al., 2021) and Lazarus' Transactional Model of stress (Lazarus & Folkman, 1987).

Figure 1: Conceptual model for risk factors of alarm fatigue



Personal characteristics of interest to the study of the contributing factors to the burden of AF include the clinician's age, sex, cadre, and professional years of experience in acute care settings, specialization status, alarm training history, terms of employment, comorbidity status and the department of work(Nyarko et al., 2023)(Lwiza & Lugazia, 2023). Deductively, levels of knowledge, practice and attitudes are hypothesized to determine the clinician's alarm fatigue levels as exhibited by self-reported practice and knowledge on response and coping strategies for clinical alarms(Meng'anyi et al., 2017).

Clinical safety culture has also been observed to influence clinical practice and safety interventions related to response to clinical alarms and minimization of AF (Lee et al., 2021). Staff burnout levels has also been previously associated with AF in other settings(Nyarko et al., 2023), therefore

we posit a significant relationship between AF levels and burnout scores of the study clinicians in respective study departments. Clinical workload may be a contributor to burnout and fatigue (AF) among health care workers especially when the demand for clinical tasks such as response to clinical alarms amidst other primary clinical tasks overwhelms their capacity and resources to meet those demands(Lazarus & Folkman, 1987)(Lwiza & Lugazia, 2023). Therefore, we have included perceived mental workload for alarm management task in the causal conceptual framework, as a reliable and proven subjective workload measure for clinicians(Tubbs-Cooley et al., 2018), to investigate its association with AF.

Alarm fatigue (AF) will be assessed using a subjective feelings from the impact of clinical alarms by the clinician on a scale of 0% to 100% (Wunderlich, Amende-wolf, Spies, & Balzer, 2023). The first 5 questions of the literature-based tool on AF examines subjective feelings from the impact of clinical alarms including: "*With too many alarms on my ward, my work performance and motivation decreases*", "*Too many alarms trigger physical symptoms for me, e.g. nervousness, headaches, sleep disturbances*", "*Alarms reduce my concentration and attention*", "*My or neighboring patients' alarms or crisis alarms frequently interrupt my workflow*", "*There are situations when alarms confuse me*". These question elicit high scores when the clinician reports negative feelings related to dealing with clinical alarm conditions.

The other part of the tool measures self-reported coping strategies with clinical alarms including : '*In my ward, a procedural instruction on how to deal with alarms is regularly updated and shared with all staff.*", "*Responsible personnel respond quickly and appropriately to alarms*", "*The audible and visual monitor alarms used on my ward floor allow me to clearly assign patient urgency*", and "*Alarm limits are regularly adjusted based on patients' clinical symptoms (e.g., blood pressure limits for condition after bypass surgery*)". These questions elicit the coping resources available for the clinician. Should the clinician respond negatively to these questions, this will be indicative of lack of coping resources, hence, contributing to the score on increased risk of alarm fatigue, a situation of failure to respond to alarm adequately due to mistrust and perceived lack of resources to deal with the problem(Wunderlich et al., 2023).

CHAPTER 3: METHODOLOGY

3.1 Design

This is an analytical cross-sectional study design applying quantitative survey and observational methods for data collection on health workers' knowledge, practice, alarm fatigue, staff burnout and perceptions on clinical alarms.

3.2 Study setting and area

The study will be conducted in the acute and critical care units of Kenyatta National Hospital. These include Accident and Emergency; Pediatric intensive care unit (PICU) and Main Critical Care Unit where clinical alarm devices are crucial and mandatory for optimal continuous monitoring of critical patients. Kenyatta National Hospital is the largest tertiary referral hospital in Kenya that offers specialized health services

3.3 Study population

The study population will be nurses and physicians working in the acute and critical settings of the Accident and Emergency, Critical Care and pediatric Intensive Care Units and have been at the present department of work over the last 3 month. Non-identifying alarm data on patients occupying critical and acute care beds shall be gathered through observations on alarm devices such as cardiac monitors, fluid pumps and ventilators.

3.4 Sample size determination

Participants for the alarm survey will be selected based on proportional probability sampling in each study department.

Sample of participants for the survey on clinical alarms will be computed using Fisher's formula for single proportions.

$$n = Z^2_{\frac{\alpha}{2}} * p(1-p)/d^2$$

n = desired sample size

$Z_{\alpha/2}$ = standard normal deviate at 95% confidence level, 1.96

p = proportion of alarm fatigue in a previous study, 0.62 (Seok, Cho, Kim, & Suh, 2023)

d = level of precision, 5%

$n = 1.96^2 * 0.62(1 - 0.62)/0.05^2$

$no = 362$

Desired sample size, n_o = 362

Preliminary data on the number of nurses and medical doctors per study department was collected through informal enquiries with departmental heads for study planning. This information guides the proportions of the sample size needed from each department of study as follows:

Table 1: Departmental distribution of the study population

Department	**Nurses-N**	**Doctors - D**	**Total**	**Sample Proportion (%)**	**Departmental Cadre ratio(N/D)**
Accident & Emergency	101	42	143	52%	2:1
Main ICU	88	10	98	36%	9:1
PICU	29	7	36	13%	4:1
Total (N, population size)			277	100%	

Given a higher sample size relative to the finite study population, sample size correction formula (Nanjundeswaraswamy & Divakar, 2021) was applied to obtain the actual sample size reflective of the small study population (277) as follows:

$$n = \frac{N \cdot n_0}{N + n_0 - 1}$$

,

Where, n is the adjusted sample size

- N is the population size, 277
- n_o is the initial desired calculated sample size , 362

Therefore,

$n = {}^{277*362} / {}_{277+362-1}$

n= 157*, is the adjusted total sample size.*

To obtain minimum sample from each department, the departmental proportion was multiplied by the total sample as follows:

- A/E, 51% * 157 = 80
- Main ICU, 36% * 157 = 57
- PICU, 13% * 157 = 20

To obtain proportionate sample per cadre (nurses and medical doctor) in respective departments, cadre ratios in table 1 were multiplied by the departmental sample as follows:

- A/E
  - nurses 2/3 * 80 = 53 nurses
  - doctors 1/3 * 80 = 27 doctors
- Main ICU,
  - nurses 9/10 * 57= 51 nurses
  - doctors 1/10 * 57= 6 doctors
- PICU,
  - nurses 4/5 * 20= 16 nurses
  - doctors 1/5 * 20= 4 doctors

Therefore, 53 nurses and 27 doctors at A/E, 51nurses and 6 doctors at Main ICU and 16 nurses and 4 doctors at PICU will be sampled.

Sample size for qualitative interviews will be convenient target of

3.5 Sampling Procedure and selection of participants

The departments of interest (Main ICU, A/E and PICU) have been purposively selected for study based on the specialization design in acute and critical patient care , availability of alarm producing devices and hence the potential for availability of sufficient data on staff exposure to and encounters with clinical alarms.

The selection of the staff participants per department and cadre shall be through simple random sampling to minimize systematic selection bias during the working hours of the study period. The research assistant will randomly approach staff working in respective departments and invite them

for participation. For A&E department, only staff deployed at the critical and resuscitation rooms will be sampled to minimize bias in alarm exposure when including staff working in A&E sections without alarms such as medical and surgical rooms.

Research assistants, trained on applying the study's alarm observations tool, shall randomly sample occupied critical patient beds as non-participant observers. The observer will focus on any two critical care bed and alarm devices occupied by a patient during the scheduled hourly observation blocks. The observations will be conducted at random hourly intervals for 2 hours per 6-hour shift in each unit for random 7 day-shifts and 7 night-shifts distributed across a month of the study period. Random allocation of observations within the shift and across the study month will allow random distribution of within-shift variance as well as within the month variance on alarm exposure brought by varying patient volume and severity. This is aimed at minimizing observations bias likely to happen for specific hours of the shift and specific weeks of the month.

3.6. Recruitment and consenting procedures

In each respective department, a research assistant will approach and invite the working staff randomly. At the convenience of the staff, a written informed consent shall be issued and explained. Upon obtaining voluntary willingness to participate and signing of the written consent form, the study questionnaire (section 3.9) will be administered to the study participants.

Consent for clinical observations shall be sought from the departmental heads and managers not involved in bedside roles and day to day response to clinical alarms. Both cadres of the clinical staff shall be blinded on the actual alarm response data to be observed by the research observer to minimize observer effect (Hawthorne effect) and to protect the non-participant observation approach. Trust and consolidated relationships are essential to make the conduct of non-participant observations easier and feasible, therefore, several strategies will be applied to familiarize and consolidate relationship between the alarm observers and the staff in respective departments(Cooper, Lewis, & Urquhart, 2004). First, initial data collection for one week will entail the random administration of the study questionnaires to the eligible staff in respective departments by the research assistants who will subsequently serve as observers. This period will allow for familiarization between the research assistants and the respective department staff. The period will also allow for sensitization of the departmental staff on the alarm fatigue study. The departmental managers will have disclosure on the information for observational methods for

alarm response but will not be fully disclosed to the bedside nurses and doctors. Second, the recruitment of the 3 research assistants will consider their familiarity with the respective study departments either as staff with official administrative permission to serve as research assistants or as medical research assistants with experience collecting data within the respective study departments in previous research projects. The working relationship and the rapport of the research assistants with the department will minimize observer suspicions and enquiries on exact data collection objectives.

Sensitive and confidential information including identity of staff on duty and the identity of patients will not be collected be anonymized while date and time of observations will be de-identified and kept secure from any other personnel apart from the research team to avoid tracing and match-up of the specific shifts, patients and personnel with departmental staff working rosters.

3.7 Variables

Alarm fatigue will be the outcome variable as the primary study outcome. The hypothesized predictors of alarm fatigue include participant characters, patient safety culture score, burn out score, knowledge, attitude and practice levels and alarm response mental workload (table 2). Clinical alarm frequency and typology will be measured separately and descriptively reported.

Table 2: Study Variables

Independent variable	Dependent outcome
• Staff Characteristics (professional and sociodemographic)	• Alarm fatigue
• Patient safety culture	
• Burn out	
• Knowledge	
• Attitude	
• Practice on alarm safety	
• Perceived mental workload	
• Perceived barriers to alarm safety	

Table 3: Social demographic and professional variables of the study participants

Objectives	**Variable**	**Type of Data**
Objective 1: To establish the level of practice, attitudes, knowledge on optimal alarm management at acute care hospital settings.	1. Level of knowledge	Continuous (%)
	2. Level of optimal practice	Continuous (%)
	3. Patient safety culture	Continuous (%)
	4. Attitudes	Nominal (negative or positive (%)
	5. Ranked Barriers	Ordinal (%)?
Objective 2: To establish the prevalence of alarm fatigue among nurses and physicians at acute care hospital settings.	• Prevalence of Alarm fatigue	Continuous
Objective 3: To establish the predictors of alarm fatigue among nurses and physicians at acute care settings	1. Overall perceived Mental workload on alarm management task. 2. Department of work. 3. Personal and professional characteristics (table 3). 4. Knowledge, attitudes and practice levels. 5. Perceived Safety culture score. 6. Burn out score	Continuous (%) (4,5,6) Categorical (1,2,3)
Objective 4: To determine the frequency of clinical alarms within acute care settings (total alarm load per patient, per hour, per unit and the proportion of false, valid ,nuisance, leads off , actionable and non-actionable alarms).	1. Total alarm load, alarms per patient/ per hour / per unit 2. Clinical description of alarms observed e.g PVC, SPO2 low 3. Class of alarms: e.g False, valid, nuisance, leads off, actionable and non-actionable alarms. 4. Response type e.g Ignore, acknowledge, silence, review and adjust monitor parameters, assess patient and intervene appropriately.	Continuous (%) (1,2,3) and categorical data (4)

3.8 Data collection procedures, Instruments, material and tools

Quantitative data collection procedures will include a researcher-administered questionnaire for study the objectives 1, 2 and 3, and an application of the alarm observational tool for objective 4 by the non-participant observer for the study objective 4. Upon consenting, the research assistants will assist the study participant to fill in the study questionnaire by clarifying each section and question of the tool and follow-up to ensure completeness of the responses with the aim improving quality of the data. Redcap software adopted and supported by Kenyatta National Hospital department of medical research will be utilized for real-time data collection on clinical observations of clinical alarms and also for data entry from questionnaire survey responses.

Data collection tool (appendix III) has been developed and adopted from validated alarm fatigue assessment tools in literature. The tool is structured into 7 sections: section 1, 2 and 3 were adopted from ACCE Health Technology Foundation alarm fatigue study tool (2006) as well as from other validated study tools including. Section 1 assesses the socio-demographics and professional characteristics of the study participants, section 2 assesses the level of practice, attitudes, and knowledge on alarm management, and section 3 assesses the perceived barriers to optimal alarm management. Section 4 establishes patient safety culture scores and was adapted from previous studies investigating the impact of patient safety culture on alarm management practices (Lee et al., 2021)(Chae & Lee, 2014). Section 5 examines the perceived mental workload on alarm management task by the study participants and has been adopted from the modified National Aeronautics and Space Administration-Task Load Index (NASA-TLX) tool (Tubbs-Cooley et al., 2018). Section 6 investigates the prevalence and the burden of alarm fatigue (AF) among the participants and was adopted from the Charité Alarm Fatigue Questionnaire published by Wunderlich et al. (2023). Section 7 evaluates burn out scores among the participants using the Maslach burnout Inventory (MBI) tool (Human Performance Research Group (NASA), 1986). Overall burn out scoring criteria across dimensions of emotional exhaustion (EE) , personal Accomplishment (PA) and depersonalization (DP)will be adopted from previous literature with scores of 27 and over for EE , 13 or over for DP and low score between 0 to 31 for PA being the criteria for classifying the staff as having burn out (Nyarko et al., 2023).

Sections 2, 4 and 6 employs 5-point Likert scales rather than binary responses to increase sensitivity of the tool in detecting nuanced responses and perceptions on AF predictors among the study participants while also enhancing the construct validity and the reliability of the study tool.

Previous literature cites 6-point or 7 point Likert scales as ideal, however, the 5-point Likert scale of the adopted tools were chosen for this study to minimize confusion, response burden and enhance response rate among the study participants(Taherdoost, 2019).

The 5-point Likert scales in section 2 and 4 includes a neutral mid-point of "neither agree nor disagree", to avoid the bias of forcing the respondents into either sides of the agreement or disagreement(Johns, 2010). These scales in these sections will be quantitatively coded as 1 to 5 from strongly disagree to strongly agree respectively, with an assumption of equal distance between the scales.

The Likert scale of the Charité Alarm Fatigue Questionnaire in section 6 contains non-neutral midpoint of 'I AGREE IN PART" (Johns, 2010)(Wunderlich et al., 2023). This forces respondents to be on either sides of agree scale or disagree scale. By maintaining this non-neutral midpoint scale of the Charite AF questionnaire, we seek to maximize distinctness of the responses on the AF as the outcome variable by minimizing respondents who may refrain from taking a position on the impact of clinical alarms. These scales in this section will be quantitatively scored from 0 to 4 (same as original scale from literature) for "I DO NOT AGREE AT ALL to "I VERY MUCH AGREE" respectively, with an assumption of equal intervals in the scales. However, the scores are applied in reverse for items 6, 7, 8 and 9 (appendix III, and section 6).

The last section includes the Alarm frequency observational tool, adopted from Baillargeon's study (2013). The tool will be developed into the Redcap software for real time observational data collection (Baillargeorn 2013) (Ruskin & Hueske-Kraus, 2015).

3.9 Training procedure

To train the observers and improve robustness of observations using the study questionnaire and the observational tool, a pre-study questionnaire administration and observational exercise using the same tools but in non-study critical care departments will be conducted. The findings from these pre-study exercises will be used to improve clarity and rectify errors of the data collection tools and the responses will not be included in the final data analysis

3.10 Quality assurance procedure

The research team and the assistants will adhere to the ethical standards in the course of all study activities including confidentially, respect for rights of persons voluntarily participating, declining or opting out of the study and anonymity. The research assistants will trained on the data collection

tools prior to the study to improve the quality of data collection processes and outcomes. The selection of research assistants will include a criteria that comprises of familiarity with data collection within the study departments, and formal nursing and medical qualification at diploma level with over 15 years of clinical experience or bachelors level qualification with previous experiences in qualitative and quantitative data collection methods within the study departments. The research assistants will be required to have a proof of vaccination against COVID-19 disease and will be required to observe Infection prevention and control (IPC) measures of the respective study departments.

Written informed consent will be provided prior to the administration of the study questionnaire to all participants. Where non-participant observations will be conducted, the right to privacy and confidentiality will be observed while applying strategies to building trust and cordial relations with the working staff to allow for smooth working relations. Consent for withholding information being observed by the observer will be sought from the departmental heads and the managers to allow for realistic data about current practice on clinical alarm response. This will minimize observer bias on the response to clinical alarms. Any crisis alarm not noticed by the staff will be reported by the research assistants in respective departments to the relevant clinical staff in a timely manner to prevent undetected deterioration of the patient. Therefore, the research team will endeavor not to disrupt service delivery and prevent any cause of patient harm. Data storage will be secured to restrict data use to the scope of this protocol and prevent any unintended usage of the data or any authorized access to the data.

3.11 Ethical considerations

Approval for this study will be sought from the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (KNH-UoN-ERC) and NACOSTI Further permission and registration of the study will be done at the Kenyatta National Hospital (KNH) administration and support sought from respective departments where the study will be conducted.

Following ERC approval, written informed consent will also be sought from the study participants. Confidentiality and anonymity of the participants will be guaranteed and safeguarded. Data gathered from patient monitors as well as from staff will be de-identified during entry and thus patient and staff identifier information will not be collected. Where identifier information is

collected and is available, it will be de-identified through anonymization and kept confidential from both the staff and the hospital managers except only for the purposes of research under this study protocol.

Permission for survey and observational data collection shall be sought from the Unit Managers. The non-participant observers will trained on the tools for gathering data and will be working in shifts across all the study departments to minimize inter-observer bias. The observers will be primarily deployed at critical and acute rooms for administering the study questionnaires to the clinical staff. This will be fully communicated to the clinicians to enhance their cooperation for ease of having the non-participant observers frequenting the clinical areas. However, the observers will not be required to disclose full information to the clinicians on data collection for alarm response observations to minimize observer-effect bias. Nonetheless, the observers will be required to alert the nursing or medical staff on any unrecognized patient signals for resuscitation needs, to assure patient safety and reduce any harm to the patients.

3.12 Data Management plan

Data entry and cleaning

Data collection and entry will be done using REDCAP software, downloaded as an Ms Excel file for initial data visualization and correction for errors then exported into R studio for advanced analysis. Further clean-up will include removal of duplicates, structuring and formatting for advanced statistical analysis.

Storage, security and quality assurance

Data will be password-protected, observations anonymized, and kept confidential for the purposes of this study only. Data will be preserved under appropriate scientific databases in line with principles of findability, accessible, interoperability and reusability (FAIR).

Data analysis plan

Data analysis will be conducted in line with study objectives. First, descriptive analysis for levels of knowledge, practice and attitudes will be reported in percentages for the first objective. A descriptive analysis of the social demographic and professional characteristics of the study participants will also be tabulated in percentages.

The second objective will be accomplished through computation of statistical proportion of overall alarm fatigue and respective departmental and cadre alarm fatigue. Chi square test will be applied

for hypothesis testing of the statistical difference of the AF proportions across departments and cadre. Statistical significance will be at 95% confidence intervals for all hypothesis tests.

The third objective will be accomplished through multilinear regression modelling in view of alarm fatigue scores as continuous outcome variable as well as logistic regression analysis where the outcome variable is transformed into binary outcome. The predictors included in the model will include participant's characteristics, percentage levels of attitudes, knowledge and practice on clinical alarms, patient safety cultures scores, burn out scores and mental workload indices. Mixed models will be applied to control for confounders, describe interaction and the multi-collinearity arising from multilevel and hierarchical variables (department of work and cadre) with the aim of developing a predictor model for alarm fatigue with the least Akaike Information Criteria (AIC) and Bayesian Information Criteria (BIC) values.

The fourth objective will be accomplished through tabulation (table 8) of alarm frequency measures and the mean counts. The distribution of alarm typology and frequencies across the departments of the study will be reported in form a bar chart.

CHAPTER 4: PROPOSED PRESENTATION OF RESULTS

4.1 Dummy Tables

Table 4: Social demographic characteristics of survey participants

Characteristics	N (%)
Age	
Sex	
Cadre	
Professional experience (Years)	
Specialization	
Department of work	

Comorbidity status	
Terms of service	
Training Status on alarm management	

Table 5: Knowledge, practice and attitudes on alarm safety

Item	Mean ±SD x/
The purpose of clinical alarms is to alert staff of an existing or potentially hazardous patient condition	
Alarm sounds and /or visual displays should differentiate the priority of alarms	
Alarm sounds and/or visual displays should be distinct on the parameter or source (BP,SPO2,EKG)	
Alarms should impact multiple senses (audible, visual, proprioceptive, etc.)	
Nuisance alarms occur frequently	
Nuisance alarms disrupt patient care	
Nuisance alarms reduce trust in alarms and cause care givers to turn alarms off at times other than setup or procedural events	
The staff is sensitive to alarms and responds quickly	
The alarms used on my floor/area of the hospital are adequate to alert staff of potential or actual changes in a patient's condition	
The medical equipment used on my unit/floor all have distinct outputs (sounds, repetition rates, visual displays etc) that allow differentiation of the source of the alarms.	
When a number of device with alarms are used with a patient, it can be confusing to determine which device is sounding an alarm.	
Environmental background noise has interfered with alarm recognition	
Properly setting alarm parameters and alerts is overly complex in existing devises	
There have been frequent instances where alarms could not be heard and were missed	

Table 6: Knowledge, perceived barriers and mental work load and burn out scores

Characteristics	**Mean ±SD**
1. Mental workload scores (%)	
2. Patient safety culture (%)	
3. Burn-Out scores (Intensity | Frequency) Emotional exhaustion EE Depersonalization DP	

Personal accomplishment PA	
4. Knowledge and recognition level % (Mean scores)	
5. Alarm management Practice (%)	
6. Alarm fatigue scores (%)	
	N (%)
7. Ranked Perceived Barriers to optimal alarm response	

Table 7: Predictors of Alarm fatigue (AF) from multilinear and multivariable regression model

Predictors of AF	**B(SE)**	**OR at 95% CI**	**P value**
Age			
Sex			
Cadre			
Training on Alarm management			
Mental Workload			
Patient Safety culture			
Knowledge			
Attitudes			
Department of work			
Work experience (YRS)			
Terms of Employment			
Comorbidity status			
Training status			
Burn out score			

Table 8: Alarm frequency and typology based on Baillargeon's Tool

Descriptive on alarm frequency	N (mean , counts)
Monitors (type) Department 1 Department 2 Department 3	
Total clinical alarms, observation time in hours, number of patients observed.	
Type of alarms	

Sample of beds	
Total beds	
Number of patients monitored	
Description	
Response time to leads off	
Response time to critical alarms	
Response time to valid alarms	
Response type (valid, nuisance , technical , false alarms , leads off)	

4.2 Study results dissemination plan

The dissemination plan of the study findings will include development and publication of policy and issue briefs based on the findings per study objective, virtual webinar presentation in the KNH-UON webinar series platform and other webinar platforms, submission of study abstract to apply for oral and poster presentation at local and international scientific conferences, developing and submitting manuscript for peer-reviewed journal publications. Respective departmental workshops will be organized in study departments to sensitize staff about study findings and study recommendations as the basis for further research or improvement actions.

4.3 Study limitations

The study is not without limitations. First, temporal sequence of the contributing factors to AF cannot be ascertained in view of cross sectional design of the study. However, inclusion of multiple variable equation regression modelling will improve validity of our inference on statistical association of AF with key occupational exposure variables while controlling for confounders. Second, observer effect and selection biases are rife limitations in our study methods. Therefore, non-participant observer method will be implemented to minimize observer effect on the alarm response behavior among study departments while simple random sampling will be applied to minimize bias in selecting and recruiting participants in respective departments. Third, there is a chance that the study population might not be a representative to the population of nurses and doctors working in other acute and critical care settings owing to differential hospital alarm management policies, training programs and hospital designs. To improve generalizability of our

findings, we have maintained a precision of 5% and a relatively larger sample size using sample size correction formula favorable to our finite study population of 277 nurses and physicians. Therefore, the prevalence of alarm fatigue AF established under this study may be generalized in similar hospital settings.

REFERENCES

AAMI. (2020). *ANTHOLOGY Alarm Management Solutions 2014-18*.

Ashrafi, S., Najafi Mehri, S., & Nehrir, B. (2017). Designing an Alarm Fatigue Assessment Questionnaire: Evaluation of the Validity and Reliability of an Instrument. *Journal of Critical Care Nursing*, *10*(4). https://doi.org/10.5812/ccn.11647

Baillargeon, E. (2013). *Digital Commons @ RIC Alarm Fatigue : A Risk Assessment*.

Bliss, J. P., & Dunn, M. C. (2000). Behavioural implications of alarm mistrust as a function of task workload. *Ergonomics*, *43*(9), 1283–1300. https://doi.org/10.1080/001401300421743

Chae, D. H., & Lee, C. Y. (2014). Development and psychometric evaluation of the Korean version of the cultural competence scale for clinical nurses. *Asian Nursing Research*, *8*(4), 305–312. https://doi.org/10.1016/j.anr.2014.06.004

Claudio, D., Deb, S., & Diegel, E. (2021). A Framework to Assess Alarm Fatigue Indicators in Critical Care Staff. *Critical Care Explorations*, *3*(6), e0464. https://doi.org/10.1097/cce.0000000000000464

Cooper, J., Lewis, R., & Urquhart, C. (2004). Using participant or non-participant observation to explain information behaviour. *Information Research*, *9*(4).

Deb, S., & Claudio, D. (2015). Alarm fatigue and its influence on staff performance. *IIE Transactions on Healthcare Systems Engineering*, *5*(3), 183–196. https://doi.org/10.1080/19488300.2015.1062065

Dubale, B. W., Friedman, L. E., Chemali, Z., Denninger, J. W., Mehta, D. H., Alem, A., … Gelaye, B. (2019). Systematic review of burnout among healthcare providers in sub-Saharan Africa. *BMC Public Health*, *19*(1247). https://doi.org/doi.org/10.1186/s12889-019-7566-7

ECRI Institute. (2012). Top 10 Health Technology Hazards for 2013. In *Health Devices* (Vol. 41). Retrieved from www.ecri.org/2013hazards

Fleischman, W., Ciliberto, B., Rozanski, N., Parwani, V., & Bernstein, S. L. (2020). Emergency department monitor alarms rarely change clinical management: An observational study.

American Journal of Emergency Medicine, *38*(6), 1072–1076. https://doi.org/10.1016/j.ajem.2019.158370

Human Performance Research Group(NASA). (1986). *NASA Task Load Index (TLX) User Manual v. 1.0* (p. 19). p. 19. Retrieved from https://humansystems.arc.nasa.gov/groups/TLX/downloads/TLX.pdf

Johns, R. (2010). LIKERT ITEMS AND SCALES-SURVEY QUESTION BANK: Methods Fact Sheet 1 (March 2010) LIKERT. In *QUESTION BANK*. https://doi.org/10.1108/eb027216

Johnson, K. R., Hagadorn, J. I., & Sink, D. W. (2017). Alarm Safety and Alarm Fatigue. *Clinics in Perinatology*, *44*(3), 713–728. https://doi.org/10.1016/j.clp.2017.05.005

Lazarus, R. S., & Folkman, S. (1987). Transactional theory and research on emotions and coping. *European Journal of Personality*, *1*(3), 141–169. https://doi.org/10.1002/per.2410010304

Lee, S. J., Lee, Y. M., Seo, E. J., & Son, Y. J. (2021). Impact of hospital nurses' perception on clinical alarms and patient safety culture on alarm management practice. *International Journal of Environmental Research and Public Health*, *18*(8). https://doi.org/10.3390/ijerph18084018

Lwiza, A. F., & Lugazia, E. R. (2023). Burnout and associated factors among healthcare workers in acute care settings at a tertiary teaching hospital in Tanzania: An analytical cross-sectional study. *Health Science Reports*, *6*(5), 1–7. https://doi.org/10.1002/hsr2.1256

Maslach, C., & Jackson, S. E. (1981). The measurement of experienced burnout. *Journal of Organizational Behavior*, *2*(2), 99–113. https://doi.org/10.1002/job.4030020205

Meng'anyi, L. W., Omondi, L. A., & Muiva, M. N. (2017). Assessment of nurses interventions in the Management of Clinical Alarms in the critical care unit, Kenyatta National Hospital, a cross sectional study. *BMC Nursing*, *16*(1), 1–9. https://doi.org/10.1186/s12912-017-0235-1

Mirzoev, T., & Kane, S. (2017). What is health systems responsiveness? Review of existing knowledge and proposed conceptual framework. *BMJ Global Health*, *2*(4). https://doi.org/10.1136/bmjgh-2017-000486

Nanjundeswaraswamy, T. S., & Divakar, S. (2021). Determination of Sample Size and Sampling Methods in Applied Research. *Proceedings on Engineering Sciences*, *3*(1), 25–32. https://doi.org/10.24874/pes03.01.003

Nyarko, B. A., Yin, Z., Chai, X., & Yue, L. (2023). Nurses' alarm fatigue, influencing factors, and its relationship with burnout in the critical care units: A cross-sectional study. *Australian Critical Care*, (xxxx). https://doi.org/10.1016/j.aucc.2023.06.010

Oliveira, A. E. C. de, Machado, A. B., Santos, E. D. Dos, & Almeida, É. B. de. (2018). Alarm fatigue and the implications for patient safety. *Revista Brasileira de Enfermagem*, *71*(6), 3035–3040. https://doi.org/10.1590/0034-7167-2017-0481

Quine, L. Y. N., & Pahl, J. A. N. (1991). *Stress and Coping in Mothers Caring for a Child with Severe Learning Difficulties : A Test of Lazarus ' Transactional Model of Coping*. *I*(February), 57–70.

Ruskin, K. J., & Hueske-Kraus, D. (2015). Alarm fatigue: Impacts on patient safety. *Current Opinion in Anaesthesiology*, *28*(6), 685–690. https://doi.org/10.1097/ACO.0000000000000260

Seok, Y., Cho, Y., Kim, N., & Suh, E. E. (2023). Degree of Alarm Fatigue and Mental Workload of Hospital Nurses in Intensive Care Units. *Nursing Reports (Pavia, Italy)*, *13*(3), 946–955. https://doi.org/10.3390/nursrep13030083

Sowan, A. K., Reed, C. C., & Staggers, N. (2016). Role of large clinical datasets from physiologic monitors in improving the safety of clinical alarm systems and methodological considerations: A case from philips monitors. *JMIR Human Factors*, *3*(2), 1–10. https://doi.org/10.2196/humanfactors.6427

Taherdoost, H. (2019). What Is the Best Response Scale for Survey and Questionnaire Design; Review of Different Lengths of Rating Scale / Attitude Scale / Likert Scale. *International Journal of Academic Research in Management (IJARM)*, *8*(1), 2296–1747.

The Joint Commission. (2013). The Joint Commision sentinel event alert: medical device alarm safety in hospitals. *The Joint Commision*, (50), 1–3. Retrieved from https://www.jointcommission.org/assets/1/6/SEA_50_alarms_4_26_16.pdf

The Joint Commission. (2021). National Patient Safety Goals Effective January 2022 for the Hospital Program. *Patient Safety*, (25 oct), 1–12. Retrieved from https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/2022/npsg_chapter_hap_jan2022.pdf

Torabizadeh, C., Yousefinya, A., Zand, F., Rakhshan, M., & Fararooei, M. (2017). A nurses' alarm fatigue questionnaire: development and psychometric properties. *Journal of Clinical Monitoring and Computing*, *31*(6), 1305–1312. https://doi.org/10.1007/s10877-016-9958-x

Tubbs-Cooley, H. L., Mara, C. A., Carle, A. C., & Gurses, A. P. (2018). The NASA Task Load Index as a measure of overall workload among neonatal, paediatric and adult intensive care nurses. *Intensive and Critical Care Nursing*, *46*, 64–69. https://doi.org/10.1016/j.iccn.2018.01.004

Vockley, M., Howard, M., Flack, M. N., & Blair, K. (2015). Clinical Alarm Management Compedium. In *Association for the Advancement of Medical Instrumentation*. https://doi.org/10.1097/NMC.0b013e31824c5b4a

Wunderlich, M. M., Amende-wolf, S., Spies, C., & Balzer, F. (2023). *A Brief Questionnaire for Measuring Alarm Fatigue in Nurses and Physicians in Intensive Care Units*. 1–19.

APPENDICES

APPENDIX I: INFORMED CONSENT FORM

KNH-UON Ethics and research committee,

P.O. Box 20723-00202,

Nairobi, Email: uonknh_erc@uonbi.ac.ke.

Study title: EVALUATING LEVEL OF PRACTICE, KNOWLEDGE AND ATTITUDES TO OPTIMAL ALARM MANAGEMENT, THE BURDEN AND THE PREDICTORS OF ALARM FATIGUE AMONG HEALTH CARE WORKERS (HCWS) IN ACUTE CARE SETTINGS OF KENYATTA NATIONAL HOSPITAL: A CROSS-SECTIONAL STUDY DESIGN

Introduction: Hello, we are inviting you inviting you to participate in this research study. The study will be evaluating alarm fatigue and its predictors as well as alarm counts and frequencies at the acute and critical care setting of Kenyatta National Hospital. You have the right not to participate in this study. Your participation will help us obtain data on healthcare workers perceptions of alarms, alarm fatigue and barriers to alarm management in the units.

Purpose of the Study: The main aim of this study is to evaluate knowledge, practice and attitudes, and barriers on clinical alarm safety, alarm fatigue among health care workers in acute care settings of Kenyatta National Hospital.

Risks: Participation in this study does not involve any financial or physical risks. However, it may require a few minutes of your time from your busy schedule to complete the questionnaire.

Benefits of the Study: Knowledge on clinical alarm type and frequency can inform specific strategies to reduce non-actionable and nuisance alarms. Understanding alarm fatigue among health care workers and its predictors will inform measures for enhancing staff alarm coping strategies and enhanced awareness on alarm types and need for timely response to crisis and valid clinical alarms as a patient safety strategy.

Confidentiality and Voluntary Participation: All the information that you will share by answering the questionnaire will be kept confidential. All filled questionnaires will be locked in a cabinet with the principal researcher only having access. Participation in this study is entirely voluntary, and you have the right to withdraw from the study at any given time without facing any consequences or penalties. Your decision to participate or withdraw will in no way affect your current or status as an employee of Kenyatta National Hospital. Your privacy and confidentiality will be respected throughout the study, and your personal information will be kept confidential.

Sharing of results: Results of this research will be shared in research forums and will be possibly published in health journals.

Contact person: If you have any queries or require further information regarding this research, please feel free to get in touch with the Principal investigator:

Principal Investigator: John Macharia Kiragu,

Contact Information: +254719311135, **Email address**: kiragu.jonny@gmail.com

Institution Affiliation: Kenyatta National Hospital.

APPENDIX II: CONSENT FORM

Participant's statement: I have read and understood the content of this consent form. I have also had the chance to discuss any concerns or queries with the researcher and have received satisfactory answers. I have been adequately informed about the benefits and risks associated with participating in this study. I understand that my participation is completely voluntary, and I have the right to withdraw from the study at any point without any negative consequences.

I understand that signing this permission form does not take away my legal rights as a study participant.

Participant signature ……Date……...

Researcher's statement: I, mentioned below, hereby confirm that the participant mentioned above has fully understood and willingly consented to participate in the study. I have provided a detailed explanation of all relevant information regarding the study to the participant.

Researchers name……

Signature……...

Date …….

APPENDIX III: STUDY QUESTIONNAIRE

Section 1 Social demographics

Section 2 Alarm survey: Knowledge, practice, attitudes, obstacles

Section 3: Perceived Barriers to Alarm Safety

Section 4: Patient Safety Culture

Section 5: Perceived mental workload on alarm management task

Section 6: Alarm fatigue assessment

Section 7: Burn out assessment

Section 8: Modified Baillargeon's tool

SECTION 1: SOCIAL DEMOGRAPHICS

1. Age……
2. Sex…….
3. Years of professional work experience ……
4. Cadre: Nurse☐ Medical Doctor /Specialist/ Resident ☐ Others☐
5. Department of work…….
6. Academic qualifications

   Masters☐, Degree☐, Higher diploma☐, Diploma☐, Certificate☐, others☐

7. Have you received any training on clinical alarm management within the hospital or during your training for diploma or degree?
   Yes☐ No☐ Not sure ☐
8. Any Pre-existing comorbid conditions Yes ☐ No ☐ Not sure ☐
9. Last Body Mass Index (BMI) taken (recall)……..
10. Terms of employment :

    Temporary contract☐ Permanent and pensionable ☐ Residency/Internship ☐

SECTION 2: KNOWLEDGE, PRACTICE, ATTITUDES TO ALARM SAFETY

Kindly indicate your agreement with the following statements in the table below

	Strongly agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1. The purpose of clinical alarms is to alert staff of an existing or potentially hazardous patient condition					
2. Alarm sounds and/or visual displays should differentiate the priority of alarm					
3. Alarm sounds and/or visual displays should be distinct based on the parameter or source (e.g. device)					
4. Alarms should impact multiple senses (audible, visual, proprioceptive, etc.)					
5. Nuisance alarms occur frequently					
6. Nuisance alarms disrupt patient care					
7. Nuisance alarms reduce trust in alarms and cause care givers to turn alarms off at times other than setup or procedural events					
8. The medical equipment used on my unit/floor all have distinct outputs (sounds, repetition rates, visual displays, etc.) that allow differentiation of the source of the alarm.					
9. Environmental background noise has interfered with alarm recognition					
10. There have been frequent instances where alarms could not be heard and were missed					

11. Policies and procedures exist within the hospital to regulate alarms and they are followed					
12. Properly setting alarm parameters and alerts is overly complex in existing devices					
13. The alarms used on my floor/area of the hospital are adequate to alert staff of potential or actual changes in a patient's condition					
14. The staff is sensitive to alarms and responds quickly					
15. There is a requirement in my hospital department to document that the alarms are set and are appropriate for each patient					

SECTION 3: PERCEIVED BARRIERS TO ALARM SAFETY

Please rank the following issues below concerning alarms; 1 = most important, 9 = least important. Read all issues first, then rank each issue with only one ranking.

		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
1	Difficulty in setting alarms properly									
2	Difficulty in hearing alarms when they occur									
3	Difficulty in identifying the source of an alarm									
4	Difficulty in understanding the priority of an alarm									
5	Frequent false alarms, which lead to reduced attention or response to alarms when they occur.									
6	Inadequate staff to respond to alarms as they occur.									
7	Over reliance on alarms to call attention to patient problems									
8	Noise competition from non-clinical alarms and pages									
9	Lack of training on alarm systems									
10	Other…….									

SECTION 4: PERCEIVED PATIENT SAFETY CULTURE

Please indicate the level of your agreement with following statements in the table below:

1. OVERALL PERCEPTIONS OF SAFETY	**Strongly disagree**	**Disagree**	**Neither agree or disagree**	**Agree**	**Strongly Agree**
• Patient safety is never sacrificed to get more work done.					
• Our procedures and systems are good at preventing errors from happening.					
• It is just by chance that more serious mistakes don't happen around here.					
• We have patient safety problems in this department.					
2. SUPERVISOR/MANAGER EXPECTATIONS & ACTIONS PROMOTING PATIENT SAFETY					
• My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures.					
• My supervisor/manager seriously considers staff suggestions for improving patient safety.					
• Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts.					
• My supervisor/manager overlooks patient safety problems that happen over and over.					
3. ORGANIZATIONAL LEARNING – CONTINUOUS IMPROVEMENT					
• We are actively doing things to improve patient safety.					
• Mistakes have led to positive changes here.					
• After we make changes to improve patient safety, we evaluate their effectiveness.					
4. TEAMWORK					
• People support one another in this department.					

• When a lot of work needs to be done quickly, we work together as a team to get the work done.					
• In this department, people treat each other with respect.					
• When one area in this department gets really busy, others help out.					
• Hospital departments do not coordinate well with each other.					
• It is often unpleasant to work with staff from other hospital departments.					
5. COMMUNICATION OPENNESS					
• Staff will freely speak up if they see something that may negatively affect patient care.					
• Staff feel free to question the decisions or actions of those with more authority.					
• Staff are afraid to ask questions when something does not seem right.					
6. FEEDBACK AND COMMUNICATION ABOUT ERROR					
• We are given feedback about changes put into place based on event reports.					
• We are informed about errors that happen in this department.					
• In this department, we discuss ways to prevent errors from happening again.					
7. NON-PUNITIVE RESPONSE TO ERROR					
• Staff feel like their mistakes are held against them.					
• When an event is reported, it feels like the person is being written up, not the problem.					
• Staff worry that mistakes they make are kept in their personnel file.					
8. STAFFING					

• We have enough staff to handle the workload.						
• Staff in this department work longer hours than is best for patient care.						
• We use more agency/temporary staff than is best for patient care.						
• We work in "crisis mode," trying to do too much, too quickly.						
9. HOSPITAL MANAGEMENT SUPPORT FOR PATIENT SAFETY						
• Hospital management provides a work climate that promotes patient safety.						
• The actions of hospital management show that patient safety is a top priority.						
• Hospital management seems interested in patient safety only after an adverse event happens.						
10. HOSPITAL HANDOFFS & TRANSITIONS						
• Things "fall between the cracks" when transferring patients from one department to another.						
• Important patient care information is often lost during shift changes.						
• Problems often occur in the exchange of information across hospital departments.						
• Shift changes are problematic for patients in this hospital.						
PERCEIVED PATIENT SAFETY GRADE (scores %)						

SECTION 5: PERCEIVED MENTAL WORKLOAD ON ALARM RESPONSE

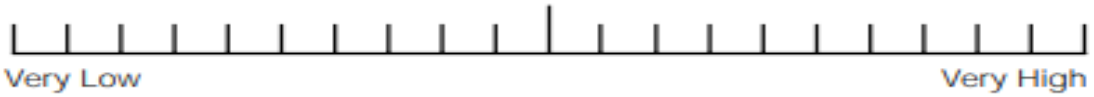
Mental workload assessment using a modified NASA-TLX Tool (Human Performance Research Group(NASA), 1986; Tubbs-Cooley et al., 2018)

Instructions*:* The tool is a spectrum of 21 ratings with extremes of very low (0 , extreme left) and very high (20, extreme right) under each of the 4 domains, namely, mental demand scale which requires the respondent to rate the level of mental energy such as thinking or deciding required to accomplish the task, physical demand which requires the respondent to rate the level of physical activity to accomplish the task, temporal demand scale requires rating on the level of pace or time pressure needed to accomplish the task, and effort demand which requires respondent's rating on how hard he/she has to work to accomplish optimal performance(in this case, optimal alarm response and management). The weight per equidistant interval is in increments of 5. Domain adjusted ratings are a product of the weight and the raw ratings. The minimum score is 0 and the maximum score is 100 per domain or an average minimum score of 0 (very low workload) and average maximum score of 100 (very high workload) across the 4 domains.

ALARM RESPONSE AND MANAGEMENT AS RECOMMENDED- *This entails clinician's response to clinical alarm conditions to monitor patients, check for specific type of alarms, evaluate patient's condition and implement safety interventions based on alarm conditions as indicated within clinical setting.*

Mental Demand

1. How **mentally demanding** is the task of **managing and responding to alarms** in your clinical setting?



Physical Demand

2. How **physically demanding** is the task of **managing and responding to alarms** in your clinical settings?

Temporal Demand

3. How **hurried or rushed** is the pace of the **task of managing and responding to clinical alarms**?

Effort Demand

4. How **hard do you have** to work to **accomplish alarm management and response** tasks as required?

SECTION 6: ALARM FATIGUE

A. Charité Alarm Fatigue Questionnaire; CAFQa) consists of alarm stress scale and alarm coping scales. (Wunderlich et al., 2023). The scale ranges between 8 and 36 points with higher score indicating high alarm fatigue scores. Items are scored as numbers ranging from 0 (≙ "I do not agree at all") to 4 (≙ "I very much agree"). Items marked with a * have a negative valence and are scored in the opposite manner

	I DO NOT AGREE AT ALL	I DO NOT AGREE	I AGREE IN PART	I AGREE	I VERY MUCH AGREE
1. With too many alarms on my ward, my work performance and motivation decreases.	☐	☐	☐	☐	☐
2. Too many alarms trigger physical symptoms for me, e.g., nervousness, headaches, sleep disturbances.	☐	☐	☐	☐	☐
3. Alarms reduce my concentration and attention.	☐	☐	☐	☐	☐
4. My or neighboring patients' alarms or crisis alarms frequently interrupt my workflow.	☐	☐	☐	☐	☐
5. There are situations when alarms confuse me.	☐	☐	☐	☐	☐
6. In my ward, a procedural instruction on how to deal with alarms is regularly updated and shared with all staff. *	☐	☐	☐	☐	☐
7. Responsible personnel respond quickly and appropriately to alarms.*	☐	☐	☐	☐	☐
8. The audible and visual monitor alarms used on my ward floor allow me to clearly assign patient, unit, and urgency.*	☐	☐	☐	☐	☐
9. Alarm limits are regularly adjusted based on patients' clinical symptoms (e.g., blood pressure limits for condition after bypass surgery).*	☐	☐	☐	☐	☐

SECTION 7: BURN OUT ASSESSMENT

Table 9: Maslach Burnout Inventory (MBI) tool

	Frequency						**Intensity**						
							Mild			**Moderate**			**Major**
Emotional Exhaustion (EE)	1	2	3	4	5	6	1	2	3	4	5	6	7
1. I feel emotionally drained from my work													
2. I feel used up at the end of the workday													
3. I feel fatigued when I get up in the morning and have to face another day on the job													
4. Working with people all day is really a strain for me													
5. I feel burned out from my work													
6. I feel frustrated by my job													
7. I feel I'm working too hard on my job													
8. Working with people directly puts too much stress on me													
9. I feel like I'm at the end of my rope													
Depersonalization (DP)													
1. I feel I treat some recipients as if they were impersonal 'objects'													
2. I've become more callous toward people since I took this job													
3. I worry that this job is hardening me emotionally													
4. I don't really care what happens to some recipients													
5. I feel recipients blame me for some of their problems													
Personal Accomplishment (PA)													
1. I can easily understand how my recipients feel about things													
2. I deal very effectively with the problems of my recipients													
3. I feel I'm positively influencing other people's lives through my work													
4. I feel very energetic													
5. I can easily create a relaxed atmosphere with my recipients													
6. I feel exhilarated after working closely with my recipients													
7. I have accomplished many worthwhile things in this job													
8. In my work, I deal with emotional problems very calmly													

SECTION 8: ALARM OBSERVATIONAL TOOL (Modified Baillargeon's tool)

Type	Description	Individual	Response time	Response type	Repeat alarm	Comment

APPENDIX IV: STUDY BUDGET

Key: ppc- pages per copy.

Components	Unit of Measure	Duration/ Number	Unit Cost (Kshs)	Total Cost (Kshs)
PERSONNEL				
Research Assistants for alarm observation	6	14 days	1500	126,000.00
Research assistants for survey data collection	3	5 days	1500	22,500.00
Training of research assistants	6	3 days	1000	18000.00
Statistician Analysis		1	30,000	30000.00
Research coordination airtime	Airtime per coordinator (1)	30 days	200 per day	6000.00
PRINTING				
Consent Form	Pages	6	10	60.00
Questionnaires	Pages	9	10	90.00
Interview Guide	Pages	2	10	20.00
Final Report	1 Copies	300	10	3000.00
PHOTOCOPYING				
Consent Form	Copies	160 copies*3ppc	5	2400.00
Questionnaires	Copies	160 copies*10 ppc	5	8000.00
Final Report	Copies	6 copies*150ppc	5	4500.00
Final Report Binding	Copies	7 copies	1000	7000.00
OTHER COSTS				
ERC Fees			5,000	5000.00
NACOSTI			5,000	5000.00
Pens	10	1	50	500.00
Notebooks	10	1	50	500.00
Audio recorders	pcs	2	2440	4880.00
Box files	pcs	5	500	2500.00
Poster Printing	1	3	5,000.00	15000.00
Stopwatches	1	6	600	3600.00
Research Dissemination Workshop refreshments(KNH catering department)		2	10,000	20,000.00
1 international scientific conference registration, travel cost for participation and presentation			-	25,000
1 local scientific conference participation and presentation			-	50,000
TOTAL				**312570.00**

Budget Justification/ Narrative

1. **Personnel**
    a. 6 Research assistants will be recruited. Each will be allocated shs 1500 per day. They will work for cumulative 14 days across 3 departments to collect non-participatory observational data on clinical alarm frequency.
    b. 3 research assistants will also collect data using structured survey questionnaire for 5 days being paid shs1500 per day for a minimum of 157 study participants proportionately drawn from each department of study.
    c. Training of the 6 research assistants will be done for 3 days, with each participant being paid 1000 per day. The training will also include pilot testing of the tools (the survey, observational tool, and the interview guide) and induction on the use of data and entry collection software (RedCap).
    d. The fee for statistician has been capped at Kshs 30,000 for quantitative analysis.
    e. Airtime cost of shs 200 per day for the research coordinator, who will be the principal investigator, will be allocated for a total of 30 research activity days.
2. **Printing and photocopy**
    a. Printing cost per page has been capped at shs10. Cost for printing each copy of the study tools will be calculated assuming the final report will have 150 pages, consent form 6 pages, questionnaire 9 pages and interview guide 2 pages.
    b. Cost for photocopy will be capped at shs 5 per page. Assuming each final report will have 150 pages, the cost of photocopying 6 reports will be shs 4500.
3. **Other costs**
    a. A lump sum cost of shs 5000 for NACOSTI and shs 5000 for KNH-UON Ethical review submission will be incurred based on available submission rates.
    b. The cost per pen and notebook has been capped at shs50. These stationeries will be used by research assistants and the researchers who will be 10 in number.
    c. To monitor response time for clinical alarms, stopwatches for the research assistant will be bought at a cost of shs 600 per stopwatch for 6 observers.
    d. 5 box files will be bought at a costs of shs500 per piece. This will support storage and filing of printed consent and questionnaires.
    e. A budget for dissemination the findings of the study :
        i. A physical workshop has been estimated at shs 20000 to cater for refreshments (tea and mandazi) for attendees.
        ii. Poster printing costs for 3 posters at shs5000 each.

APPENDIX V: GANTT CHART

Activities | Month	Sept/2023 Dec/2023	Jan 2024 June 2024	July/2024 Aug/2024	Sept/2024	Oct/2024
Proposal Development					
Departmental letter of support and co-author support					
Submission of documents seeking ERC approval					
ERC review and potential working on corrections					
Data collection					
Data cleaning and analysis					
Discussion and report writing					
Manuscript Writing and submission, Dissemination and Publication					