

**Alarms in ICU: A study investigating how ICU nurses respond to alarm limits
for patient safety**

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Abstract

Introduction

There is a need to identify alarm management challenges in South African ICU units, to revise and structure educational and training programmes to ensure ICU nurses utilise technological resources for patient safety and to deliver quality patient care.

Aim

This research study is aimed to investigate the responses of ICU nurses to alarm limits in their ICU environment for patient safety.

Research methods

This descriptive survey study was conducted with permanent and sessional ICU nurses at a private healthcare institution in Durban, KwaZulu-Natal. A quantitative design was used with a structured questionnaire as the data collection instrument. The total of 120 ICU registered and enrolled nurses were chosen as the sample population and a total of 91 questionnaires were completed and returned.

Results

The results indicated that the challenges with alarm management experienced were related to inadequate education and training on alarm management and the distraction of managing frequent and numerous false alarms in the ICU facility contributed to delayed responses of the ICU nurses to alarming limits.

Recommendations

Recommendations included reviewing the current content and methods of education and training of alarm management and medical equipment that was done on a frequent basis.

Conclusion

Alarm specific training is required to keep ICU nurses updated with changes in technology so that they are better equipped to ensure patient safety and quality of care.

DECLARATION

I, Amy Ramlaul, declare that the contents of this dissertation represent my own work. This dissertation has not previously been submitted for any academic examination towards any qualification. Referencing of authors has been acknowledged in this research. This research study represents my own work and statements and not necessarily that of the School of Nursing & Public Health, University of KwaZulu-Natal.

Signature

Date

Supervisor

Date

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TABLE OF CONTENTS

1. Title Page	Page	1
2. Abstract	Page	ii
3. Declaration	Page	iii
4. Acknowledgments	Page	iv
5. Table of contents	Page	v

CHAPTER ONE: INTRODUCTION

1.1. Background	Page	1
1.2. Problem statement	Page	6
1.3. Aim	Page	7
1.4. Research objectives	Page	7
1.5. Research questions	Page	7
1.6. Significance of the study	Page	7
1.7. Operational definitions	Page	8
1.8. Conceptual framework	Page	9

CHAPTER TWO: LITERATURE REVIEW

2.1. Operator causes	Page	14
2.1.1. Education and user ability	Page	14
2.1.2. Alarm fatigue	Page	17
2.2. Patient causes	Page	20
2.3. Device causes	Page	23

2.4. Nursing concerns	Page	24
2.5. Alarm adverse events	Page	28
2.6. Solutions to alarm management	Page	29

CHAPTER THREE: RESEARCH METHODOLOGY

3.1. Research design	Page	32
3.2. Research setting	Page	32
3.3. Population and sampling	Page	33
3.4. Data collection tool	Page	34
3.5. Data collection process	Page	35
3.6. Data analysis	Page	36
3.7. Validity and reliability	Page	37
3.7.1. Content validity	Page	39
3.8. Ethical considerations	Page	40
3.9. Data management	Page	41

CHAPTER FOUR: RESULTS AND DISCUSSION

4.1. Pilot Study	Page	43
4.2. Demographics	Page	43
4.3. Alarm information and priority ranking	Page	46
4.3.1. Operator causes	Page	49
4.3.1.1. Operator causes on education and training	Page	49

4.3.1.2. Operator causes: distracted attention	Page 55
4.3.2. Environmental causes	Page 57
4.3.2.1. Environmental variables in ICU	Page 58
4.3.3. Human factor designs	Page 59
4.3.4. Passive patient causes	Page 61

CHAPTER FIVE: CONCLUSION AND RECOMMENDATIONS

5.1. Summary of findings	Page 64
5.3. Recommendations	Page 68
5.3.1. Nursing education	Page 68
5.3.2. Research	Page 68
5.3.3. Administration and practice	Page 69
5.5. Limitations	Page 69
5.6. Conclusion	Page 70

REFERENCES

References	Page 71
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LIST OF TABLES

Table 1.1	Page 12
Table 4.1	Page 43
Table 4.2	Page 44
Table 4.3	Page 44
Table 4.4	Page 45

Table 4.5	Page 46
Table 4.6	Page 48
Table 4.7	Page 50
Table 4.8	Page 53
Table 4.9a	Page 54
Table 4.9b	Page 54
Table 4.10	Page 55
Table 4.11	Page 58
Table 4.12	Page 60
Table 4.13	Page 61

LIST OF FIGURES

Figure 1.1	Page 13
Pie chart 4.1	Page 51
Pie chart 4.2	Page 52
Pie chart 4.3	Page 52

LIST OF ANNEXURES

Annexure 1: Covering letter and declaration	Page 75
Annexure 2: Alarm survey	Page 77
Annexure 3: Proof of permission granted by Rhodes Island College & the Healthcare Technology Foundation	Page 80
Annexure 4: Permission by University of KwaZulu-Natal, Humanities & Social Science Research Ethics	Page 82
Annexure 5: Permission granted by Netcare	Page 83

LIST OF ACCRONYMS AND ABBREVIATIONS

ICU Intensive care unit

PCA Patient controlled analgesia

CHAPTER ONE: INTRODUCTION

1.1. Background

Effective alarm management in an intensive care unit (ICU) can be influenced by various factors; the culture of the department, nursing practice and technology. The aim of effective alarm management in ICU is to create an environment conducive to patient safety. ICU environments deliver advanced care for patients that are critically ill and thus they require close constant monitoring of their condition. In an ICU environment nurses are also dependant on clinical alarms of the various monitoring devices/equipment being used. The purpose of clinical alarms is to ensure that nurses are given an alert or warning that the patient is requiring urgent attention and/or alerting them that there is a change in patients' condition that could be related to a potential problem. Nurses do rely on these clinical alarms to notify them of changes in the patient's condition (ACCE Healthcare Technology Foundation, 2006).

Based on the researchers' experience in a South African private ICU setting, generally the minimum equipment required for each patient is the hemodynamic monitor, the ventilator and infusion pumps. Additional common medical devices used in an ICU environment are cardiac monitors aimed at more specific management than the standard hemodynamic parameters, dialysis devices for hemodialysis and continuous veno venous hemodialysis for renal impairment as well as pressure care and relieving devices i.e. mattresses and calf pumps.

Hannibal's (2011) article highlights that hospital alarms are generally from and not limited to monitors/equipment specific to an ICU environment such as cardiac monitors and ventilators but other sources of alarms or alerts such as the telephones, pagers, patient nurses calling bells, anti-embolism devices, patient controlled analgesia (PCA) devices and infusion pumps etc.

Staffing in ICUs in South Africa is currently a challenge as the number of ICU trained registered nurses is scarce. Most of these scarce skilled ICU staff emigrate from the country for better financial prospects and better working conditions and resources (De Beer, Brysiewicz and Bhengu, 2011). Other reasons for the critical shortage of ICU nurses is limited career opportunities, increased workload on the current ICU staff, inadequate leadership and also a lack

of security in terms of safety that they experience in their current work environments (De Beer, Brysiewicz and Bhengu, 2011).

The shortage of skilled staff is resultant in there being less experienced, registered and enrolled nurses in our ICU facilities. The availability of ‘one to one nurse patient’ ratios, as the ideal, is not always practical or a realistic expectation. King, Fortino, Stevens, Shah, Fortino-Mullen and Lee (2012), state that normally critical care nurses taking care of two patients have the responsibility to monitor their patients and share other tasks for patient care. Examples highlighted were the coordination of nursing care goals or planning, medication administration, wound care and activities of daily living such as feeding and bathing their patients. Clinical alarms are in place to assist their role and support the nursing staff in carrying out all their allocated duties for the patients.

The number of sessional staff presently used in our ICU facilities is high and generally these staff come with minimal ICU skills or training. Staff is reliant on clinical alarms to assist their care. If a culture is created where staff is reliant on clinical alarms only for patient care, this is potentially a risk to patient safety. Alarm limits should be correctly set and functioning to avoid an adverse event for the patient (ACCE Healthcare Technology Foundation, 2006). The aim of ICU trained nursing staff is to be able to manage current healthcare problems in patient care and also to be able to identify potential problems and complications from either the medical diagnosis as well as from interventions including medical, surgical, nursing and technological.

Pergher and Da Silva (2013), indicate that approximately twenty five years ago alarms systems were not available for medical equipment. With current technology available to us, nurses are required to use these alarm systems optimally. The alarm systems in medical equipment assist the nurse to identify an actual or potential risk for appropriate intervention. The thorough knowledge of patient conditions and management is crucial to not only identifying problems but also useful in managing alarm limits appropriately to be able to flag and immediately recognize changes in a patient’s condition.

Historically the earlier ICU settings in the 1950’s as described by Hannibal (2011), electrical monitoring was not available in comparison with medical devices available today. The devices from this era were limited to chest tubes, oxygen delivery methods through mechanical

ventilation, metal tracheotomy tubes and sphygmomanometers. From these examples it is evident that there were no advanced electrical monitoring devices in place.

Hannibal (2011) discusses how the original attempts in 1960 to introduce electrical monitoring with monitors for heart rhythms included an alarm to notify the staff of a decline in cardiac and respiratory events but they discovered that the resuscitation interventions were poor because staff was not sure of their expectations in response to an alarm limit being triggered. In addition some equipment was not equipped with an alarm system and if the patient was not being observed and had disconnected themselves or their condition deteriorated with the patient not being readily observed, this led to a patient crisis or event that was responded to late and resulted in an adverse event. It is this history that initiated the development of more advanced and complex alarm systems to alert staff of either equipment failure or fault and patients' physiological changes.

Effective alarm management in an ICU is therefore crucial to assist nursing staff in managing patient safety. If alarm management is ineffective the aim of ensuring patient safety is compromised (Wyckoff, 2009). Due to the potential of numerous triggered alarms that are available on most medical devices, it can be a risk to the nursing staff to gradually become desensitized to these alarming limits. If these are poorly managed by either ignoring, silencing or switching them off, the alarms that are intended to assist and alert nurses to patient needs then becomes a risk to patients care and safety as the patients immediate needs may not be identified (Bell, 2010).

The question that needs to be asked is whether or not this therapeutic system is being utilized optimally to ensure that appropriate patient care and management is rendered as per patient needs or are there challenges experienced with managing alarms in an ICU. The alarm limits once triggered, can alert the nursing staff to a patient's condition that is changing which may not necessarily be visible to the nursing staff based on clinical signs and symptoms. In this instance the alarms that are used will only be as effective as the staff that is directly involved in setting them and responding to the alarming limits appropriately (Wyckoff, 2009).

It is important to note that these alarm limits are not to be seen in isolation, trends related to different parameters based on patient diagnosis and medical intervention need to be reviewed continuously through the patients day and holistically to ensure appropriate management and

identification of potential problems. The alarm systems, both invasive and non-invasive, that are used in monitoring patients' physiological parameters are useful in managing the patients' clinical and medical diagnosis, guiding the care that is to be given to the patient. This does help to contribute towards the safety of the critically ill patient in an ICU environment (Pergher and Da Silva, 2013).

Human factors as defined by Shepherd (2004) that assist the use of the device setup for alarm management are inclusive of checklists, guidelines or standards that are set by the manufacturer to allow the user, in this study the nurse, to be able to operate the device physically and cognitively. The operation of the device is dependent on the layout and presentation for the nurse to manipulate as required. If there is a flaw in the manner or technique which a nurse operates the device, it can possibly lead to an adverse incident for patient safety.

Dul, Bruder, Buckle, Carayon, Falzon, Marras, Wilson and van der Doelen (2012) explain that human factors and ergonomics are also referred to as comfort and/or functional design. It is a technique of designing a device that takes into consideration the interaction between the device and the people who use them. The users' capabilities and limitations, in this study the nursing staff is taken into account during the design.

The alarm limits generally to a non-medical person are seen a concern or regard it as a medical emergency. These sounding alarms can therefore be seen as a source of stress to the patient (Inokuchi, Sato, Nanjo, Masahiro, Tanaka, Ishii, Matsubara, Doi, Gunshin, Hiruma, Nakamura, Shinohara, Kitsuta, Nakajima, Umeza and Yahagi (2013). The inappropriate alarming limits is an additional stress to the patient who is currently already in a stressful environment and health condition. The long term patient is familiar with the medical devices and the alarming limits but based on their current health condition and severity of illness this will still be seen as a source of stress and anxiety to the patient.

According to Inokuchi, *et al* (2013), alarm sounds are also associated with patient delirium. In addition, the frequent alarming limits impacts on nursing staffs' judgment due to exhaustion and a decreased sensitivity to alarming limits. This is also supported by Darbyshire and Young (2013), who highlighted that over 30% of patients who were receiving care in an ICU

environment present with confusion and delirium and these symptoms are linked not only to sedation and invasive procedures but also attributed to noise induced sleep disturbances.

Similar to the interpretation of the alarming limits to patients, from the researchers experience in the ICU environment, family members of patients equally respond in a similar manner. Based on their limited exposure to the ICU environment and the feeling of being overwhelmed by the number of medical devices surrounding and in use for their loved one, they also interpret alarming limits as a concern and/or a medical emergency that requires immediate intervention. The noise polluted environment with numerous sounds unfamiliar to general public is what the family, patients and staff have to endure (Cvach, 2012).

Alarming limits that are not indicative of a medical emergency or deterioration in a patient's condition are generally false or nuisance alarms. This can be related to equipment sensitivity. A normal patient activity can trigger the alarm i.e. movement, verbal and emotional status that causes the patients parameters to move out of range from the expected normal resting parameters set. Funk, Clark, Bauld, Ott and Coss (2014), in their article on the Attitudes and Practices Related to Clinical Alarms discuss that nursing staff may not respond to alarming limits as they are aware that most of them are non-actionable or false. In addition becoming desensitized to these alarming limits that they consider non-actionable they ignore the alarm, silence, switch off or even widen the parameter settings for the alarms and this is a risk to patient safety as the nurse can either miss the alarm or have delayed responses to the alarming limits.

Family education and explanation of alarming limits is important and this needs to be considered by the multidisciplinary team as an essential aspect to patient care. Inappropriate perceptions of family members can be transferred to the patient and can lead to additional unnecessary stress response from the patient regarding their care and trust in the medical team in charge of him or her.

The nursing staff working in an ICU environment is dependent on the medical devices for patient monitoring and care. The alarm management of these devices is a part of their daily environmental checks and is used to alert them to the changing needs of the patient. The alarming limits can also impact on the nursing staff that is exposed to numerous alarms during the course of their shift. There are numerous devices for an individual patient and how the ICU

nurses set these alarms and manage them during their shift is important and is a priority to ensure patient safety.

1.2. Problem statement

With the advent of technology, there is an increase in the number and type of medical devices introduced in ICU's. According to Lopes (2014), with changes and advancement in healthcare, there are more options available for patient care with new innovative treatment. Some hospitals aim for the best quality and services for patient care delivery and try to ensure they are in line with the latest technology. New devices are more advanced with many alarm indicators and settings. Each device/piece of equipment that is used on a patient has its own signature alarm indicator. Pergher and Da Silva (2013) support that technology is becoming more a part of the ICU environment and daily care and consideration must be given that the advancing technology can expand the normal ability of the human senses. The newer technology has brought an increase in both audible and visual alarms into the ICU setting.

Changes in patients' condition can present suddenly and requires immediate emergency medical intervention or it can be a gradual process which will not be immediately identified but can be determined through the analysis of more than one patient vital parameter or trends (Graham and Cvach, 2010). The great dependence on physiological monitoring devices to assist in closely monitoring patients and also alerting the nursing staff to an actual or potential problem is standard practice. The response to these alarming limits is important in managing patient safety and care (Graham and Cvach, 2010).

Alarm fatigue of staff in an ICU setting is a potential clinical problem that needs to be identified as the lack of attention and response to valid alarms that require actionable intervention can lead to/cause delayed responses which may contribute towards patient deterioration and mortality (Lopes, 2014). Alarm fatigue can lead to incorrect alarm settings whereby the threshold limits are adjusted and are not in line with patient needs as per their baseline data.

This area remains relatively unexplored in the South African ICU setting and this quantitative study was undertaken to identify this problem in a private hospital setting in South Africa.

1.3. Aim

This research study aimed to identify and describe the responses of ICU nurses to all alarming limits in their ICU environment.

1.4. Research objectives

- To identify how ICU nurses respond to alarm limits for patient safety.
- To describe how ICU nurses respond to alarm limits for patient safety.

1.5. Research questions

- What human/ergonomical factors related to ICU nurses, contribute towards a response to alarm limits for patient safety?
- What patient factors contribute towards the response of ICU nurses to alarm limits for patient safety?
- Are there any factors in the ICU environment identified that impact negatively on ICU nurses responses to alarm limits for patient safety?

1.6. Significance of the study

1.6.1. Nursing education:

Research related to alarm limits in ICU is currently limited in South Africa. Nursing education would contribute to understanding alarm management in an ICU setting in a private hospital in South Africa. The findings of this research may impact on the education and training needs of current ICU nurses in the facility. It may contribute towards reviewing the current curriculum for post basic ICU students. With the advancement in medical equipment, this would emphasize the integration of theoretical and practical nursing in the application of safe patient care. Training programmes and management of alarms in the ICU environment is needed to ensure that these devices can best assist in the quality and efficiency in nursing a critically ill patient in ICU.

1.6.2. Nursing practice:

ICU nurses are using numerous medical devices in the care of their patients. The medical equipment is a crucial part of patient care and it is important that the nursing staff is aware of

how these devices function to best be able to use them in the monitoring and management of patients in their care. Identifying challenges with alarm management is important as this is a daily part of their duties to ensure patient safety. This would be specific to the hospital and per ICU department. The knowledge and degree of these challenges can assist in developing a unit specific or hospital specific standard operating procedures to ensure effective and safe alarm management.

1.6.3. Nursing administration:

The findings of this research could make recommendations for managing patient safety in an ICU setting. Methods to ensure safety and environmental checks in an ICU setting can be reviewed and evaluated further so as to avoid errors of mismanagement as well as legal implications for safety issues that are raised due to inappropriate care due to lack of adherence and attention of detail to indicators for patient safety.

1.6.4. Nursing research:

Currently alarm fatigue is not an area of focus in the South African context in comparison to international standards as seen in the literature review. This is an area of research with awareness can assist with patient safety. The findings could not only be useful in the nursing field but may also impact on research and development in the biomedical field.

1.7. Operational definitions

1.7.1. Alarms:

An alarm is an audible indicator on clinical patient monitoring devices intended to alert the healthcare workers of a patient or device problem. Medical equipment used in an ICU that have alarms are cardiac monitors, ventilators, infusion pumps, patient-controlled analgesia, pressure relieving devices, oxygen saturation devices etc.

1.7.2. Alarm limits:

In this study alarm limits refers to the minimum and maximum limits per parameter to be set according to a patient's baseline parameters so that when the patient parameters move outside of

these limits an alarm is sounded and the ICU nurses can be alerted to changes in patient's condition.

1.7.3. ICU nurses:

In this study nurses currently working in ICU who must be a registered nurses both non-ICU trained and ICU trained or enrolled nurses, according to the South African Nursing Council (South African Nursing Council [SANC], 2016)

1.7.4. False/Nuisance alarms:

A non-actionable alarm due to an artifact produces false data which is transmitted and displayed on the monitoring device (Welch, 2011).

1.7.5. Alarm fatigue:

Alarm fatigue is the failure to recognize and respond to true alarms that require bedside clinical intervention due to the high occurrence of alarms (Welch, 2011).

1.7.6. Human factors:

Human factors and ergonomics is also referred to as the comfort and functional design that is incorporated in designing a device which considers the interaction between the device and the people capabilities, as well as the limitations of those who use them. In this study it is the nurse (Dul, Bruder, Buckle, Carayon, Falzon, Marras, Wilson and van der Doelen, 2012).

1.8. Conceptual framework

Healthcare according to Shepherd (2004) is dependent on technology with the need for medical equipment and monitoring devices, hence healthcare is delivered through these systems and mini-systems. If these systems fail to deliver the clinical benefit it can have negative consequences for patient safety. The Shepherd's System Risk Model is a generic model that can analyse the functioning of a mini-system (Shepherd, 2004). It has detail of the interacting components of the mini-system and provides a practical guide toward the root causes of an adverse event. Such designed delivery systems assists in reducing medical errors but with

regards to the Shepherd's System Risk Model it has been adapted with recent advances to better facilitate an analysis of causes and suggestions for improvement in prevention strategies.

The Shepherd's Systems Risk Model was chosen for this study as it was applicable to the various components in the ICU environment that impact directly on alarms in the ICU. The Shepherd's Risk Model has been used for more than 20 years to analyse device related adverse events and it does so considering all of the factors or variables surrounding the situation and the persons that interact with these systems and devices. This assists in identifying the root cause of the problem with the device (Shepherd, 2004). The Shepherd's Systems Risk Model (2004) details the components and sub components that contribute to the environment directly or indirectly, in this study the ICU nurses responding to alarm limits. The environmental, facility, operator and patient related components are acknowledged in the model.

The Shepherd's Systems Risk Model is made up of five components and 16 sub components. The five components of this model are; Facility, Device, Patient, Operator and Environment. These are the direct causes of a system failure. Failure codes occur at the time of an event and indicate potential causes that can be associated to a failure. All the components failure codes, an example is a Facility failure and Device failure (ACCE Healthcare Technology Foundation, 2006).

The subcomponents of each of these five components are listed as follows: Facility and device four subcomponents are human factors design, parts/systems design, deterioration and the maintainer. Patient sub components are active and passive related causes. Operator subcomponents are related to education/training, user errors, diverted attention and potential criminal intent and the Environmental component is subdivided into internal and external variables (ACCE Healthcare Technology Foundation, 2006). Errors located within the subcomponents can lead to a component failure (Shepherd, 2004).

With regards to nurses, the operators of the devices, the following errors or failure codes can be identified as the root cause. Human factors and ergonomics apply the knowledge of a person's ability and limitations to the design of the medical systems or devices. The goal of this is to obtain the best interaction between people or users and the device elements to enhance patient safety (Shaver and Braun, 2008). Human factors consider the design of the devices and their user

friendliness for the operator which is the nurse. Operators or persons using the devices will be any member of the multidisciplinary team (ACCE Healthcare Technology Foundation, 2006).

In relation to alarm fatigue and desensitization to alarms due to the numerous false/nuisance alarms that ICU nurses are exposed to, if there is an error related to these aspects, it will be linked to an operator failure code with the root cause linked to distracted attention, as described above they may have the relevant knowledge about the use of the device but other conditions prevail that lead to the error occurring.

Valid and false alarms can be linked to patient failure codes, either active or passive in this case either valid clinical need for acute intervention versus a passive action of the patient that triggered because the sensitivity of the equipment alarm. When the device itself is designed in such a manner that there are no SMART alarms to alert the operator to genuine alarm triggers, this adds to the amount of false and nuisance alarms that the operator in this case the ICU nurse is subjected to. SMART alarms are where multiple parameters, rate of change of the parameters and the signal quality being transmitted from patient to device are being automatically assessed in their entirety (2006, ACCE Healthcare Technology Foundation).

Human factors and ergonomics aims to improve human performance with regards to the use of equipment (Shaver and Braun, 2008). This is done by the use of the hardware and software design of the device allowing it to be more compatible with the ability of the user population.

The human factors can be divided into the following categories; physical and sensory which includes vision, hearing, strength and manual dexterity which will impact on how they sense and interpret the audibility and distinctiveness of alarms and managing controls, perceptual and cognitive abilities which would be related to the controls and the alarms and a higher level of mental memory, information processing and troubleshooting or problem solving abilities (Sawyer, 1996). In the context of the study this would refer to the user friendliness of the devices used. Staff that find the medical devices to be complex to set alarms on and use for their patient care would be affected by how they interpret the controls and impact on perceptual and cognitive abilities. Medical equipment can be effectively and safely used depending on the interaction between the following aspects: operating environment which would be in the study related to the ICU, user capabilities which relates to the nurses cognitive and physical ability to use the

devices, stress levels related to managing the device, processing the data being received on the patients health status and troubleshooting/intervention for the identified alarm (Sawyer, 1996).

Table 1.1: *Shepherd Systems Risk Model Failure Classification and Definitions (Updated 3/23/06) (ACCE Healthcare Technology Foundation, 2006)*

Direct Causes	Root Causes (Failure Codes)
D = Device Failures	<p>D1 = Device - Human Factors Design</p> <p>D2 = Device – component/circuit design (Unexpected Failure)</p> <p>D3 = Device – Deterioration (slow, predictable deterioration that requires a PM) (Includes battery failures, worn brushes, etc.)</p> <p>D4 = Device – Maintainer Error</p>
E = Environmental Failures	<p>E1 = Environment (within hospital); internal minisystem affected outcome, i.e., EMI, etc.</p> <p>E2 = Environment (external to hospital); external minisystem affected outcome, i.e., EMI, etc.</p>
F = Facility Failures	<p>F1 = Facility – Human Factors Design</p> <p>F2 = Facility – Parts/System (unexpected failure; electrical, systems, etc.)</p> <p>F3 = Facility – Deterioration (slow, predictable deterioration that requires a PM)</p> <p>F4 = Facility – Maintainer Error</p>
O = Operator Failures	<p>O1 = Operator Error (desirable human factors design but operator education/training was inadequate)</p> <p>O2 = Operator Error (human factors design predisposes operator to make an error “use” error)</p> <p>O3 = Operator Error – Distracted Attention (operator is well versed in the HFD’s but other conditions prevailed to cause an error, i.e., workload, long hours, personal problems, drugs, etc.)</p> <p>O4 = Operator Error – Criminal intent (the operator intends to use the device in such a manner as to cause harm to the patient). Note an operator can be a nurse, doctor, technician, patient, family member.</p>
P = Patient Failures	<p>P1 = Patient, Active; patient action affected the outcome</p> <p>P2 = Patient, Passive; patient condition affected outcome</p>
	G = Cant analyse the event

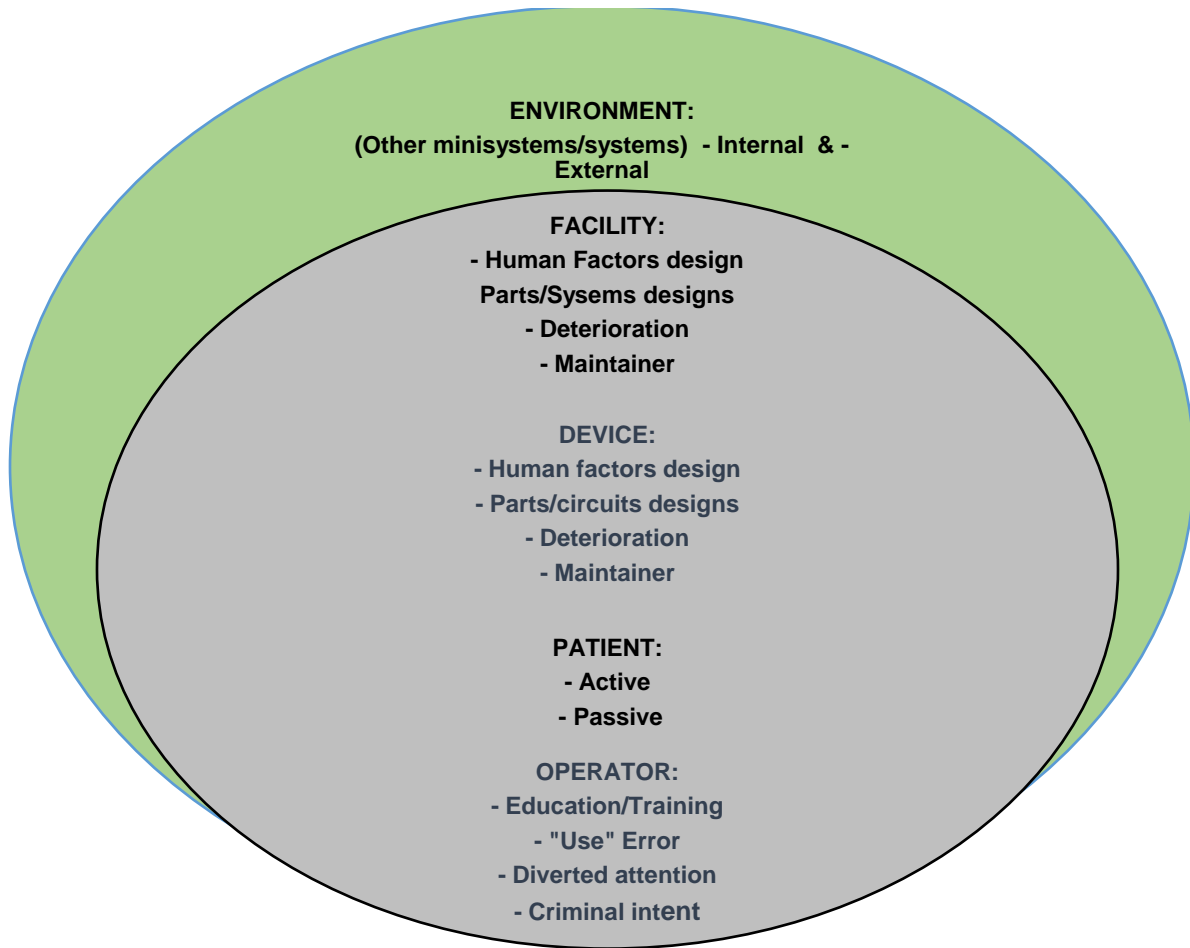


Figure 1.1: *Shepherd's System Risk Model (ACCE Healthcare Technology Foundation, 2006)*

CHAPTER TWO: LITERATURE REVIEW

2.1. Operator causes

This chapter explains the content for the different factors described in the Shepherd's System Risk Model as per the conceptual framework. The different variables considered in the design of medical device in relation to the user and the environment is explained in chapter two in relation to the Shepherd's System Risk Model.

Operator failures are related to the following factors: education and training, an error in the manner of 'use' of the device, diverted attention and criminal intent. These are reflected in the Shepherd's System Risk Model which is a Systems Safety Engineering Model (ACCE Healthcare Technology Foundation, 2006). Operator failures and the subcomponents in the model are directly linked to human errors. In this study the operator of the devices in the ICU environment are the ICU nurses comprising of our Registered Nurses ICU or Non-ICU trained registered nurses and enrolled nurses according to the South African Nursing Council (South African Nursing Council, 2016).

The literature to follow discuss broadly aspects related to alarm management and will support the Shepherd's System Risk Model (2004) subcomponents for the operator related failure codes. ICU trained staff that has inadequate training and education on the devices and also ICU nurses that do not use the device in the manner it was intended to optimize quality and effective patient care can potentially have a negative effect on patient care.

2.1.1. Education and user ability

The Emergency Care Research Institute – ECRI (ECRI Health Devices, 2014), identify alarm hazards as one of their top ten health technology hazards for 2015. The first hazard as listed in this report is, Alarm Hazards: Inadequate Alarm Configuration Policies and Practices. The examples listed in this report related to inappropriate practices with alarm set ups, an example, the failure to reset equipment with the arrival of new patients and inappropriate choice of alarm limits chosen for the patient.

Recommendations put forward do highlight training needs for the clinical staff related to how to configure the alarms and ensure it is in line with policy. Training is re-emphasized with regards to orientation and updates (ECRI Health Devices, 2014).

This is in line with two of the direct operator failure related causes as per the Shepherd's Systems Risk Model. This risk model breaks the operator codes into four subcomponents. The first two subcomponents are indicated as O1 and O2 with the first looking at inadequate training and education and the latter with regards to user error, in context to clinical staff related to ICU nurses (ACCE Healthcare Technology Foundation, 2006).

Supporting this model is also Hannibal (2011) that discusses human oversight with regards to monitor alarms and alarm fatigue. The placement of the monitors in relation to the persons manning them such as their medical technicians was discussed as challenges were around the audibility of the alarms. Further to this advancement in technology it could improve the effectiveness of the monitoring system with audibility and visibility of the alarming devices.

In the South African private hospital ICU setting, this is not a problem as there are no allocated medical technicians, it is the nurse allocated to the patient that is in charge and responsible for patient monitoring devices and alarms. In addition in the South African context the alarms are at each bedside and at a central duty station that is able to view the basic parameters overall for all patients in the unit. Patients are not left unattended, in the absence of the allocated ICU nurse for the patient, the neighboring staff member will overlook and respond to patient and Doctor needs in their absence.

Hannibal (2011) further explains other errors related to human factors that can also be related to operator failure related incidents with alarm management. False monitoring related to poor skin preparation and placement of electrodes is used as a simple example to highlight how the operator in this case (the ICU nurse) can due to a lack of attention to detail, impact on the monitoring of the patient. This is a valid example as false alarms could be related to ineffective monitoring of the patient. In addition if the ICU staff are aware that the alarming limits may not be very accurate or positional, they would ignore these alarms and possibly not detect or be alerted to a potential problem.

Supporting this is Funk, Clark, Bauld, Ott and Coss (2014) who mention that nursing knowledge is essential to customizing the alarm settings for the patients' specific needs. This requires training and emphasis with regards to the rationale for these actions so as to ensure that staff appropriately manages alarm limits as it is valid and important for patient safety.

In a pilot study conducted in a 15 bedded unit with 30 nurses that were responsible for managing their patients' alarms and monitors, the aim was to reduce the number of false/nuisance alarms that did not require urgent medical attention as these impacted on the response time of nurses to alarming limits. Quality improvement initiatives were tried and one of the areas for quality improvement was related to ensuring that staff had the appropriate training about the monitoring systems. In addition to this, there had to be regular assessments that encompassed all aspects related to managing the alarm systems all of which were related to the nurses being able to prioritize patient needs and respond to alarming limits (Graham and Cvach, 2010).

This study yielded positive results with regards to the training programme put in place and devised tools and a competency checklist for alarm management. This tool also included basic principles related to electrode placement and preparation, troubleshooting and monitoring skills (Graham and Cvach, 2010).

The emphasis on the degree of training required does support the Shepherd's Risk Model (ACCE Healthcare Technology Foundation, 2006) as these are aspects that can impact on the response times of the attending ICU nurses to patients' needs and alarming limits. Bell (2010) supports this by stating that training is required consistently with hospital or unit policy or standards to set alarms. This will reduce the number of false/nuisance alarms that nurses have to respond to.

In the article on improving how we use and respond to clinical alarms (Wyckoff, 2009), part of the guidelines to avoid errors related to a lack of education and user ability include in-service training and simulation training, monthly discussion on adverse incidents that were associated with alarms and one of the recommendations also made by the American College of Clinical Engineering Healthcare Technology Foundation (2006) is that the staff should be assessed with regards to their understanding of monitors and alarms.

According to a study conducted by the Phillips Healthcare group (2013), excessive alarms can have many causes. A few of the solutions put forward with regards to managing excessive

alarms are educating staff and patients on behaviours that can trigger the alarms, use of high quality devices and sensors, troubleshooting equipment frequently to ensure no interference, adjust the limits in line with the patients diagnosis and clinical presentation, use alarm limits and volume settings appropriately per alarm so that important alarms are acknowledged to allow health care workers to prioritize these as per patient needs (Phillips Healthcare, 2013).

According to Carroll (2010), two categories are listed to manage alarm dilemmas and these are linked to technology; the technology itself and the manner in which it is used. It involves both an understanding of technology and the pathophysiology of the clinical diagnosis one is caring for is crucial so that key patterns will be identified in the parameters to give early warning signs for patient management. This highlights pre-requisite knowledge about ones field in nursing that would impact on the use of the devices, so a sound knowledge and education in the equipment and patient care is required, in addition refresher training is crucial to maintain effectiveness and also responses from the staff to alarming limits.

The skill of the healthcare worker responding to alarms is that they do not look at one parameter in isolation; it is as per their knowledge base and understanding of pathophysiology that one can confirm the patient's condition and also eliminate artifacts that can occur due to false alarm triggers. The combination of integrating the use of technology to synthesize data with the nurses knowledge of patient diagnosis, can limit patient safety issues (Carroll, 2010). An example to highlight this would be a life threatening condition such a tension pneumothorax which would present with a combination of abnormal parameters; decreased oxygen saturation, increased heart rate, high pressure alarms noted with ventilation evidently highlighting that multiple changes in patient parameters can confirm a clinical important emergency event that needs intervention.

Supporting this are the recommendations as per Graham and Cvach, (2010) that nurses should monitor their alarms to see if they are set appropriately. These alarms need to be set to actionable levels which would assist in reducing the number of false or nuisance alarms and thereby reduce the potential lack of response due to desensitization (Graham and Cvach, 2010).

2.1.2. Alarm fatigue

The Shepherd's Systems Risk Model (ACCE Health Technology Foundation, 2006), as mentioned has 5 components each with their own subcomponents. With regards to the operator

component, two subcomponents were discussed; the third one is related to O3 – Operator Failure code 3 which is linked to Operator Error-Distracted Attention. This code implies that the operator is already knowledgeable and has had training on how to use the devices in relation to patient care and needs. Despite these being compliant there are other conditions that exist that can cause an error. These are related to work load, long hours, social and personal issues (ACCE Healthcare Technology Foundation, 2006).

One of the aspects related to alarm management is alarm fatigue that impacts negatively on the nurses' ability to respond to alarms appropriately thereby impacting negatively on patient care and safety. Alarm fatigue is categorized as a condition that despite staff adherence to policy and practice are unable to optimally respond to alarming limits. Nurses were found to be at risk for experiencing alarm fatigue due to their exposure to high alarm frequency and most of the alarming limits being false and nuisance alarms (Baillaregeon, 2013).

Alarm systems were implemented to be used in assisting in the prevention of human error. Despite the positives of having an alarm system in place to assist with managing patient care it also does have a negative consequence which was not intended and this is alarm fatigue. This is due to a high number of false/nuisance alarms, staff deactivating or silencing alarms and the lack of attention to patient needs from the nursing staff (Hannibal, 2011). The Joint Commission for the national patient safety goals had highlighted the problem of alarm fatigue as a danger as early as 2004.

Frequent non-relevant alarms are very distracting and can negatively affect healthcare workers from carrying out important tasks; it desensitizes them that they are unable to respond to alarms that are triggered for a real event that needs intervention from a nurse or other healthcare worker (ACCE Healthcare Technology Foundation, 2006). The desensitization to the sounds combined with the information that is received is considered to be overwhelming which leads to alarm fatigue.

Supporting the Shepherd's System Risk Model (Shepherd, 2004) is Carroll (2010) that highlighted some nursing concerns regarding alarms. The article discusses the frustration nurses experience with false alarms and that these are disruptive to the care they are delivering to patients. Due to frequent alarming limits they tend to ignore these alarms and react less urgently

to the alarm. Due to the high volumes of false alarms that nurses have to respond to they see this as another task that they have to do and something that is not helpful in their caring for the patient. Graham and Cvach (2010) in discussing contributing factors specific to alarm management also support the problem of false alarms and inappropriately set alarms and limits.

Ignoring important alarms due to alarm fatigue can impact on patient care resultant in delayed response times for actionable alarms. As an extreme this can lead to patient mortality if a problem has not been detected early to be managed (Lopes, 2014). The frequent alarms that are false and have no effect on patient care do cause a sense of distrust in the system by the nursing staff, this distrust in the system is a problem that is a distraction to their ability to respond or take the alarms seriously with regards to their responses (Baillargeon, 2013).

The concern with a lack of response to frequent false and nuisance alarms is a ‘cry wolf’ syndrome, which is related to this distrust in the alarm system. When there is valid genuine alarm limit that is alerting the staff to a potential or current problem and the staff is desensitized to the alarming limits, this can cause a delayed response to the detriment of the patient (Baillargeon, 2013). Desensitization occurs with exposure to numerous alarms which are commonly false/nuisance alarms causing staff to not act immediately or miss an alarm because staff become overwhelmed (ECRI Institute, 2013).

Methods related to reducing alarm fatigue were due to common responses noted by the Phillips Healthcare audit (2013) was to increase the sensitivity settings to minimize hearing the alarms so often. In a study conducted by Funk, Clark, Bauld, Ott and Coss (2014) one of the survey questions they had to rank the importance of the different alarm issues and their responses highlighted the most highly ranked alarm issue was related to frequent false alarms, if these were decreased it would have a positive impact by ensuring that the alarming limits are more clinically relevant and thereby decrease staff lack of response to alarms.

The fourth subcomponent of the Shepherd Systems Risk Model is Operator O4 – linked to criminal intent, whereby the user of the device intends to use it intentionally to cause harm to a patient. The operator is not necessarily the nurse; it could be any other member of the multidisciplinary team that has contact with the patient. This aspect we will not focus on in relation to research study.

2.2. Patient causes

In the Shepherd's Systems Risk Model, one of the components is related to the patient. This has only two subcomponents; active and passive causes. P1 is the code for patient failure code or cause related to the active subcomponent and means that the patients' actions affect the outcome of the alarming limit and the P2 is the code failure or cause related to the passive subcomponent which means that the patients' condition not action affected the outcome of the alarming limit (ACCE Healthcare Technology Foundation, 2006).

Non-actionable alarms are true alarms that do not require patient therapeutic intervention (Welch, 2011). Non-actionable alarms are also considered to be nuisance alarms or false alarms, those alarms that are non-actionable and also due to artifact that produces false data that is transmitted and displayed on the monitoring device (Welch, 2011). Actionable alarms are those that require a response by the nurse to the patient who is in need of therapeutic intervention so as to avoid a potential problem or adverse event (Welch, 2011).

The non-actionable alarm is related to a physically active patient that triggers the alarm from the preset settings. The actionable and warrant therapeutic intervention will be the passive causes as these will be directly related to the patient's condition and means that there is a need to intervene. False alarms according to Schmid, Goepfert and Reuter (2013) can be considered to be clinically irrelevant.

Supporting this, a false alarm can be either a false negative or a false positive. A false negative alarm is considered to be more detrimental as in this event the patient is in need of urgent clinical attention but the health care worker is not alerted to the need versus a false positive result which is the opposite where the patient is not in need of urgent attention but a healthcare worker is alerted to the alarming limits (Phillips Healthcare, 2013).

With regards to alarms two concepts are discussed; specificity and sensitivity. Sensitivity as per Carroll (2010) refers to "how much of a problem it takes to sound an alarm" in relation to specificity which refers to whether or not the alarm is in fact related to a genuine valid concern that requires intervention. Alarming related to sensitivity can be related to factors that are not related to the condition of the patient but can be related to other factors i.e. patient movement or

coughing or when the sensor falls off from the device or patient. This would be a false positive. Specificity indicates an actual area of concern that the nurse is alerted to.

Similar to issues around sensitivity, excessive alarms can be attributed to many factors that may not imply a clinical problem with the patient. These are related to the following: The data that is generated is not a true indication of the patients underlying health status at the time. An example of this is related to patient activity such as standing up or coughing or disconnection of the sensor or line. If the settings are too sensitive it will alarm for immediate changes without allowing for transient changes to be factored in. With so many alarming limits it is also possible that the healthcare worker may miss some or the alarming limit if not investigated correctly and managed appropriately (Phillips Focus Healthcare, 2013).

In a study conducted by Siebig, Kuhl, Imhoff, Langgartner, Reng, Scholmerich, Gather and Wrede (2010) that was observational in a Medical ICU, their findings were that in a 12 bedded ICU, 38 patients were monitored overall and their findings were that only 17% of the alarms were relevant.

Schmid *et al* (2013) study looked primarily at the comparison with theatre patients in the peri-operative setting and was unable to make a direct comparison as ICU patients are consciously sedated as opposed to being anesthetized. Due to this ICU patients presented with higher rate of artifacts linked to patient movement. Artifacts are a common source of these false alarms and most are related to a physiological reason and the risk of these false alarms leads to the “Crying-Wolf-Phenomenon” and causes the staff to become desensitized and ignore the clinically relevant alarms.

Supporting this is Cvach (2012) that explains that excessive alarms that are false/nuisance are due to patient manipulation and also refer to these as motion artifacts that has a negative effect on the nurses as it is disruptive to patient care and also causes them to not trust the alarming limits. False alarms are seen to be able to endanger patient safety if the healthcare workers no longer believe or trust that the alarming limits are giving valuable data that is an accurate reflection of the patients’ parameters (Carroll, 2010). False/nuisance alarms are characterized by a high incidence of clinically non-actionable alarms, false means it is produced by artifacts

creating false data, that is not of value to nurses, hence also referred to as nuisance alarms (Lopes, 2014).

A web survey conducted by Phillips Focus Healthcare group (2013) highlights that false/ nuisance alarms do have clinical consequences such as delayed response time to urgent alarms that require intervention. These alarms add to the stress levels for healthcare workers, patients and their family members. The study also revealed that this can negatively increase costs to the hospital by delaying patient recovery time.

In a study done by Inokuchi Sato, Nanjo, Echigo, Tanaka, Ishii, Matsubara, Doi, Gunshin, Hiruma, Nakamura, Sinohara, Kitsuta, Nakajima, Umeza and Yahagi (2013), 18 patient alarms were monitored and only (6.4%) of these alarms were considered as clinically relevant. This is one of many studies that highlight the number of irrelevant alarms that healthcare workers and patients are exposed to. According to a 2014 study by Lopes (2014) the “distressing” amount of nuisance alarms from monitoring could lead to the staff setting the threshold limits too low or too high as opposed to the individualized patient specific needs.

Welch (2011) discussed in his analysis of the problem in the article: An Evidence –Based approach to reduce nuisance alarms and alarm fatigue, speaks of the high rate of false/ nuisance alarms that lead to staff ignoring alarm limits triggered. This is a concern for nurses but is a problem that requires attention from a multidisciplinary team including clinicians, biomedical engineers and industry. Alarm hazards based on the ECRI – Emergency Care Research Institutes report depicts alarm hazards in their top ten technology hazards (Welch, 2011). This article focuses primarily on the saturation alarms and the specifics of the monitoring device linked to sensor application and choice, cable management and instrumentation as well as signal processing in the management of false and nuisance alarms.

Excessive alarms are considered to be a concern as these can directly impact on the quality of care patients receive due to poor efficiency in managing patient needs. In addition it negatively impacts on the patient satisfaction levels (Phillips Healthcare, 2013). An audit was conducted by Phillips Healthcare at one customer site which revealed the following findings: a nurse within one minute had to respond to 3.7 alarms. This affected the response time per alarm because time was taken to respond to alarming limits but all could not be addressed simultaneously. Inokuchi

et al (2013) support this by highlighting that an increase in alarms can decrease the nurses attentiveness as they begin to not see them as always being important therefore impacting negatively on patient safety, by decreasing the nurses sensitivity and leading to alarm exhaustion.

Phillips Healthcare (2013) clearly explains the results of active patient related activities as causes linked to false/nuisance alarms. An example of an active patient related activity is a patient trying to move in the bed to reposition oneself for comfort, but due to this movement it triggers the alarm limits which are set for a patient at rest. Due to the activity i.e. movement the heart rate will increase. These are not valid reasons for any therapeutic intervention by the ICU nursing staff. These, also in the researcher's experience, are common alarm limits that the ICU nurse is exposed to. Many different ICU related nursing procedures would trigger these non-actionable false alarms. Examples of these activities are the common pressure care rounds, physiotherapy, suctioning, mobilizing the patient, weaning a patient off sedation and ventilation and any other procedures related to the patient care and treatment. As nurses adapt and become familiar to these alarms, the risk does lie with the fact that they are so familiar hearing these audible alarms, that they may not take any special notice or consideration to alarms for their patients' in their care or environment.

2.3. Device causes

According to the Shepherd's Systems Risk Model (ACCE Healthcare Technology Foundation, 2006) the component on devices has four subcomponents; human factors designs, parts/circuits designs which is related to unexpected failures, deterioration which is inclusive of battery failures, and the fourth subcomponent is maintainer error (ACCE Healthcare Technology Foundation, 2006).

These alarms are technology related alarm problems which are not clinically relevant alarms. The technical alarms validity can be either technically true, technically false or indeterminable (Inokuchi *et al*, 2013). Nurses are exposed to numerous alarms in their ICU environment that are not related directly to the patient.

The Step by Step guide on Taking Alarm Management from Concept to Reality (Phillips Healthcare, 2013) categorized the different causes for excessive alarms and those that were discussed in relation to the devices and failure modes were as follow. The first failure mode was

related to the data being generated not reflecting the underlying status of the patient and is usually linked to a transient change that does not have any clinical relevance for the nursing staff, an example would be related to a saturation monitoring device or ECG monitoring device. Secondly, there could be a problem with the sensor that is not capturing the patients' data correctly. The signal that is also being transmitted is not actually a true reflection of the data that is actually being generated by the patients' condition (Philips Healthcare, 2013). Other concerns are linked to the limits not being meaningful in relation to the patients' condition. These are the possible failure points in the alarm pathway as discussed from the results of the Philips survey.

In line with the issues around sensitivity, excessive alarms can be attributed to many factors that may not imply a clinical problem with the patient. Those related to the patients active causes linked to motion artifacts have already been discussed. If the sensor is not connected appropriately to the main processor unit or monitor this could hamper the signal to the monitor for display and in addition be seen as interference. If the settings are too sensitive as well, the device will alarm for immediate and all changes without allowing for transient changes. With so many alarming limits it is possible that ICU nurses could miss some of the alarming limits if not investigated correctly and managed appropriately.

2.4. Nursing concerns

The article on Alarm Fatigue: Impact on Nursing Care (Carroll, 2010) briefly highlights what nursing staff concerns to alarms and the findings are that they are generally frustrated by false alarms as it is disruptive to patient care and referred to as a nuisance. The negative impact on caring is that these frequent non-actionable alarms are ignored by healthcare workers and hence they react more slowly to these or even switch the volume of these alarming limits off or significantly lower the volume of these devices. They become a task to comply with as opposed to being used to manage patients' clinical presentation and condition. In addition a constant staffing crisis can affect the ability to respond to these alarming limits.

Carroll (2010, page 2) highlights the challenge about responding to alarm limits well: "...convincing others that the psychomotor tasks we perform are actually carefully integrated with high level cognitive knowledge, assessment and analysis that can't be seen or easily replaced by non-licensed assistants."

The frustration of staff is noted with high levels of false/nuisance alarms as it takes up a lot of the health care workers time at the bedside. Decreased numbers and frequency of alarms would help them to see the benefits of the alarms and thereby respond more quickly and appropriately (ACCE Healthcare Technology Foundation, 2006).

Chambrin (2001) discusses that an alarm is generated when it crosses a set limit. The set limit is useful to nurses to identify any changes in physiological parameters in a patient to guide management decisions for the patient. Despite this many alarms are perceived as unhelpful to the staff due to a high incidence of alarms with no clinical significance. The reason for high levels of these alarms as per discussion from the ACCE Healthcare Technology Foundation (2006), there is no standard for default alarm setting as it differs from one monitor to another. For an experienced nurse that is familiar with locating the relevant alarm triggered, it is the repetition of these alarms that becomes bothersome (Chambrin, 2001).

The ACCE Healthcare Technology Foundation (2006) had an initiative in 2005 which was aimed to improve patient safety through the identifying challenges and opportunities to enhance clinical alarms. The areas that were considered to improve clinical alarms for patient safety were on the alarm design, operational use and response to alarms, communication and appropriate intervention to resolve alarm related incidents. A task force was initiated that included forums open for discussion, audio conferences, reviewing existent literature, developing educational information and analyzing clinical alarm surveys. This task team developed the questionnaire used in the current study and one of the contributing associations with regards to the development and validity of the tool was the American Association for Critical Care Nurses (ACCE Healthcare Technology Foundation, 2006). The aim of the survey was to obtain relevant data on the extent to which managing clinical alarms was an issue in hospitals so that both nurses and engineers can take corrective measures.

A national online survey in the United States by Rhode Island College was conducted in 2008 as referenced in a research study by Lopes (2014) and this survey was conducted to identify why health care workers did not respond to alarms of which 51% of these were nursing staff. The study was based on trained healthcare workers in the area of audible alarms. The results of this study showed that they did identify the importance of prioritizing alarms and that they found nuisance alarms to be a problem and disruptive to patient care. What was concluded is that

taking an active role in patient care would mean increasing their knowledge and understanding about the equipment, its use and how to obtain optimal benefits to improve effective alarm management.

The research study by Lopes (2014) was to investigate the impact of alarm fatigue on nursing staff and the degree or level of impact and effect on nursing work processes. This study was a descriptive study that looked at the clinical conditions and their link to alarm fatigue in ICU nurses. The study's participants were registered nurses in two twenty eight bedded units and there was no exclusion criterion for this group. The data was collected using a 15 question survey. This tool was designed by the researcher as there was no existing tools from which to benchmark their survey and was designed based on the researchers own clinical experience and literature reviewed for the study. The survey included Likert responses, open ended and demographic questions. This tool was used for the purposes of this research study.

In the two units, one unit had an 86.2% response rate that they strongly agreed or agreed they experienced alarm fatigue. The second unit 73.3% strongly agreed or agreed that they experienced alarm fatigue. In Unit One 93.1% had strongly agreed or agreed and in Unit Two 93.3% strongly agreed or agreed that they experienced nuisance alarms. In Unit One 72.4% strongly agreed or agreed and in Unit Two 93.3% strongly agreed or agreed that these nuisance alarms did indeed disrupt their patient care. In Unit One 75.8% strongly agreed or agreed and in Unit Two 66.6% strongly agreed or agreed that these nuisance and false alarms reduced their trust in alarms. In Unit One 82.7% strongly agreed and agreed and in Unit Two 86.6% strongly agreed and agreed that it also contributed towards a lack of response to the alarms. For confidence in adjusting alarm parameters Unit One had 80.2% and Unit Two 86.6% that strongly agreed and agreed to this statement.

The percentage in Unit One of 61.9% and in Unit Two of 53.3% strongly agreed and agreed that they felt overwhelmed by the number of alarms. Also Unit One 51.7% and Unit Two 46.6% strongly agreed and agreed that clinical alarms significantly contributed to a rise in their stress levels. Most of the staff had a Bachelors degree in Nursing with the majority of these participants having less than two years experience in the position and had the necessary training. The suggestions put forward from this study were recommendations to review alarm monitoring policies in relation to use of devices, response times, the frequency of parameters and settings to

be reviewed in an individual patient, actions to improve and reduce nuisance alarms and to ensure that these policies put forward are also audited to ensure compliance (Lopes, 2014).

In another study conducted in 2010 by Graham and Cvach; “Monitor alarm fatigue: standardizing use of physiological monitors and decreasing nuisance alarms”, they initiated a quality improvement programme for patient safety related to alarm management. A pretest survey was conducted with registered nurses to identify their baseline knowledge and how they responded to alarms. The results from this study revealed that 83% of the staff changed their alarms once a patients’ condition and vital parameters changed. It also revealed that 78% changed it at the start of their allocated shift but in circumstances where patients had moved between different areas of care only 41% were likely to change default settings (Graham and Cvach, 2010).

The above mentioned results in the post test survey in Graham and Cvach’s (2010) study, did indicate an improvement overall due to a quality improvement programme focusing on changing the culture of patient safety in the unit. When they had to rank noise levels, they rated overall noise as 4.0 and alarms were rated as 3.1 with 5 being the noisiest. The noise ratings post intervention had also improved overall (Graham and Cvach, 2010). The interventions of a project planned to address advisory alarms in a cardiac care unit was an alarms management task force which had planned a year long process. This plan was on focusing on educating staff with regular assessment of patient specific parameters and how to use medical devices in line with a hospital protocol to ensure patient safety.

Noise levels were indicated as a link to alarm fatigue in the above mentioned study by Lopes (2014) and the impact it has on patient rest and/or sleep patterns is linked to patient stress levels and a hindrance to the healing or recovery process. According to Schwartz (2013) false positive alarms create a lot of unnecessary noise placing nurses in a difficult situation, with concerned patients and families who don’t always know what the alarm may mean add to those pressures.

Wyckoff (2009) explains that as healthcare workers or individuals, one generally has difficulty in discerning from six different alarm signals/sounds per device used in the ICU, when they were evaluated. This highlights that nurses tend to recognize only the common alarm sounds. The risk lies when a nurse cannot differentiate which alarm they heard and the relevance of that alarm for

the patients care. An example that was highlighted in this article on improving how we use and respond to alarms, is how one may confuse an oxygen saturation alarm with a heart rate alarm, and in the event of an airway difficulty, if the alarm is not correctly identified or distinguished appropriately due to potential desensitization this could lead to an adverse event for the patient by not identifying a problem in time.

Kleinpell (2010) discusses in the American Journal of Critical Care, a study conducted by Cvach on cardiac monitor alarms in a medical progressive care unit. The study evaluated the type and frequency of alarms through an interdisciplinary task team that was commenced in 2006. The study was done over a 4 month period and the study assisted in identifying challenges that nurse's experience in relation to alarm response to ensure and manage patient safety. Duplicate alarms were identified increasing false/nuisance alarms, excessive noise associated with alarms and educational methods were evaluated.

2.5. Alarm adverse events

In cases where there were near miss events and or adverse events linked to poor alarm management, common findings were linked to situations where the alarms were not customized per patient needs, alarms were turned off without using the option for delay and where alarms were not heard. The ACCE Healthcare Technology Foundation (2006) indicated that some users could rely heavily on the alarms to alert them to a change in patient condition and it would be inappropriate to use these alarms as a replacement to the degree of attentiveness required from the health care worker. Staffing levels and skill needs according to the availability of alarm limits on devices can have potentially serious adverse consequences for patient safety as nurses cannot be reliant on only alarms to manage their patients.

According to a Wyckoff (2009), alarms can alert nurses to acute patient deterioration. This would generally not be able to be detected from only a clinical presentation of a patient. Therefore alarm limits on devices are only as good as the nursing staff that use and set these alarm limits by determining appropriate levels to alert them to individual patient needs. By not setting the alarm limits correctly this can hinder the warning system that these alarms were intended to provide to the nursing staff (Wyckoff, 2009).

In a study done by Inokuchi *et al* (2013) it is also stated that being surrounded by frequently alarming limits not only distracts the health care workers but in addition also contributes to patient delirium in an ICU setting.

2.6. Solutions to alarm management

As alarms are in place to improve patient safety, they assist by communicating information to the health care workers which does require an immediate intervention (ACCE Healthcare Technology Foundation, 2006). The user of the devices in this case the healthcare workers caring for patients have the ability to either switch on or off these parameter limits, including the adjustment of the volume of the alarming limits. The alarm once activated is the healthcare workers responsibility to acknowledge, identify the source and respond in an appropriate manner. It is clear that the user, the healthcare workers are the persons that are the expected and responsible to manage device alarms best to ensure patient safety and early detection of potential problems.

Environmental checks are important to ensure effective alarm management. These would include the checking of alarm limits for patient safety. Medical equipment tests on product and software are just as important. These alarm limits need to be set per patient and adjusted per shift. Training and supervision will assist in identifying and managing problematic areas (Phillips Healthcare, 2013). In addition, product evaluations for monitoring devices are an important task for healthcare workers to ensure devices are made to suit the user (Carroll, 2010).

In the study done by Inokuchi *et al* (2013) the methods that they looked at to reduce the number of alarms was setting a delay, calibrating and switching off an alarm prior to a procedure. This did not always work efficiently. The concern here would be switching of the alarms prior to a procedure as this is a high risk, changes that patients are exposed to from basic physiotherapy to invasive procedures can still trigger a negative bodily reaction or complication and it is at these moments where close monitoring of changes is definitely required in the event of an adverse situation.

According to Hannibal (2011) human factors can also be manipulated to assist with reducing the number of negative incidents related to alarm fatigue and other hazards linked to alarm systems. Suggestions highlighted that false cardiac monitoring alarms can be limited by ensuring correct

and new electrodes are placed on patient, those patients no longer requiring to be monitored should be removed from monitoring devices and testing alarm audibility in and around the bedside to ensure actionable alarms are responded to timeously.

A more recent report supporting this is the Emergency Care Research Institute (ECRI) report on the Top Ten Health Technology Hazards for 2015 (ECRI Health Devices, 2014) that looks at recommendations that also indicate the need for training requirements for educating clinical staff with periodic retraining and providing access to readily available policies to facilitate a continued adherence to these policies and procedures linked to alarm management.

Additional support is in the Joint Commissions Hospital for the National Patient Safety Goals (The Joint Commission, 2014). Goal 6 is to reduce the harm associated with clinical alarm systems. This goal directive discusses that universal solutions are yet to be identified but what is feasible is that individual hospitals attempt to understand their unique situations so that a systematic coordinated approach in managing clinical alarms can be structured (The Joint Commission, 2013). The elements of performance that this goal is to be reviewed against are establishing alarm system safety as a priority. By identifying the most important alarms collaboratively, potential risks associated with specific alarm challenges can be identified i.e. alarm fatigue, alarm noise, malfunctioning alarm system, alarm limit guidelines, policies and procedures linked to specifics as per the tool for the organizations and staff education.

Wyckoff (2009), also discusses the use of a buddy system to test and double check alarm limits and settings and the implementation of clinical monitoring rounds by a senior member of the team to ensure focus and compliance. The implementation of this with each shift that starts will assist in promoting this as routine practice.

Technology and technologically based solutions are also an area that can be explored by clinical and biomedical engineers with regards to designing better alarm systems in devices that can help consolidate and organize the information for the nursing staff can assist in decreasing false alarm rates. The literature refers to this advancing technology as SMART alarms as they are based on algorithms (Wyckoff, 2009). Smart alarms consider other parameters before an alarm is triggered unnecessarily.

In an evidence based review and discussion conducted in the American Journal of Critical Care (Kleinpell, 2010) on a study conducted in 2006 in a medical progressive care unit that evaluated type and frequency of alarms, three initiatives were implemented. Default parameters were reviewed on the monitors and recommendations were made to reduce the number of duplicate alarms. Noise levels were addressed by a task team by programming benign alarms to have a visual display as opposed to an audible alarm. The staff knowledge was tested on physiologic monitors and alarm management for patient safety and devised a policy on alarm management that was specific to alarm audibility, escalation and troubleshooting. The results of this study were positive with a noticeable reduction in the number of alarms.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1. Research design

The research conducted is a quantitative research study to investigate how ICU nurses respond to alarm limits for patient safety. A descriptive non-experimental research design was used which uses surveys/questionnaires that are for fact finding enquires. The data was collected by means of a questionnaire hence there was no manipulation of variables ensuring it was a non-experimental design (Singh, 2006). The term descriptive research refers to the type of research question, design and data analysis that will be applied to a given topic. Descriptive studies are aimed at finding out "what is," so observational and survey methods are frequently used to collect descriptive data hence the purpose of this approach is to describe the current situation of how ICU nurses respond to alarm limits for patient safety. The researcher can only report on what the findings are as the researcher has no control over any of the variables in the study (Polit and Hungler, 2013)

3.2. Research setting

The research setting was based at a private hospital in KwaZulu-Natal, Durban, South Africa. The hospital has 3 adult ICU departments and 1 Neonatal ICU. Each unit has four shifts per month. The 3 Adult ICUs will be referred to as ICU 1, ICU 2 and ICU 3 and the neonatal ICU as ICU 4.

ICU 1 is a 26 bedded unit which has 2 isolation cubicles and all other beds are partitioned. The types of patients in this unit are predominantly medical patients. High care patients are also accommodated in this ICU. Common types of patients that ICU 1 manages are cardiac patient that have had a myocardial infarction, post catheterisation where cardiac patients have interventions done for their conditions as well as other medical cases: renal failures, communicable diseases e.g. tuberculosis, malaria etc. and other non-surgical cases that require advanced levels of care.

ICU 2 is a 25 bedded unit with 4 isolation cubicles. All the other beds are not partitioned from each other. There are 8 high care beds inclusive in the unit. The types of patients that this ICU receives are predominantly surgical cases that are elective or planned surgical cases that require

advanced level of care. These surgical cases though exclude patients that have an elective or planned surgery to the brain and cardiac surgery such as a cardiac bypass. ICU 2 also receives trauma cases.

ICU 3 is a 9 bedded unit with 1 isolation cubicle. All the other beds are not partitioned from each other. The types of patients in this ICU are mostly elective planned surgical cases for brain surgery and cardiac surgery.

ICU 4 has 20 beds of which 9 are ICU beds and the remaining are high care beds. The admission criteria for newborns require that they are under a year old and were delivered in the hospital maternity department adjacent to the NICU unit. These newborns are generally premature babies that require additional advanced level of care until discharge and management of complications after birth. No external admissions are allowed in ICU unit 4.

3.3. Population and sampling

The target population in this research study was the all the ICU registered and enrolled nurses in a private hospital setting. These registered and enrolled nurses are directly involved in setting and managing alarm limits for their allocated patients.

ICU 1 has 39 staff which is inclusive of registered nurses and enrolled nurses. This number excludes the enrolled nursing auxiliaries or healthcare workers. The registered nurses are inclusive of the Unit Manager.

ICU 2 has 36 staff which is inclusive of registered nurses and enrolled nurses. This number excludes the enrolled nursing auxiliaries or healthcare workers. The registered nurses are inclusive of the Unit Manager.

ICU 3 has 20 staff which is inclusive of registered nurses and enrolled nurses. This number excludes the enrolled nursing auxiliaries or healthcare workers. The registered nurses are inclusive of the Unit Manager.

ICU 4 has 25 staff which is inclusive of registered nurses and enrolled nurses. The registered nurses are inclusive of the Unit Manager.

The inclusion criteria were as follows:

1. Registered and enrolled nurses who had worked at least one month in the ICU in the current hospital.
2. Registered nurses included ICU and non-ICU trained staff.
3. Sessional staff that met the above criteria and those that were working during the handout of the survey were included.

The exclusion criteria are as follows:

1. Registered and enrolled nurses that had worked less than one month in the ICU in the current hospital.
2. Student nurses were not considered for participate in the survey.
3. Enrolled nursing auxiliaries were not considered for participate in the survey.

The sample chosen by the researcher included all the registered nurses and enrolled nurses working in the ICU units. The sample size was purposefully selected and was an all inclusive sample N=120. Ninety-one questionnaires were received (N=91) resulting in a 91% response rate. This is a non-probability sampling design. In this research the purposive sampling is specific to the categories of staff that are directly involved with alarm management in the ICU setting.

3.4. Data collection tool

The data collection tool with covering letter and a declaration letter was issued with the questionnaire as per Annexure 1 and Annexure 2. This questionnaire comprised of 6 sections labeled A to F. A questionnaire was chosen as it can be distributed to a large group of people in order to obtain data.

Sections A, B and C focused on demographic information.

Section D was solely directed to extracting alarm related information. The questions in section D related to the conceptual framework of alarms and alarm limitations and the different components with regards to operator, patient, environment and human factor design. There are 21 items in this section and each question was to be answered on a likert scale. This scale is used

in quantitative research for collection of data. It allows for degrees of opinion ranging from strongly agree to strongly disagree and it allows for a neutral response. The data collected using this scale is easy to analyse. The participants are required to indicate with a tick (√) in the appropriate box to rate their level of agreement or disagreement.

Section E is a scale that requires the respondent to rank 9 related issues according to their level of importance and priority. In the original survey these 9 statements are statements that inhibit effective management of clinical alarms (ACCE Healthcare Technology Foundation, 2006).

The goal of the survey in the original study done by ACCE Healthcare Technology Foundation (2006) was to assist in gaining reliable data of the extent of the challenges that were current in managing clinical alarms in hospitals to assist nurses and clinical engineers in taking appropriate measures.

Section F asks 3 questions that require the participants to share their opinions, recommendations and possible solutions in improving alarm recognition and responses by nurses in an ICU.

Approvals for the use of the questionnaire were provided by the following University and Institution. The Rhodes Island College, School of Nursing (2014), which designed and implemented the research questionnaire ‘Alarm Fatigue’ for their data collection and the ‘Clinical Alarms Survey’ as approved by the ACCE Healthcare Foundation (2006). Approvals from the Rhodes Island College were granted by Kieran Ayton, the Emerging Technologies Librarian, the Interim Head of Digital Initiatives and J. Tobey Clark the President of HTF (Healthcare Technology Foundation). Permission was obtained to use these tools and is available in Annexure 3.

3.5. Data collection process

The steps that were followed with regards to data collection are as follows:

After obtaining permission to conduct the study from the ethics committees from the University and the hospital management of the selected private healthcare institution, the researcher made appointments with the unit managers of the respective units in order to explain the purpose of the study and asked for support with the issuing of the surveys.

A covering letter with a declaration form was attached to each questionnaire as per annexure A, outlining the details of the study together with two envelopes. These details regarding the anonymity, confidentiality and voluntary participation of registered nurses and enrolled nurses was explained to the Unit Managers of the 3 Adult ICUs and neonatal ICU before issuing them questionnaires for self administration to the staff.

The researcher and the Unit Managers explained to the staff what the research was about and what the expectations were from participants willing to participate. All Unit Managers were guided to commence rollout at the same time. In addition the researcher was on standby daily and would visit the ICU departments daily to be available to answer any questions and queries related to the questionnaires administered to the staff.

The distribution of the questionnaires to the staff was done in duty time. The staff were granted permission to take the questionnaire home to complete in their own time if it was more suitable for them to do so. On completion of the questionnaire, the staff member sealed the survey and the declaration of consent in the envelopes provided and returned them to the Unit Managers marking both as confidential. A 2 week period was allowed to ensure as many staff have the opportunity to be given the survey and option to participate. The reason for this time frame is due to the fact that the ICU nurses work different shifts.

The researcher collected completed questionnaires; daily from the Unit Managers per department as their Unit Managers will be the central point of submission.

3.6. Data analysis

A descriptive statistical analysis was done using IBM SPSS Statistics 23. Statistics were captured electronically using IBM SPSS and represented in a table and graph format to summarise the data for analysis. The likert scale is a commonly used in questionnaires, it is a simple method of gaining information on people's opinions. This is known as the likert method of attitude measurement and is able to gain feedback on the unobservable phenomena. The advantages of this measurement are that it is universal and simple to use indicating an overall positive or negative orientation or perception towards the subject matter being analysed. Neutral responses indicate that the participants neither agree nor disagree to a statement. The disadvantage of this response is that depending on the sample size it has the potential to impact negatively on the

quality of the data collected. The statistics were captured electronically and represented in the format of tables and graphs to summarise the findings.

3.7. Validity and reliability

Validity means that the tool being used to collect data does measure what it is intended to measure (Heale and Twycross, 2015). There are two types of validity, internal and external validity. Internal validity looks at the extent the research design is able to test the hypothesis. External validity relates to the extent that the findings may be generalized outside the sample and setting.

In the original survey conducted by ACCE Healthcare Technology Foundation (2006), an alarm task force was initiated to focus on management of clinical alarms. The survey was developed with the most valuable information and feedback from experts in the American Association for Critical Care Nurses. In addition there was consultation with various other clinical, technical and engineering companies to strengthen the face and content validity of their tool that was used nationally online. This tool was used towards the current study with the exclusion of questions related to that countries commission for patient safety goals, central alarms communication and communication systems such as pagers which is not applicable to the current context in the South African ICU setting.

The data collection tool was designed by the researcher in a study done by Lopes (2014) and by the Health Technology Foundation (2006) on alarm fatigue. In the study conducted by Lopes (2014) the questionnaire was based on the literature review from the study. This tool was designed on the survey used by the ACCE Healthcare Technology Foundation with additional questions asking for commentary on suggestions to improve alarm recognition and response which was added as section F in the current tool. Permission was sought to use the tools of the study conducted by Lopes from Rhode Island College in the United States and the Health Technology Foundation were these tools were implemented. Refer to Annexure C for proof of permission from both Rhodes Island College and The Health Technology Foundation.

The data collection instruments used to design the current tool were tested and used in previous research study conducted as per Lopes (2014) and as per the ACCE Healthcare Technology Foundation (2006).

Content validity ensures that the tool is measuring what it is intended and meant to measure. Refer to Table 3.7.1 below.

3.7.1. Content validity

Conceptual Framework domain	Research Questions	Questionnaire Item
Operator: Education and Training	What human factors (Refer to operational definition) related to ICU nurses, contribute towards a response to alarm limits for patient safety?	Question D. No 1 Question D. No 9 Question D. No 11 Question E. No 1 (rank) Question E. No 3 (rank) Question E. No 4 (rank) Question E. No 9 (rank)
Operator: Diverted attention	What human factors related to ICU nurses, contribute towards a response to alarm limits for patient safety? Are there any factors in the ICU environment identified that impact negatively on ICU nurses responses to alarm limits for patient safety?	Question E. No 7 (rank) Question E. No 9 (rank) Question D. No 10 Question D. No 12 Question D. No 13 Question D. No 18 Question D. No 15 Question D. No 16 Question D. No 18 Question E. No 2 (rank) Question E. No 5 (rank)

		Question E. No 6 (rank) Question E. No 8 (rank)
Environment: Internal	Are there any factors in the ICU environment identified that impact negatively on ICU nurses responses to alarm limits for patient safety?	Question D. No 14 Question D. No 19 Question D. No 20 Question D. No 21 Question E. No 8 (rank)
Device: Human Factors Design	What human factors related to ICU nurses, contribute towards a response to alarm limits for patient safety?	Question D. No 2 Question D. No 3 Question D. No 4 Question D. No 17
Patient: Passive	What patient factors contribute towards the response of ICU nurses to alarm limits for patient safety?	Question D. No 5 Question D. No 6 Question D. No 7 Question D. No 8

The researcher piloted the questionnaire on five registered nurses. The registered nurses were currently registered to complete their ICU Diploma course. The pilot study that was done helped the researcher to identify if there were any limitations to the questionnaire prior to issuing to the staff. No problems were encountered during the pilot study.

The tool designed to rate the participants level of agreement to statements about clinical alarms and assessing their response to rank 9 statements that list issues that inhibit effective management of clinical alarms, aims to identify what the current issues are in the South African context with regards to clinical alarm management that require enhancement aimed at improving patient safety.

3.8. Ethical considerations

Ethical approval was obtained from the University of KwaZulu-Natal and the institution that the research study was conducted at. Annexure 4 and Annexure 5 make reference to the evidence of ethical clearance obtained.

Ethical aspects that are important are that the participants were made aware of the details of the research study and informed that they can withdraw at any time from the study as their participation was voluntary. Confidentiality and anonymity of the participants' responses was maintained as there were no names or identifying details requested within the survey on distribution and the declaration of consent were sealed in separate envelopes to ensure that their consent could not be linked to their response surveys. ICU nursing staff could volunteer to complete the survey or withdraw as participants and this information was made available to them on the covering letter of the questionnaire. Informed consent is ensuring their freedom to refuse or withdraw from the study (Emanuel, Wendler, Killen and Grady, 2004). The presence of the researcher on a daily basis in the departments was available to the staff to allay any concerns related to anonymity.

The surveys were distributed with two envelopes, one in which the tool was sealed in after completion before handing it to the submission point (which was the unit manager) and the other for the signed consent to participate to be completed and marked as confidential. The researcher collected these sealed envelopes from the unit managers on a daily basis and reviewed and shared these surveys only with the supervisor of the research study. The envelopes ensured anonymity of the participants. The sharing of the data collected was only with the supervisor which also ensured that none of the participants that participated in the study were known to the ICU unit managers in the facility that the research was conducted in. As the researcher works in the same institution in a clinical educator role and manager, this was the best option with regards to the process of data collection with the unit managers. The researcher used this as a way to remain neutral.

A covering letter explaining the nature of the research and the participants' rights was emphasised to ensure that they received informed consent prior to participating in the survey. This ensured anonymity was maintained. The name of the department and the institution would

not be referred to as well to ensure confidentiality. The covering letter of the survey for volunteering participants also included the contact details of the researcher so that the researcher may be contacted if required. There were participants that did utilize this option with regards to the completion and guidance with regards to the questions.

All registered and enrolled nurses working the four units were included in the survey, no staff member was excluded from participating. This was inclusive of the sessional staff that frequently works in the ICU units as their feedback was considered to be equally important and valued. The exclusion criteria omitted the new staff with only a month's experience in the current setting.

There was no harm as identified by the researcher for the participants' of the study. As this is a non-experimental research there are no risks associated for the participants in the study. The researcher provided the participants about the nature of the study and that they had a right to withdraw. This allows the participants to be involved having informed consent which is necessary to understand the scope and nature of the research study to make a decision. The principles for beneficence and non-maleficence are considered in this regard.

Non-maleficence is to do no harm; this study in no way puts the participants or patients at any risk of being harmed due to it being non-experimental and also excludes the patients in the ICU setting. The staff were ensured no harm as they were protected with regards to their anonymity. This attempted to eliminate any potential concerns for the staff against being identified and victimized for their feedback. A positive environment was created welcoming their feedback and participation in the research; staff was made to feel that their opinions were valued.

3.9. Data management

The data was locked in a safe place accessible only to the researcher and her supervisor. The research data was maintained electronically where it was being saved onto a CD and the files were password protected. The responsibility for the storage lies with the researcher. The hard copies of the surveys were kept securely locked away in a locked filing cabinet that can only be accessed by agreed members of the research team, which would be the supervisor and the researcher only. The data was anonymised before being stored to ensure that the data is not traceable to any personally identifying data. The key is maintained by the supervisor at the

University. Hard copies of the data collected was communicated between the researcher and supervisor in person, no copies were shared via email communication. After report writing, all materials used to collect data is stored in a secure place for a period of 5 years, thereafter it will be destroyed by shredding and burning. The original data is maintained by the university, a copy of this data may be held by the researcher. Data on the computer hard drives was erased as well.

CHAPTER FOUR: RESULTS AND DISCUSSION

4.1. Pilot study

A pilot study was done with 5 qualified registered nurses that work in an ICU environment. These five registered nurses selected were currently registered to complete their Critical care diploma. All had completed the survey well with the researcher explaining the purpose of the research and the structure of the survey. The participants answered the surveys; their feedback on completion did not indicate any challenges with the comprehension of the questions asked. The general consensus that they responded to the researcher was that they considered the topic of research to be of interest to them based on their own experiences of alarm limits in the ICU units. All five participated and completed the surveys in full which was a 100% feedback. No changes were made to the questionnaire and the data obtained was not included for analysis.

4.2. Demographics

The total amount of questionnaires administered was 120 of which 91 completed questionnaires were received thus a response rate of 75.8%. Twenty four point one percent was not returned after the allocated two week period for data collection. The response rate per ICU department was further broken down as follows in Table 4.1 and 4.2.

Table 4.1 Survey response rate

Information	Number of Questionnaires' N = 120
Questionnaires' returned	91 (75.8%)
Questionnaires' not returned	29 (24.1%)

The allocated time for data collection was two weeks, the returns on the survey questionnaires were as per Table 4.1.

Table 4.2 Response rates of survey per ICU

Information	Number of Questionnaires N = 120, n = 91
Questionnaires' received in total	91 (75.8%)
ICU 1 returned of 39 issued	29 (31.9%)
ICU 2 returned of 20 issued	20 (22%)
ICU 3 returned of 35 issued	20 (22%)
ICU 4 returned of 26 issued	22 (24.2%)

Of the 91 that did respond the percentage of the categories of nurses were broken down as follows in Table 4.3. It was positive to note the large percentage of returns from the staff employed in the facility as it allows for a good representation of alarm management in the ICU's in the research setting chosen. The following Table 4.3 represents this.

Table 4.3 Nursing categories response rate

Nursing category	Number of participants n = 91
Permanent RN ICU trained	25 (27.5%)
Permanent RN Non ICU trained	37 (40.7%)
Permanent EN	12 (13.2%)
Unit Managers	3 (3.3%)
Sessional RN ICU trained	2 (2.2%)
Sessional RN Non ICU trained	4 (4.4%)
Sessional Enrolled nurses	8 (8.8%)

The participants as described per nursing category were further broken down according to their years of experience as a nurse. There were 23.1% that were between 0 to 3 years experienced, 16.5% had between 4 to 6 years experience, 27.5% had between 7 to 11 years experienced. There were 33% of the participants with 12 years or more experience. Overall 60.5% of these participants were well experienced in the field of nursing from 7 years and over. This indicated the level of expertise in the group of participants based on their years of experience. The following Table 4.4 highlights the data as described.

Table 4.4 Years of experience of participants

Information	Number of participants n = 91
0 – 3 years of experience	21(23.1%)
4 – 6 years of experience	15 (16.5%)
7 – 11 years of experience	25 (27.5%)
12 years or more experience	30 (33%)

Due to the number of years in the facility their orientation and knowledge to the company, this experience in ICU and the advancing technological medical equipment, feedback on alarm management and impact on their ability to deliver patient care safely would be valuable.

4.3. Alarm information and priority ranking

The following section will display the responses for the survey questions for section D (alarm related information) and for section E (priority ranking). The results are presented in a table format that displays the number of participants and valid percentage as per the 5 point likert scale namely; strongly agreed, agreed, neutral, disagreed and strongly disagreed.

Table 4.5 below shows the results for section D in the survey asking 21 statements to be ranked by the participants on a five point likert scale. These questions relate to the five components of the Shepherd's System Risk Model (2004). The percentage shown indicates the valid percentage of responses. The last column indicates the missing data where there was no response to the question, this number and percentage is not to be included in the total percentage of 100% or total number of participants of 91.

Table 4.5 Section D Alarm related information

No.	Questionnaire Item	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Nil response /Missing data
D1	The purpose of clinical alarms is to alert staff of an existing or potentially hazardous patient condition	78 (86.7%)	10 (11.1%)	0	0	2 (2.2%)	1 (1.1%)
D2	Alarm sounds and/or visual displays should differentiate the priority of alarm	69 (76.7%)	17 (18.9%)	3 (3.3%)	0	1 (1.1%)	1 (1.1%)
D3	Alarm sounds and/or visual displays should be distinct based on the parameter or source (e.g. Device)	56 (62.9%)	26 (29.2%)	4 (4.5%)	2 (2.2%)	1 (1.1%)	2 (2.2%)
D4	Alarms should impact multiple senses (audible, visual, proprioceptive, etc.)	54 (61.4%)	28 (31.8%)	4 (4.5%)	0	2 (2.3%)	3 (3.3%)
D5	Nuisance alarms occur frequently	10 (11.6%)	38 (44.2%)	17 (19.8%)	13 (15.1%)	8 (9.3%)	5 (5.5%)
D6	Nuisance alarms disrupt patient care	12 (13.3%)	42 (46.7%)	15 (16.7%)	10 (11.1%)	11 (12.2%)	1 (1.1%)
D7	Nuisance alarms reduce trust in alarms and cause care givers to turn alarms off at times other than setup or procedural events	18 (20%)	32 (35.6%)	15 (16.7%)	16 (17.8%)	9 (10%)	1 (1.1%)
D8	Nuisance alarms contribute to lack of responses by many nurses	15 (16.5%)	48 (52.7%)	9 (9.9%)	12 (13.2%)	7 (7.7%)	0

No.	Questionnaire Item	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Nil response /Missing data
D9	Properly setting alarm parameters and alerts is overly complex in existing devices	5 (5.7%)	26 (29.5%)	10 (11.4%)	32 (36.4%)	15 (17%)	3 (3.3%)
D10	Based on the above definitions have you experience alarm fatigue in the past 6 months	6 (6.7%)	22 (24.7%)	18 (20.2%)	28 (31.5%)	15 (16.9%)	2 (2.2%)
D11	I feel confident in adjusting monitor alarm parameters in order to reduce nuisance/false alarms	41 (46.6%)	33 (37.5%)	4 (4.5%)	7 (8%)	3 (3.4%)	3 (3.3%)
D12	I feel overwhelmed by the number of alarms on the unit	5 (5.6%)	14 (15.7%)	19 (21.3%)	38 (42.7%)	13 (14.6%)	2 (2.2%)
D13	Clinical alarms are a significant contributor to my stress level	3 (3.4%)	8 (9.1%)	20 (22.7%)	37 (42%)	20 (22.7%)	3 (3.3%)
D14	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	47 (52.8%)	39 (43.8%)	1 (1.1%)	1 (1.1%)	1 (1.1%)	2 (2.2%)
D15	There have been frequent instances where alarms could not be heard and were missed	5 (5.6%)	17 (18.9%)	11 (12.2%)	36 (40%)	21 (23.3%)	1 (1.1%)
D16	The staff is sensitive to alarms and responds quickly	36 (40.9%)	33 (37.5%)	9 (10.2%)	10 (11.4%)	0	3 (3.3%)
D17	The medical equipment used on my unit/floor have distinct outputs (sounds, repetition rates, visual displays, etc.) that allow differentiation of the source of the alarm	33 (37.1%)	48 (53.9%)	6 (6.7%)	1 (1.1%)	1 (1.1%)	2 (2.2%)
D18	When a number of devices with alarms are used with a patient, it can be confusing to determine which device is in alarm	5 (5.6%)	24 (26.7%)	6 (6.7%)	36 (40%)	19 (21.1%)	1 (1.1%)
D19	Environmental background noise has interfered with alarm recognition	3 (3.4%)	20 (22.5%)	10 (11.2%)	40 (44.9%)	16 (18%)	2 (2.2%)
D20	Policies and procedures exist within the facility to regulate alarms and they are followed	30 (34.1%)	37 (42%)	14 (15.9%)	5 (5.7%)	2 (2.3%)	3 (3.3%)
D21	There is a requirement in your institution to document that the alarms are set and are appropriate for each patient.	47 (51.6%)	31 (34.1%)	5 (5.5%)	5 (5.5%)	3 (3.3%)	0

Table 4.6 below shows the ranking of participants' from the most important to the least important statement. There are 9 statements as per Table 4.6 below, related to alarm management. The results indicate the level of importance that the ICU nurses have assigned to these different aspects to alarms in the ICU setting. The 9 statements below indicate issues that could inhibit effective management of clinical alarms (ACCE Healthcare Technology Foundation, 2006).

Table 4.6 Section E priority ranked statements

E		1 Most important	2	3	4	5	6	7	8	9 Least important	No response
1	Difficulty in setting alarms properly	47 (51.6%)	6 (6.6%)	8 (8.8%)	3 (3.3%)	10 (11%)	3 (3.3%)	2 (2.2%)	2 (2.2%)	10 (11%)	0
2	Difficulty in hearing alarms when they occur	42 (46.7%)	7 (7.8%)	4 (4.4%)	8 (8.9%)	6 (6.7%)	3 (3.3%)	4 (4.4%)	5 (5.6%)	11 (12.2%)	1 (1.1%)
3	Difficulty in identifying the source of an alarm	42 (47.2%)	8 (9%)	5 (5.6%)	3 (3.4%)	10 (11.2%)	1 (1.1%)	2 (2.2%)	5 (5.6%)	13 (14.6%)	2 (2.2%)
4	Difficulty in understanding the priority of an alarm	42 (47.2%)	16 (18%)	4 (4.5%)	3 (3.4%)	7 (7.9%)	1 (1.1%)	0	4 (4.5%)	12 (13.5%)	2 (2.2%)
5	Frequent false alarms, which lead to reduced attention or response to alarms when they occur	33 (36.7%)	10 (11.1%)	6 (6.7%)	9 (10%)	9 (10%)	5 (5.6%)	2 (2.2%)	6 (6.7%)	10 (11%)	1 (1.1%)
6	Inadequate staff to respond to alarms as they occur	32 (36%)	8 (9%)	8 (9%)	11 (12.4%)	6 (6.7%)	8 (9%)	3 (3.4%)	3 (3.4%)	10 (11.2%)	2 (2.2%)
7	Over reliance on alarms to call attention to patient problems	38 (42.2%)	11 (12.2%)	5 (5.6%)	7 (7.8%)	6 (6.7%)	5 (5.6%)	8 (8.9%)	6 (6.7%)	4 (4.4%)	1 (1.1%)

E		1 Most important	2	3	4	5	6	7	8	9 Least important	No response
8	Noise competition from non-clinical alarms and pages	25 (28.7%)	11 (12.6%)	8 (9.2%)	4 (4.6%)	8 (9.2%)	4 (4.6%)	2 (2.3%)	11 (12.6%)	14 (16.1%)	4 (4.4%)
9	Lack of training on alarm systems	43 (47.8%)	7 (7.8%)	4 (4.4%)	6 (6.7%)	7 (7.8%)	5 (5.6%)	3 (3.3%)	5 (5.6%)	10 (11.1%)	1 (1.1%)

The discussions in relation to the results presented in Table 4.5 and 4.6 will follow. These questions will be displayed according to the Shepherds' Systems Risk Model (ACCE Healthcare Technology Foundation, 2006). The model defines the five components and the subcomponents linked to failure errors, classifications and definitions (ACCE Healthcare Technology Foundation, 2006).

4.3.1. Operator causes

Operator causes has two sub components. These are related to education and training of the user and the distracted attention of the nurses. These will be discussed in relation to the statistics yielded from questionnaires.

4.3.1.1 Operator causes on education and training

Operator causes as per the Shepherds Systems Risk Model (ACCE Healthcare Technology Foundation, 2006) is classified into five major components.

The first that will be discussed below is the operator related component. The following questions related to this in the survey responses as represented in Table 4.5; D1, D9, D11, E1, E3, E4, E7 and E9 from Table 4.6 section E that will be discussed below. Table 4.7 below depicts only these questions from the table for easy reference.

Table 4.7 Operator education and training on devices

No.	Questionnaire Item	Strongly agree	Agree	Neutral	Dis-agree	Strongly disagree	Nil response/ Missing data
D1	The purpose of clinical alarms is to alert staff of an existing or potentially hazardous patient condition	78 (86.7%)	10 (11.1%)	0	0	2 (2.2%)	1 (1.1%)
D9	Properly setting alarm parameters and alerts is overly complex in existing devices	5 (5.7%)	26 (29.5%)	10 (11.4%)	32 (36.4%)	15 (17%)	3 (3.3%)
D11	I feel confident in adjusting monitor alarm parameters in order to reduce nuisance/false alarms	41 (46.6%)	33 (37.5%)	4 (4.5%)	7 (8%)	3 (3.4%)	3 (3.3%)

Question D1 showed that the vast majority of the participants 86.7% strongly agreed and 11.1% agreed on the purpose of the alarm. This indicates that 97.8% of the participants were aware of the purpose of clinical alarms in the ICU environment. The purpose of alarms in medical devices in the clinical setting is to share information to the health care providers that awareness or a response is required from them (ACCE Healthcare Technology Foundation). The biomedical profession does contribute towards the implementation and maintaining through constant upgrades devices that do support the needs of the clinicians combined with cost effective technology to the medical discipline (Welch, 2011).

Question D9 states properly setting alarm parameters and alerts is overly complex in existing devices. The valid percentage responses were as per Table 4.5 and indicate a high score in those that disagreed and strongly disagreed. Just over half of the participants (53.4%) disagreed with this statement indicating that just over half of the participants did not feel that the use of the device with regards to alarms being set was not complicated for them to do. There was however a relatively large percentage 35.2% that did agree with this statement and some that chose to remain neutral which may indicate that this could be a challenge that could be addressed when training nurses with regards to the use of the medical equipment or devices.

As technology has advanced so too this has occurred with medical equipment and devices that have been adapted and become more sophisticated. Devices and upgrades are also devised in relation to a need that has been identified in the clinical setting. This question is aimed at

identifying if the technological advancement is a challenge for ICU nurses because this may impact on their alarm management (Lopes, 2014). It is possible to deduce that ongoing training and updates related to training and equipment is not being done as often as is required to allow these ICU nurses to feel confident and comfortable in the use of the equipment in ensuring patient safety is maintained.

The following pie chart 4.1 further indicates the categories of staff that strongly agreed, agreed and chose a neutral option for questions D9.

Figure 4.1. Categories of nurses strongly agreed to section D no 9 properly setting alarm parameters and alerts is overly complex in existing devices

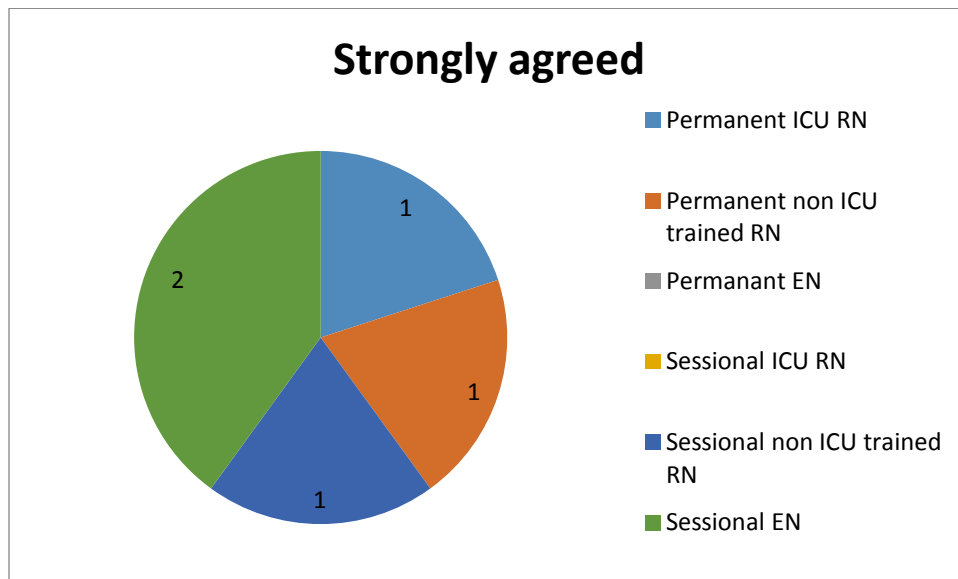


Figure 4.2 Categories of nurses agreed to Section D No 9

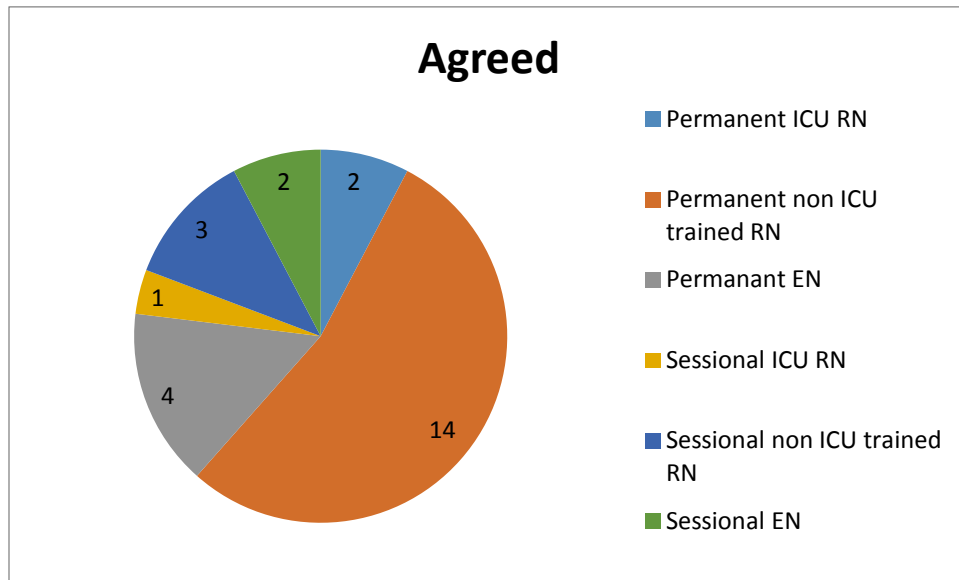
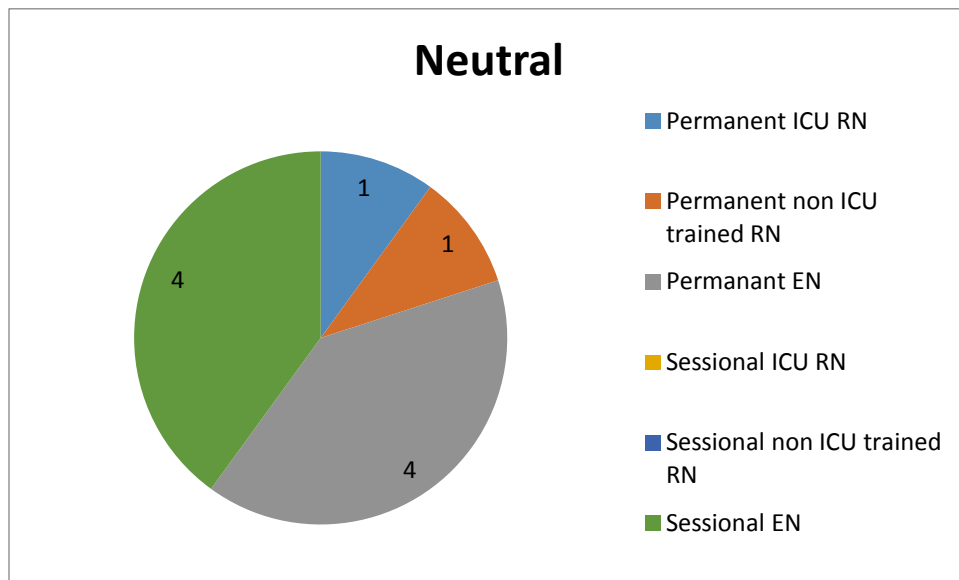


Figure 4.3 Categories of nurses that was neutral to Section D No 9



The percentages of staff in this group of participants that strongly agreed, agreed or chose to be neutral for question D9 were predominantly the permanent ICU trained registered nurses, experienced registered nurses and enrolled nurses.

Participants with between 0 to 3 years experience that agreed was 14 and neutral was 3. From the participants with years of experience between 4 to 6 years, 7 agreed and 1 was neutral. From the

participants with years of experience between 7 to 11 years, 4 strongly agreed, 3 agreed and 3 were neutral and participants with years of experience greater than 12 years, 1 strongly agreed, 2 agreed and 3 were neutral.

It is indicative that the complexity of setting alarms it is not limited to the participants with less years of experience; it is applicable to all nurses irrespective of years of experience. Alarms are useful but improper use of alarm monitoring systems can compromise patient safety. Staff needs to be able to understand alarm limits to determine appropriate alarms according to their patients' baseline data (Graham and Cvach, 2010).

Question D11 states *I feel confident in adjusting monitor alarms parameters in order to reduce nuisance or false alarms*. The valid percentage responses were predominantly positive with the responses being 46.6% strongly agreed and 37.5% that agreed.

In section E the lack of training on alarms systems, 47.8% highlighted this as number 1 most important on a scale from 1 to 9 with 9 being the least important. Please see Table 4.8 below.

Table 4.8 Operator priority ranked statements

E		1 Most NB	2	3	4	5	6	7	8	9 Least NB	No respon se
1	Difficulty in setting alarms properly	47 (51.6%)	6 (6.6%)	8 (8.8%)	3 (3.3%)	10 (11%)	3 (3.3%)	2 (2.2%)	2 (2.2%)	10 (11%)	0
3	Difficulty in identifying the source of an alarm	42 (47.2%)	8 (9%)	5 (5.6%)	3 (3.4%)	10 (11.2%))	1 (1.1%)	2 (2.2%)	5 (5.6%)	13 (14.6%)	2 (2.2%)
4	Difficulty in understanding the priority of an alarm	42 (47.2%)	16 (18%)	4 (4.5%)	3 (3.4%)	7 (7.9%)	1 (1.1%)	0	4 (4.5%)	12 (13.5%)	2 (2.2%)
7	Over reliance on alarms to call attention to patient problems	38 (42.2%)	11 (12.2%)	5 (5.6%)	7 (7.8%)	6 (6.7%)	5 (5.6%)	8 (8.9%)	6 (6.7%)	4 (4.4%)	1 (1.1%)
9	Lack of training on alarm systems	43 (47.8%)	7 (7.8%)	4 (4.4%)	6 (6.7%)	7 (7.8%)	5 (5.6%)	3 (3.3%)	5 (5.6%)	10 (11.1%)	1 (1.1%)

These questions in section E indicate statements that hinder the appropriate and effective management of clinical alarms. The ranking placed by the participants aid in gaining reliable information to the extent that these are considered a challenge to nurses working with medical devices in order to ensure patient safety as their main goal.

Below in Table 4.9. a and b, three open ended questions were available for the staff to comment at the end of the survey that focused on what training they received, did they feel that the training was adequate and what their thoughts were on what is needed to improve clinical alarm recognition and response. The following Tables 4.9.a and 4.9.b indicates the responses accordingly.

Table 4.9.a. Section F1, What training did you receive on alarm monitoring system and its functionality.

<u>No training received</u>	<u>Received orientation</u>	<u>Received additional training after orientation</u>
16.5%	72.5%	11%

Table 4.9.b. Section F2, Do you feel this training was adequate?

<u>Yes</u>	<u>No</u>
75.8%	24.2%

In section F, the feedback of the showed 16.5% received no training on alarm management, 6.6% asked for alarm specific training and 17.6% asked for additional training in general. There was 15.4% of the staff that did receive training on alarm management but the content of the training programmes need to be revised. Unrelated to training 2.2% indicated that they need more staff to work with on the ICU floor and 7.7% said that there needs to be more supervision of ICU nurses

to identify and reinforce the standards and expectations of alarm management. There were 33% of the participants that did not respond to section F of the questionnaire.

Education and training based on the feedback highlights the need for revision of this process in the institution as well as the follow through with regards to updates and continuous staff development.

4.3.1.2 Operator causes on distracted attention

Another subcomponent to operator failures is O3, distracted attention, whereby the operator is knowledgeable with regards to the device and use of the device but there are other factors that play a role in the failure such as long hours, work load, or other problems. In section D, refer to Table 4.5 and 4.6 to the following questions that will be discussed related to distracted attention for the operator. Table 4.10 below highlights only these questions from the survey for easy reference.

Table 4.10 Operator alarm related information on distracted attention

No.	Questionnaire Item	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Nil response /Missing data
D 10	Based on the above definitions have you experience alarm fatigue in the past 6 months	6 (6.7%)	22 (24.7%)	18 (20.2%)	28 (31.5%)	15 (16.9%)	2 (2.2%)
D 12	I feel overwhelmed by the number of alarms on the unit	5 (5.6%)	14 (15.7%)	19 (21.3%)	38 (42.7%)	13 (14.6%)	2 (2.2%)
D 15	There have been frequent instances where alarms could not be heard and were missed	5 (5.6%)	17 (18.9%)	11 (12.2%)	36 (40%)	21 (23.3%)	1 (1.1%)
D 18	When a number of devices with alarms are used with a patient, it can be confusing to determine which device is in alarm	5 (5.6%)	24 (26.7%)	6 (6.7%)	36 (40%)	19 (21.1%)	1 (1.1%)

Question D10; almost half of the participants either disagreed or strongly disagreed that they experienced alarm fatigue in the last 6 months, 31.5% disagreed and 16.9% strongly disagreed indicating a total of 48.4% that did not feel that they had experienced alarm fatigue. There was 20.2% that opted for a neutral as a response and did not commit to either agree or disagree. The questionnaire given to the staff did highlight the definition of alarm fatigue as a point of

reference for the participants to relate to. The definition for alarm fatigue in this research study is when staff become overwhelmed by the sheer number of alarms. This can result in alarm desensitization, which in turn can lead to missed alarms or delayed response (ECRI, 2010).

Question D12 the responses were, 42.7% disagreed and 14.6% strongly disagreed. The larger percentage disagreed or strongly disagreed to this statement and 21.3% that chose a neutral response neither committing to a positive or negative. Question D13 the responses were; 22.7% neutral responses, 42% disagree and 22.7% strongly disagreed. These questions are an indication as to whether or not the staff is experiencing alarm fatigue. The greater percentage overall either disagreed or strongly disagreed with these statements and therefore we can deduce that in this setting and population this is not an area of concern to the ICU registered and enrolled nurses.

According to Pergher and Silva (2013), alarm fatigue is a current topic that is not well researched internationally and with proper staff training and specific alarm training on individual parameters for adjustment these will aid in prevention of alarm fatigue. More discussion on this topic is encouraged as the last barrier is the nursing teams to prevent errors from occurring. King, Fortino, Stevens, Shah, Fortino-Mullen and Lee (2012) mentions that having too many alarms can cause more harm than good and discusses the importance of SMART alarms that are designed to reduce the number of false alarms that can contribute towards reducing the potential problem of alarm fatigue. Alarm fatigue in this study is not a problem at present based on the staff feedback but in relation to the neutral responses where staff was unable to commit to either a positive or negative response means that this is an area that needs more investigation.

Question D15 states there have been frequent instances where alarms could not be heard and were missed, 40% disagreed and 23.3% strongly disagreed to this statement. Question D16 states that the staff are sensitive to alarms and respond quickly of which 40.9% strongly agreed and 37.5% agreed. Baillargeon (2013) discussed that delayed responses to alarm limits is related to being overwhelmed number of alarms that cause desensitization and that the frequency of non-actionable alarms, causes distrust in the alarm systems. The results discussed here states that the staff did not feel overwhelmed and were responsive to the alarming limits.

Question D18 that states when a number of devices with alarms are used with a patient, it can be confusing to determine which device is alarming; the following were the valid percentages 40%

disagreed and 21.1% strongly disagreed. Overall 61% of the responds either disagreed or strongly disagreed with this statement that indicated generally staff were aware of and comfortable with the alarm devices in the unit which supports with the discussion above.

The National Association of Clinical Nurse Specialist (2013), worked on an alarm fatigue toolkit to assist with strategies to safely manage clinical alarms and prevent alarm fatigue. Healthcare workers are exposed to numerous alarming limits on a shift worked and there are many factors that can contribute to a feeling of being overwhelmed. The factors that can distract the health care workers are technology, human factors, staffing and environment. A small percentage of 2.2% in Section F3 did comment that they needed more staff and this was their recommendation with regards to improving clinical alarm recognition. The participants also included sessional nurses which indicate that the units do rely on sessional nurses but is not conclusive in this study to indicate that staffing with sessional nurses is inadequate.

Section E5 – frequent false alarms which lead to reduced attention or response to alarms when they occur had as per Table 4.6 indicated that 36.7% agreed that this was an important factor. Section E6 – inadequate staff to respond to alarms as they occur, 36% ranked it as most important, 9% ranked it as second importance, 9% ranked it as third importance and 12.4% ranked it as fourth importance on a ranking scale. Overall 67% of the responses marked the level of importance under 5 highlighting the amount of importance in this statement to the participants.

4.3.2 Environmental causes

Environmental factors related to the Shepherd Systems Risk Model Failure classification and definitions (ACCE Healthcare Technology Foundation, 2006) have two subcomponents; environmental variables within the hospital and environmental variables external to the hospital. The internal environment had the following that were included in the questionnaire; environmental noise levels, policies and procedures within the facility to regulate alarms and the institutions requirements with regards to documentation about alarms being set and appropriate.

4.3.2.1 Environmental variables in ICU

Question D19: environmental background noise has interfered with alarm recognition yielded results as depicted on Tables 4.5. Table 4.11 below depicts only those questions related to environmental variables within the hospital.

Table 4.11 Environmental variables within the hospital

No.	Questionnaire Item	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Nil response /Missing data
D 14	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	47 (52.8%)	39 (43.8%)	1 (1.1. %)	1 (1.1%)	1 (1.1%)	2 (2.2%)
D 19	Environmental background noise has interfered with alarm recognition	3 (3.4%)	20 (22.5%)	10 (11.2%)	40 (44.9%)	16 (18%)	2 (2.2%)
D 20	Policies and procedures exist within the facility to regulate alarms and they are followed	30 (34.1%)	37 (42%)	14 (15.9%)	5 (5.7%)	2 (2.3%)	3 (3.3%)
D 21	There is a requirement in your institution to document that the alarms are set and are appropriate for each patient.	47 (51.6%)	31 (34.1%)	5 (5.5%)	5 (5.5%)	3 (3.3%)	0

Based on the feedback of these three questions it is conclusive that internal environmental factors are not an issue within these ICU's. Question D19 that stated environmental background noise has interfered with alarm recognition, 44.9% disagreed and 18% strongly disagreed with the statement. Policies and procedures indicate a high overall valid percentage with regards to there being institutional formal processes in place to regulate alarms in the facility. For question D20, 34.1% strongly agreed and 42% agreed that this was available. Requirements of the institution to document alarms set and these are appropriate for each patient shows 51.6% strongly agreed and 34.1% agreed that there are requirements set for the facility and or the ICU's.

The National Association of Clinical Nurse Specialist (2013), suggested with the environmental factors to develop an alarm management policy or to address it in existing policies. An additional suggestion was to implement tools for improvement. These are in place as noted in the results above for the institution and staff was aware of the existence of policies. These policies may

need to be reinforced to address staff that are not confident with alarm management. Bell and Cox (2010), indicate that the development of a hospital or unit policy on appropriate parameters is implemented specifically to patients' clinical presentation and needs. An additional approach is to look at commencing a programme that looks at alarm testing on each shift change that incorporates volumes and parameters per patients, with this routine in place all problems identified such as inappropriate alarm settings can also be addressed and resolved (Wyckoff, 2009).

4.3.3. Human factor designs

Human factors design is related to improving human performance with regards to the use of equipment (Sawyer, 1996). This is linked to the hardware and software design of the devices ensuring that it is compatible with the user population. Question D2, D3, D4 and D17 are related to this component of the Shepherds systems risk model (2004) and the results are as represented in Table 4.5 and Table 4.6.

Medical device alarms have many aims such as detecting life threatening events, detection on imminent danger which is early warnings, diagnostic alarms, detection of any device malfunctions such as disconnection from patient and occlusions in IV lines or ventilator circuits (Schmid, Goepfert and Reuter, 2013).

The National Association of Clinical Nurse Specialist (2013) does suggest that there are evidence based practice recommendations in relation to technology and the use of SMART alarms. Smart alarm configuration as per manufacturers should be based on clinical evidence instead of accepting the default configurations; there is a lack of research in this aspect (Sendelbach and Funk, 2013).

It is a challenge for the healthcare industry to develop smart technology that is required to support patient care and safety. The risk to patient safety in relation to human factors is that insufficient or weakness in the interaction of the variables associated with design of the device with effective human use can lead to a harmful patient event (Erickson, Ditomassi, Gallivan, Pierberg and Costa, 2013).

Table 4.12 indicates only these questions from the survey related to human factors design for easy reference.

Table 4.12 Human Factors Design

No.	Questionnaire Item	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Nil response /Missing data
D2	Alarm sounds and/or visual displays should differentiate the priority of alarm	69 (76.7%)	17 (18.9%)	3 (3.3%)	0	1 (1.1%)	1 (1.1%)
D3	Alarm sounds and/or visual displays should be distinct based on the parameter or source (e.g. Device)	56 (62.9%)	26 (29.2%)	4 (4.5%)	2 (2.2%)	1 (1.1%)	2 (2.2%)
D4	Alarms should impact multiple senses (audible, visual, proprioceptive, etc.)	54 (61.4%)	28 (31.8%)	4 (4.5%)	0	2 (2.3%)	3 (3.3%)
D17	The medical equipment used on my unit/floor have distinct outputs (sounds, repetition rates, visual displays, etc.) that allow differentiation of the source of the alarm	33 (37.1%)	48 (53.9%)	6 (6.7%)	1 (1.1%)	1 (1.1%)	2 (2.2%)

Question D2 yielded a very high positive orientation towards alarm sounds or visual displays needing be able to differentiate the priority of alarms. Refer to Table 4.5 where 76.7% strongly agreed, 18.9% agreed, overall positive response was 95.6%. Strongly agreed percentage was 62.9% and agreed was 29.2%, with an overall positive response was 92.1%. Similarly question D4, stating that alarms should impact multiple senses i.e. audible, visual and proprioceptive there was 61.4% that strongly agreed, 31.8% that agreed, with an overall positive response of 93.2%.

Question D17 that states that the medical equipment on my unit or floor have distinct outputs of either sound, repetition rates and visual displays that allow a differentiation of the source of alarm indicated that 37.1% strongly agreed, 53.9% agreed, with an overall positive response of 91% response rate. This indicates that the human factor designs are an important aspect for ICU nurses in this facility to be able to differentiate the different types of alarms for device or parameters for the patients. In this study the results are indicative that the human factor design component is met in this hospitals ICU departments.

According to Schmid, Goepfert and Reuter (2013), alarm designs are typically displayed in two ways or as a combination of the both i.e. acoustic and visuals. With regards to acoustic the following has yet to be introduced into practice where the alarm systems directly mention organ systems, device hardware or directly indicating physiological problems. With regards to visual alarm devices that are able to integrate and show the relationship of different parameters for example in a spider web fashion are not available. In the healthcare sector this technological advancement has been considered to be slow.

Supporting literature is as per Fineman (2004) also discussed design implications for alarms and with regards to display an improvement with the following aspects would be beneficial; integration of patients vital signs data with trends analysis and alarm limits that is able integrate the information about their condition, the device and the patient’s body. Sendelbach and Funk (2013) support that in the development phase of alarm systems for devices the engineers should shadow nurses or the users of the devices in the clinical setting to understand how it works. This as well as usability testing is very rarely done.

4.3.5. Passive patient causes

A nuisance alarms is the high incidence of clinically non-actionable alarms (Welch, 2011). A valid alarm would be related to an actual problem that requires immediate action by the ICU nurse and this would be an actionable alarm. In the event of a non-actionable alarm, this would be considered either a false or nuisance alarm. The non-actionable alarms would trigger an alarm based on the patient movement or activity not related to an actual physiological or clinical need.

Table 4.13 Passive patient causes

No.	Questionnaire Item	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Nil response/Missing data
D5	Nuisance alarms occur frequently	10 (11.6%)	38 (44.2%)	17 (19.8%)	13 (15.1%)	8 (9.3%)	5 (5.5%)
D6	Nuisance alarms disrupt patient care	12 (13.3%)	42 (46.7%)	15 (16.7%)	10 (11.1%)	11 (12.2%)	1 (1.1%)
D7	Nuisance alarms reduce trust in alarms and cause care givers to turn alarms off at times other than setup or procedural events	18 (20%)	32 (35.6%)	15 (16.7%)	16 (17.8%)	9 (10%)	1 (1.1%)

No.	Questionnaire Item	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Nil response/Missing data
D8	Nuisance alarms contribute to lack of responses by many nurses	15 (16.5%)	48 (52.7%)	9 (9.9%)	12 (13.2%)	7 (7.7%)	0

Referring to Table 4.13 based on the responses D5 states nuisance alarms disrupt patient care, 13.3% strongly agreed and 46.7% agreed, with an overall positive response of 60% versus a total of 23.3% that did not agree. Question D6 that stated nuisance alarms occur frequently, 11.6% strongly agreed and 44.2% agreed with this statement, with an overall positive response of 55.8% versus a total of 24.4% that did not agree.

Fineman (2004), shared an insight in his cause for alarm poster on patient monitoring and medical device alarms in the intensive care unit, that nurses should not be spending their time relying on alarms but should rather be worrying about their patients as alarms do assist but are poor indications of a patient's health. Decisions need to be based on their clinical methods of assessing and examining the patients.

Question D7 states that nuisance alarms reduce the trust in alarms and can cause the caregivers to turn alarms off at times other than the setup or procedural events. Twenty percent strongly agreed with this statement and 35.6% agreed, with an overall positive response of 55.6% versus a total of 27.8% that either disagreed or strongly disagreed. Question D8 states nuisance alarms contribute to lack of response by many nurses yielded a 16.5% that strongly agreed, 52.7% that agreed with an overall positive response of 69.2% versus a total of 20.9% that neither agreed nor disagreed with the statement.

Schmid, Goepert and Reuter (2013), discusses the story of the shepherd that cried wolf where villagers heard the alarm and came running only to find there was no real reason for concern and when the alarm was sounded and it was a genuine reason for alarm, no response was received. This fable is used to annotate the effect of false or nuisance alarms on nursing staff.

Sendelbach and Funk (2013) discussed future work for the reduction of these non-actionable alarms with regards to the management of default settings being changed for a particular population. Trials already done have not been done so rigorously to determine the impact on

patient safety outcomes. There has been some progress done as discussed by Cvach (2012) that there is some research that demonstrates alarms that often self correct with a minimal delay that can potentially reduce the number of ignored and ineffective alarms.

Bell and Cox (2010) suggestions are to assess the incident rates of nuisance or false positive alarms in a set unit, ensuring there is ongoing training in line with a hospital and department policy that should also consider incorporating a specific alarm response time.

CHAPTER FIVE: SUMMARY, LIMITATIONS, RECOMMENDATIONS AND CONCLUSION

5.1. Summary of results

ICU nurses in this study were aware of the purpose of alarms in their clinical environment. Despite this awareness the results indicate ICU nurses do find that nuisance alarms occur frequently and are disruptive to patient care, resulting in the nurses turning off alarms when there is no procedural event planned and this can contribute to an adverse event or near miss. Graham and Cvach (2010), do indicate that even though alarms are needed and can contribute towards saving a life they are also capable of contributing to compromised patient safety due to nuisance alarms that are false positive alarms.

Bell and Cox (2010) also confirm that due to the many potential alarms that one can be exposed to from the various medical equipment; the risk of desensitization to the alarming limits is high and can cause a patient safety concern. Wyckoff (2009) identifies that due to a lack of understanding on the workings of alarm systems, it can lead to adverse events that could eventually cause a patient death.

According to the ACCE Healthcare Technology Foundation (2006) for a clinical alarm to be effective it needs to be activated by a problem that would adversely affect the patient, the nurses or other healthcare workers must then identify the source and the meaning of the alarm and correct the identified problem to prevent a patient event. This simple concept has still not however resulted in clinical alarm systems that meet the user friendliness and ability towards ensuring patient safety (ACCE Healthcare Technology Foundation, 2006). Lopes (2014) study on alarm fatigue discussed 73 patient alarm related deaths linked to medical devices in 2010 as per the Food and Drug Manufacturer and user facility device experience database. These were related to a combination of factors that included a failure to respond to alarms due to alarm fatigue, incorrect parameter adjustments, the switching off of alarms for detecting selected lethal arrhythmias. All of this was thus related to nuisance alarms.

The Shepherds System Risk Model (Shepherd, 2004) does discuss the components that impact on the user, in this study the ICU nurses, that impact on their ability to respond to alarming

limits. Nuisance alarms, are non-actionable alarms and the occurrence of these is related to the design of the devices, the human factor designs that are related to the sensitivity of the alarm system to detect any changes, in this instance the detection of passive related actions by the patient that do not require an immediate intervention or investigation by the ICU nurse (ACCE Healthcare Technology Foundation, 2006). Nurses often manage false alarms in their ICU environment such as an example of a patient that is coughing, causes a false alarm of a tachycardia related to the patient movement. This alarm does not warrant any clinical intervention but increased frequency of false alarms does predispose the nursing staff to alarm fatigue (Pergher and Da Silva, 2013).

Technology based solutions are not a guarantee; it depends on the new technology with regards to alarm systems and their ability to organize the patient data into trends that can assist with the reduction of false alarms. However as with all technology, these devices still need to be monitored by the personnel that are using the devices, which also means that they are required to have been educated on the systems as well (Wyckoff, 2009).

A greater percentage of ICU nurses that responded in the current study did indicate that they understood the purpose of alarms and also indicated that they were aware of the existing policies and procedures set out by the company with regards to alarm management. Thus in this study they do have an understanding of their role and expectations with alarm management but due to the nuisance alarm frequency there is an acknowledged delay in the response to these alarming limits. As indicated in the literature these non-actionable alarms are more often experienced than actionable alarms, the non-actionable alarms contribute to stress for the nursing staff that are expected to utilize most of their time to attend to them. This can potentially have negative clinical consequences for patient safety and care (Phillips Healthcare, 2013).

With regards to their attitudes towards alarms, staff do value the importance of alarms and have indicated so by their ranking of what they deem to be important in alarm management. This is positive to note. Training and education related to alarm management was also acknowledged as a matter of importance but 35.2% of the participants either agreed or strongly agreed that properly setting alarm parameters and alerts is overly complex in existing devices. Of the staff, 11.4% chose a neutral response indicating that there is a substantial amount of staff that do find the practical management of the alarms on medical devices a challenge. In addition based on

some of the written feedback requests for training or additional training and supervision have identified that there is a gap with regards to the education and training of alarm management. The findings of the research indicated that the areas of concern were related to nil or minimal training on the alarm systems of devices in the ICU environment. Wyckoff (2009) had a suggestion with regards to implementing better alarm usage and this includes training sessions that are inclusive of simulation training.

The staff working in the ICU's did have a clear understanding of the purpose and importance of the alarms in an ICU environment but staff irrespective of category and years of experience did require more frequent training and additional supervision with regards to dealing with device alarms. This could be related to changes in technology with new equipment and devices being introduced into the ICU's that would require additional training on the handling of the devices as staff is aware of the relevance of alarms in the ICU. This is evident as a large percentage of the participants did receive orientation yet there was still an indication that they needed additional training and or guidance in the form of supervision to ensure that they are in fact meeting the requirements with regards to managing alarm limits in an ICU. This is applicable to the subcomponent related to education and training (ACCE Healthcare Technology Foundation, 2006).

Alarm fatigue is not a current concern based on the general population feedback from this study undertaken by the researcher, yet there is a small group of participants that did indicate this as an area of concern. An ICU environment requires that the staff working with an ICU patient be efficient and alert when managing their patients, no room for error is allowed. The staff that have indicated this as a concern makes the researcher uneasy as this can impact negatively on patient care in an area that requires fanatical attention to detail. An additional focus on alarm limits can improve staffs perceptions of alarms and how they manage the multiple devices and alarms in their ICU environment as there are existing protocols in place for the ICU's and the institution with regards to alarm management.

The findings also indicated a high percentage of staff acknowledging that it is important that alarms are distinct based on the parameters and devices. A need for more staff training on the devices and alarm management for awareness with regards to alarm management. Devices that have the same or similar sounding alerts could potentially be a source of alarm fatigue for staff.

This was confirmed with the participants' responses on nuisance alarms that confirmed it does negatively impact on direct patient care.

Human factors are linked to the design of the equipment with regards to alarm design. Medical equipment in an ICU environment is not limited to one device; the ICU units use multiple devices. Without clear or distinct audio or visual alerts or alarms it would be difficult for the ICU nurse to easily differentiate between alarms for either devices and or parameters. With multiple devices in an ICU environment the potential to miss important actionable alarms whilst being exposed to numerous false alarms can negatively impact on patient care. The findings of the study, from the responses of the participants do confirm that it is deemed important that alarms are distinguishable from each other and for priority response. This confirms the relevance of human factor designs in alarm management.

Patient factors that contribute to delayed or poor responses by ICU nurses are related to non-actionable alarms, sensitive to patient movement or actions that are not linked to their clinical presentation or physiological well being, also known as false alarms. False alarms due their frequency and minimal importance cause ICU staff to either switch off or turn down the volume of the alarms so as not to be disturbed unnecessarily. This action is potentially dangerous as ICU nurses may miss out on an important or relevant alarm, thinking it is a false alarm, thus causing a delay in reaction.

There are no external environmental factors in the ICU environment in this study that impacted on the responses to alarming limits. There are no internal environmental factors that are considered as a hindrance in the management of alarm limits in this setting in the ICU environment. This study showed that background noise was not identified as an area of concern with regards to alarm management in the greater response of the participants. There was a percentage of staff that did indicate this interfered with alarm recognition but the majority disagreed. Other internal factors in this setting was not a challenge as the facility used in the study did have internal regulatory protocols in place with regards to alarm management which ICU staff are aware of.

5.2. Recommendations

The following are recommendations that have arisen from the study conducted. They are with regards to nursing education, research and administration and practice.

5.2.1. Nursing education

With technological advancement in the healthcare sector and challenges with availability of nursing staff especially with a scarce skill such as critical care, nursing education and training with regards to devices and alarm management is insufficient for ICU nurses of all categories, to feel confident and comfortable managing their devices for alarm management. Programmes in hospital facilities for workshops and in-service training sessions on alarm management and practical alarm training sessions must be reviewed.

The following aspects would be recommended when reviewing the training programme; the type of training presented to staff with regards to content must be reviewed i.e. this must include visual aids and practical sessions to allow staff to gain confidence away from the patient's bedside. In addition representatives for companies that sell medical equipment need to also increase their frequency and involvement with education around the devices. Representatives primarily seek companies to use their devices after which time the training and awareness about the devices is less of a priority.

The amount of time dedicated to training must be reviewed to include practical training sessions and questions and answers. The study showed that participants did receive orientation but this despite the suggestions that were put forward, to increase training and awareness, to update staff and also the suggestion to have alarm specific training. This indicates that the current training does exist but it does not fulfill the needs of the ICU staff with regards to their role in alarm management.

5.2.2. Research

There is not a lot of research in the South African context on alarm management. In first world countries alarm management is considered as one of the top ten health technology hazards. Mismanagement of alarms has the potential to impact negatively on patient outcomes in the ICU

environment. Based on the findings of this research study a recommendation would be to research if there is any evidence of alarm management in ICU's and is it reliable and representative of how alarms are managed. This would be evident in documentation. What is the comparison with the documentation on checks for alarm limits being set and alarm limits actually being set and compliant on the devices as per patient needs? This would assist with greater understanding with regards to staff knowledge versus practical competency and attitude towards alarm limits. In addition a comparison of different facilities in different settings comparing provincial and private sector can assist in adding a greater body of knowledge with regards to the South African context of alarm management in ICU's.

A recommendation for future research using the same instrument and data collection process would be to use the likert scale but omit the option of a neutral response to ensure quality of the data collected. A qualitative research approach can also be beneficial exploring more in-depth the perceptions of ICU nurses desensitization due to alarming limits and alarm management in an ICU setting.

5.2.3. Administration and practice

Policies that are existent in the facility on cardiac monitoring in ICU's and ventilation need to be reinforced, communication to staff needs to be ensured and an evaluation of staffs knowledge needs to be done thereafter to ensure that they know what these policies are. The policies can also be reviewed with regards to acceptable limits to be set from baseline patient parameters to be able to ensure that there is standardization in practice to ensure there are appropriate threshold limits set.

5.3. Limitations

Limitations of this research study was that it was only limited to one facility in a private hospital in South Africa. A comparison with a public hospital facility would be beneficial in highlighting differences as well as a better understanding of the South African healthcare sector.

The pilot study was limited to qualified registered nurses working in ICU's that were current post basic students completing their Critical Care Diploma. Additional experts could have been involved in the pilot study and to advise with regards to the validity of the tool in this South

African setting. Other options of expertise could have been sought from the ICU facilitators and lecturers from the training institution of the hospital and clinical engineers to strengthen the validity and reliability of the data collection tool.

The instrument used the likert scale which was suitable to the data being collected but the inclusion of the neutral response has the potential to affect the quality of the data collected.

For data collection, the questionnaire section E that required the participants to rank nine statements in order of importance, instruction should have read, please rank each of the questions from most important to least important. The format of the table could have been changed to make for easier understanding and ranking per question in relation to each other. The current format and directive was not clear and could be open to interpretation which would have negatively impacted on the data collected being valid. Section E was a limitation in the data collection tool and the reliability of the data from these questions is not valuable towards the findings for the study.

The data could have been analysed further to offer more valid discussions aside from only studying the frequencies in the responses, this was a limitation in the analysis and reporting of the data collected.

5.4. Conclusion

Alarm management in ICU is an important task in the management of patient care to ensure patient safety. It is an area that is not well explored and does require additional awareness. Awareness of the concepts of alarm management and what factors contribute to poor management of alarms would be beneficial. In the healthcare industry it is important that we provide appropriate working conditions and resources for healthcare staff to be able to carry out their responsibilities and duties of delivering quality patient care. Alarms on medical devices do not replace the nurses ability to manage her patient but is an aid in identifying potential changes in patient condition as a means of early warning. The misuse of these medical device alarm aids can be detrimental to patient care and hence continuous training and evaluation of alarms in ICU is a necessity.

REFERENCES

ACCE Healthcare Technology Foundation. (2006). Impact of clinical alarms on patient safety. American College of Clinical Engineering Healthcare Technology Foundation. United States of America. Butler Pike.

Baillargeon, E. (2013). Alarm Fatigue: A risk assessment. [Online] *Master of Science in Nursing*. Paper 23. Available from: http://digitalcommoms.ric.edu/school_of_nursing/23 [Accessed: 24th March 2015].

Bell, L. and Cox, B. (2010). Monitor Alarm Fatigue. *American Journal of Critical Care*, 19(1), 38.

Bridi, A.C., Silva, R.C.L. and Monteiro, J.L.S. (2013). Fatigue alarms in intensive care: describing the phenomena through integrative literature review. *Journal of Research: Fundamental Care On Line*. 2013 July./set 5(3): 27-41. Available from: <http://www.seer.unirio.br/index.php/cuidadofundamental/article/view/2308>. [Accessed: 12 March 2015].

Bryan, R.J, Hopkins, C.C and Holden. (2012). Did you hear an alarm? FIRST: Special Article. Quality and patient safety division, Board of registration in medicine. QPSD Newsletter.

Carroll, P. (2010). Alarm fatigue: Impact on Nursing Care. Atrium Medical Corporation. Atrium Clinical Update. Hudson, New Hampshire.

Chambrin, M.C. (2001). Alarms in the intensive care unit: how can the number of false alarms be reduced. *Critical Care*, 5(4). Biomed central Ltd.

Cvach, M. (2012). Monitor Alarm Fatigue. An integrative view. *Biomedical Instrumentation and Technology*, 46(4), 268 – 277.

Cvach, M. and Funk, M. (2012). Monitor Alarm Fatigue: Lessons Learned. Available from: http://thehtf.org/documents/v2NPSF-Webcast-Clinical_Alarm_Fatigue.pdf. [Accessed: 1 April 2015].

Darbyshire, J.L. and Young, D. (2013). An investigation of sound levels on intensive care units with reference to WHO guidelines. *Critical Care*, 17(5), R187.doi:10.1186/cc12870.

De Beer, J., Brysiewicz, P. and Bhengu, B. (2011). A review of critical care nursing in South Africa. *Southern African Journal of Critical Care*, 27, 6-10.

Dul, J., Bruder, R., Buckle, P., Carayon, P., Falzon, P., Marras, S.W., Wilson, J.R and van der Doelen, B. (2012). A strategy for human factors/ergonomics: developing the discipline and profession. *Journal of Ergonomics*. 2012, 1-27. Available from: http://ergonomie.cnam.fr/12_dull_bruder_buckle_carayon_falzon_marras_wilson_van_der_doel_en_a_strategy.pdf. [Accessed: 16 March 2016]

ECRI Institute. (2014). Top 10 Health Technology Hazards for 2015. ECRI Institute. A report from Health Devices, November 2014. United States of America. Available from www.ecri.org/2015hazards [Accessed: 30th March 2015].

ECRI Institute. (2013). Top 10 Health Technology Hazards for 2014. ECRI Institute. A report from Health Devices, November 2013. United States of America. Available from www.ecri.org/2015hazards [Accessed: 30th March 2015].

Emanuel E.J., Wendler D., Killen, J. and Grady, C. (2004). What makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research. *The Journal of Infectious Diseases*, 189, 930–937.

Erickson, J.I, Ditomassi, M, Gallivan, T, Perieberg, K and Costa.M.J. (2013). A case study: A leaders commitment to transparency and accountability through a serious patient harm event. *Journal of Hospital Administration*, pg 283- 287.

Fineman, B. (2004). Cause for alarm? Available from: www.docubase.com> Cause-for-alarm. [Accessed 12 March 2015].

Friesdorf, W., Buss, B. and Gobel, M. (1999). Monitoring alarms – the key to patient safety in the ICU? *Intensive Care Medical*, 25, 1350-1352.

Funk, M., Clark, T., Bauld, T., Ott, J. and Coss, P. (2014).Attitudes and practices related to clinical alarms. *American Journal of Critical Care*, 23(3), P e9 – e18.

Graham, K.C. and Cvach, M. (2010).Monitor Alarm Fatigue: standardizing use of physiological monitors and decreasing nuisance alarms. *American Journal of Critical Care*, 19(1), 28-35.

Hannibal, G.B. (2011).ECG Challenges - Monitor alarms and alarm fatigue. American Association of Critical Care Nurses, *Advanced Critical Care*, 22(4), 418 – 420.

Heale, R. and Twycross, A. (2015). Validity and reliability in quantitative studies. *Evidence-Based Nursing*, 18(3), 66-67.

Inokuchi, R., Sato, S., Nanjo, Y., Echigo, M., Tanaka, A., Ishii, T., Matsubara, T., Doi, K., Gunshin, M., Hiruma, T., Nakamura, K., Shinohara, K., Kitsuka, Y., Nakajima, S., Umezu, M. and Yahagi, N. (2013). The proportion of clinically relevant alarms decreases as patient clinical severity decreases in intensive care units: a pilot study. *BMJ Open*. Available from: www.bmjopen.bmj.com/content/3/9/e003354.full [Accessed 12 March 2015].

King, A., Fortino, K., Stevens, N., Shah, S., Fortino-Mullen, M. and Lee, I. (2012). Evaluation of a smart alarm for intensive care using clinical data. Pubmed. Available from: <http://LLwww.ncbi.nlm.nih.govLpubmedL23365858> [Accessed 12 March 2015].

Kleinpell, R. (2010). Evidence-Based Review and Discussion Points. *American Journal of Critical Care*, 19(6), 530-531.

Kothari.C.R. (2004). Research Methodology Methods and Techniques. 2nd revised edition. New Delhi: New Age Publishers.

- Lopes, I.S. (2014). Alarm Fatigue: A Technology hazard. [Online] *Master of Science in Nursing*. Paper 53. Available from: http://digitalcommoms.ric.edu/school_of_nursing [Accessed: 24th March 2015].
- Pergher, A.K and Silva, RCL. (2013). Alarms Fatigue: Integrative Review. *Journal of Nursing*, 7(4), 1241-1247.
- Phillips Healthcare. (2014). A timely response to alarm fatigue. Netherlands. Koninklijke Philips N.V.
- Phillips Healthcare. (2013). Just a nuisance. Netherlands. Koninklijke Philips N.V.
- Phillips Healthcare. (2013). Taking alarm management from concept to reality: a step by step guide. Netherlands. Koninklijke Philips N.V.
- Polit, D.F. and Hungler, B.P. 2013. *Essentials of Nursing Research: Methods, Appraisal, and Utilization* (8th Edition ed.). Philadelphia: Wolters Kluwer/Lippincott Williams and Wilkins
- Sawyer, D. (1996). *An Introduction to Human Factors in Medical Devices*. Office of Health and Industry Programmes. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Centre for Devices and Radiological Health.
- Schmid, Goepert and Reuter (2013). Patient monitoring alarms in the ICU and in the operating room. *Critical Care*, 17:216.
- Schwartz, A. (2013). Battling Alarm Fatigue. Acute and transitional care. UCSF Science of Caring. Available from: <http://scienceofcaring.ucsf.edu/acute-and-transitional-care/battling-alarm-fatigue> [Accessed: July 2015]
- Sendelbach, S and Funk, M. (2013). Alarm fatigue – a patient safety concern. *AACN American Association of Critical Care Nurses, Advanced Critical Care*, 24(4), 378 – 386.
- Shaver, E.F and Braun, C.C. (2008). What is human factors and ergonomics? Benchmark Research and Safety, Inc. Available from: <http://www.benchmarkrs.com/uploads/What-is-Human-Factors-and-Ergonomics.pdf> [Accessed: 16 March 2016]
- Shepherd, M. (2004). *Systems Approach to Medical Device Safety*. Clinical Engineering Handbook, Burlington, MA, Elsevier Science and Technology Books.
- Siebig, S., Kuhls, S., Imhoff, M., Langgartner, J., Reng, M., Scholmerich, J., Gather, U. and Wrede, C.E. (2010). Intensive care unit alarms – how many do we need? *Critical Care Medicine*, 38(2), 451 – 456.
- Silva, R.C.L., Fittipaldi, A. and Louro, T.Q. (2012). Alarms in intensive care units and its implications for the patient comfort. *Journal of Nursing UPFE on line*, 6(7), 2800-2807.
- Singh.Y.K. (2006). *Fundamentals of research methodology and statistics*. New Delhi: New Age Publishers.

The Joint Commission. (2013). 2014 National Patient Safety Goals/Joint Commission. *The Joint Commission Hospital*. Available from: <http://www.visimobile.com/wp-content/uploads/2014/05/2014-National-Patient-Safety-Goals.pdf> [Accessed: 30 March 2015]

The National Association of Clinical Nurse. (2014). Alarm Fatigue Toolkit: Alarm Fatigue Strategies to safely manage clinical alarms and prevent alarm fatigue. NACNS Alarm Fatigue Task Force. Welch, J. (2011). An evidence based approach to reduce nuisance alarms and alarm fatigue. Available from http://www.visimobile.com/wp-content/uploads/2013/02/Horizons_Alarms-Article_Welch_Spring-2011.pdf [Accessed: 24th March 2015].

Wyckoff, M. (2009). Improving how we use and respond to clinical alarms. *American Nurse Today*, 4(9), 37 – 39.

Annexure 1 – Covering Letter, Declaration of Consent

DECLARATION OF CONSENT

PROJECT TITLE: Alarms in ICU: A study investigating how ICU nurses respond to alarm limits for patient safety

RESEARCHER

Full Name: Amy Ramlaul
School: School of Nursing and Public Health
Campus: University of KwaZulu-Natal
Proposed Qualification: Masters in Critical Care & Trauma
Contact: 076 1623 158
Email: aramlaul@gmail.com

SUPERVISOR

Full Name of Supervisor: Petra Brysiewicz
School: School of Nursing and Public Health
Campus: University of KwaZulu-Natal
Contact details: 083 785 5069
Email: Brysiewicz@ukzn.ac.za

HSSREC Research Office (Humanities and Social Science Research Ethics Committee – UKZN): 031 260 4557

I, Amy Ramlaul, Student no 200270713, am a Masters student, at the School of Nursing and Public Health, at the University of KwaZulu-Natal.

You are invited to participate in a research project titled: Alarms in ICU: A study investigating how ICU nurses respond to alarm limits for patient safety. The aim of the study is to determine ICU nurses responses to alarm limits in an ICU environment.

As you are working in an ICU environment, I am inviting you to participate in this research by completing the attached survey. Through your participation; I hope to understand your opinions and suggestions to improving alarm management in an ICU environment.

I guarantee that your responses will not be linked with you personally. Your participation is voluntary and there is no penalty if you do not participate in the study. Please sign on the dotted line to show that you have read and understood the contents of this letter.

You have been provided with 2 open envelopes. Once you have signed the declaration of consent form you can detach this from your questionnaire and place it in 1 of the envelopes provided and seal it and mark as confidential. In the other envelope please place your completed questionnaire in and seal it and mark as confidential.

The questionnaire will take approximate 10 minutes to complete. Thereafter on completion of this you can place it in the other envelope provided and seal it and mark as confidential. This will ensure that anonymity is maintained as we cannot link you to the questionnaire completed. You may return both sealed envelopes to your Unit Manager. The sealed envelopes will thereafter be collected by the researcher.

Thank you

DECLARATION FOR CONSENT

I.....(Full Name) hereby confirm that I have read and understand the contents of this letter and the nature of the research project: **Alarms in ICU, a study investigating how ICU nurses respond to alarm limits for patient safety,** has been clearly explained prior to participating in this research project.

I understand that I am at liberty to withdraw from the project at any time, should I so desire.

Participants Signature.....

Date.....

Annexure 2 - Alarm Survey – ICU Nurses 2015

Please insert only one response for each question

A) ICU Name: (Tick the relevant)

ICU 1 MICU	
ICU 2 SICU	
ICU 3 CICU	
ICU 4 NICU	

B) Job Title: (Tick the relevant)

Permanent Registered Nurse ICU trained	
Permanent Registered Nurse Non-ICU trained	
Permanent Enrolled Nurse	
Unit Manager	

Sessional Registered Nurse ICU trained	
Sessional Registered Nurse Non-ICU trained	
Sessional Enrolled Nurse	
Other	
Specify other:	

C) Years of experience: (Tick the relevant)

0 – 3 years	
4 – 6 years	
7 – 11 years	
12 years +	

The following terms and definitions below are used in the content of the survey you are about to complete. Below definitions will assist in your understanding of the terms referred to in the survey

Definitions:

Alarm Fatigue: When staff become overwhelmed by the sheer number of alarms. This can result in alarm desensitization, which in turn can lead to missed alarms or delayed alarm response (ECRI, 2010).

Nuisance Alarms: Is the high incidence of clinically non-actionable alarms. A non-actionable alarm is a triggered but does not require medical intervention as it is clinically irrelevant (Welch, 2011).

False Alarms: are clinical alarms produced by artifact creating false data (Welch, 2011).

D) Alarm Related information:

	Alarm Related information	Strongly agree	Agree	Neutral	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	Nuisance alarms contribute to lack of responses by many nurses					
9	Properly setting alarm parameters and alerts is overly complex in existing devices					
10	Based on the above definitions have you experienced alarm fatigue in the past 6 months?					
11	I feel confident in adjusting monitor alarm parameters in order to reduce nuisance/false alarms					
12	I feel overwhelmed by the number of alarms on the unit					
13	Clinical alarms are a significant contributor to my stress level					
14	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					
15	There have been frequent instances where alarms could not be heard and were missed					
16	The staff is sensitive to alarms and responds quickly					
17	The medical equipment used on my unit/floor have distinct outputs (sounds, repetition rates, visual displays, etc.) that allow differentiation of the source of the alarm					
18	When a number of devices with alarms are used with a patient, it can be confusing to determine which device is in alarm					

19	Environmental background noise has interfered with alarm recognition								
20	Policies and procedures exist within the facility to regulate alarms and they are followed								
21	There is a requirement in your institution to document that the alarms are set and are appropriate for each patient.								

E) Please rank the following issues below concerning alarms; 1 = most important, 9 = least important. Read all issues first, and 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									

F) Please comment on the following:

1. What training did you receive on the alarm monitoring system and its functionality?

2. Do you feel this training was adequate? If no, what type of training would you recommend?

3. Please comment on what is needed to improve clinical alarm recognition and response?

THANK YOU!

Annexure 3 – Proof of permission Granted from Rhodes Island College and the Healthcare Technology Foundation

Amy Maharaj

From: Amy Ramlaul [aramlaul@gmail.com]
Sent: 04 June 2015 03:03 PM
To: Amy Maharaj
Subject: Fwd: Re: Research Permission Request

----- Forwarded message -----

From: "Ayton, Kieran" <kayton@ric.edu>
Date: 26 Mar 2015 17:17
Subject: Re: Research Permission Request
To: "Amy Maharaja (Ramlaul)" <aramlaul@gmail.com>
Cc: "Petra Brysiewicz" <Brysiewiczp@ukzn.ac.za>

Great! Let me know if I can do anything else for you!

Kieran Ayton
Emerging Technologies Librarian
Interim Head of Digital Initiatives
Rhode Island College
kayton@ric.edu <mailto:kayton@ric.edu>

Sent from my iPad

On Mar 26, 2015, at 2:46 AM, Amy Maharaja (Ramlaul) <aramlaul@gmail.com> wrote:

Hi Kieran

Thank you so much for your prompt feedback!

I will definitely cite the author and paper.

Your feedback is greatly appreciated.

Thank you

Kind regards
Amy Ramlaul

Sent from my Samsung Galaxy smartphone.

----- Original message -----

From: "Ayton, Kieran" <kayton@ric.edu> <mailto:kayton@ric.edu>
Date: 26/03/2015 01:12 (GMT+02:00)
To: Amy Ramlaul <aramlaul@gmail.com> <mailto:aramlaul@gmail.com>
Cc:
Subject: Re: Research Permission Request

Hi Amy!

Amy Maharaj

Subject: FW: Re: Research Permission

From: Amy Ramlaul (mailto:aramlaul@gmail.com)
Sent: 04 June 2015 01:39 PM
To: Amy Maharaj
Subject: Fwd: Re: Research Permission

----- Forwarded message -----

From: "Petra Brysiewicz" <Brysiewiczp@ukzn.ac.za>
Date: 9 May 2015 22:14
Subject: Re: Research Permission
To: "Clark, Tobey J." <Tobey.Clark@its.uvm.edu>, "Amy Ramlaul" <aramlaul@gmail.com>
Cc:

Thanks Tobey

Professor Petra Brysiewicz
School of Nursing and Public Health
University of KwaZulu-Natal

From: Clark, Tobey J.
Sent: Saturday 9 May 2015 22:10
To: Amy Ramlaul
Cc: Petra Brysiewicz
Subject: RE: Research Permission

Dear Amy:

Thank you for providing the signed document. The HTE alumni survey questions are attached in Word format.

Wishing you the best in your research project. It is nice to know of the work at University of KwaZulu-Natal in South Africa.

Best regards,

Tobey

J. Tobey Clark
President

(502)281-2088

HTE HealthCare Education
UNIVERSITY

www.thehtc.org

From: Amy Ramlaul (mailto:aramlaul@gmail.com)
Sent: Saturday, May 09, 2015 1:09 AM
To: Clark, Tobey J.

Annexure 4: Proof of permission from University of KwaZulu-Natal, Humanities and Social Science ethics committee



31 August 2015

Ms Amy Ramlal 2002270713
School of Nursing and Public Health
Howard College Campus

Dear Ms Ramlal

Protocol reference number: HSS/0714/015M
Project title: Alarms in ICU: A study investigating how ICU nurses responds to alarm limits for patient safety

Full Approval – Expedited Application

In response to your application received on 17 June 2015, the Humanities & Social Sciences Research Ethics Committee has considered the abovementioned application and the protocol have been granted **FULL APPROVAL**.

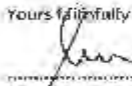
Any alteration/s to the approved research protocol i.e. Questionnaire/Interview Schedule, Informed Consent Form, Title of the Project, Location of the Study, Research Approach and Methods must be reviewed and approved through the amendment/modification prior to its implementation. In case you have further queries, please quote the above reference number.

PLEASE NOTE: Research data should be securely stored in the discipline/department for a period of 5 years.

The ethical clearance certificate is only valid for a period of 3 years from the date of issue. Thereafter Recertification must be applied for on an annual basis.

I take this opportunity of wishing you everything of the best with your study.

Yours faithfully


Dr Shanika Singh (Chair)
Humanities & Social Sciences Research Ethics Committee

/s/

Cc Supervisor: Prof Petra Brysiewicz
Cc Academic Leader Research: Prof M. Mars
Cc School Administrator: Ms Caroline Dhanraj

Humanities & Social Sciences Research Ethics Committee

Dr Shanika Singh (Chair)

Westville Campus, Govan Mbeki Building

Postal Address: Private Bag 254001, Durban 4000

Telephone: +27 (0) 31 260 8687/8860/4557 Facsimile: +27 (0) 31 260 4609 Email: shs@ukzn.ac.za / gsr@ukzn.ac.za / hr@ukzn.ac.za

Website: www.ukzn.ac.za

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Annexure 5: Permission granted from Hospitals Ethics Committee



Netcare Hospitals (Pty) Ltd
Tel: +27 (0)11 301 0000
Fax: Corporate +27 (0)11 301 0409
76 Maude Street, Corner West Street, Sandton, South Africa
Private Bag X34, Benmore, 2010, South Africa
www.netcare.co.za

RESEARCH OPERATIONS COMMITTEE FINAL APPROVAL OF RESEARCH

Approval number: UNIV-2015-0064

Ms Amy Ramlaul

E mail: Amy.Ramlaul@netcare.co.za

Dear Ms Ramlaul

RE: A STUDY INVESTIGATING HOW ICU NURSES RESPOND TO ALARM LIMITS FOR PATIENT SAFETY

The above-mentioned research was reviewed by the Netcare Research Operations Committee's delegated members and it is with pleasure that we inform you that your application to conduct this research at Netcare St Augustine's Hospital, has been approved, subject to the following:

- i) Research may now commence with this FINAL APPROVAL from the Netcare Research Operations Committee.
- ii) All information regarding Netcare will be treated as legally privileged and confidential.
- iii) Netcare's name will not be mentioned without written consent from the Netcare Research Operations Committee.
- iv) All legal requirements with regards to participants' rights and confidentiality will be complied with.
- v) Netcare must be furnished with a STATUS REPORT on the progress of the study at least annually on 30th September irrespective of the date of approval from the Netcare Research Operations Committee as well as a FINAL REPORT with reference to intention to publish and probable journals for publication, on completion of the study.
- vi) A copy of the research report will be provided to the Netcare Research Operations Committee once it is finally approved by the relevant primary party or tertiary institution, or once complete or if discontinued for any reason whatsoever prior to the expected completion date.
- vii) Netcare has the right to implement any recommendations from the research.

Directors: J du Plessis, S Chetty, R H Friedland, K N Gibson

Company Secretary: L. Bagwaledeen

Reg. No. 1296/005601/07

- viii) Netcare reserves the right to withdraw the approval for research at any time during the process, should the research prove to be detrimental to the subjects / Netcare or should the researcher not comply with the conditions of approval.
- ix) APPROVAL IS VALID FOR A PERIOD OF 36 MONTHS FROM DATE OF THIS LETTER OR COMPLETION OR DISCONTINUATION OF THE STUDY, WHICHEVER IS THE FIRST.

We wish you success in your research.

Yours faithfully,

 21/9/2015.

Prof Dion du Plessis

Full member, Netcare Research Operations Committee & Medical Practitioner evaluating research applications as per Management and Governance Policy

Shannon Neil


Chairperson: Netcare Research Operations Committee
Netcare Hospitals (Pty) Ltd

Date:

6/10/2015

Directors: J du Plessis, S Chetty, R H Friedland, K N Gibson

Company Secretary: L Bagwandeem

Reg. No. 1995/006591/07

**RESEARCH OPERATIONS COMMITTEE FINAL APPROVAL OF
RESEARCH**

Approval number: UNIV-2015-0064

Ms Amy Ramlaul

E mail: Amy.Ramlaul@netcare.co.za

Dear Ms Ramlaul

**RE: A STUDY INVESTIGATING HOW ICU NURSES RESPOND TO ALARM LIMITS FOR
PATIENT SAFETY**

The above-mentioned research was reviewed by the Research Operations Committee's delegated members and it is with pleasure that we inform you that your application to conduct this research at Private Hospital, has been approved, subject to the following:

- i) Research may now commence with this FINAL APPROVAL from the Committee.
- ii) All information regarding the Company will be treated as legally privileged and confidential.
- iii) The Company's name will not be mentioned without written consent from the Committee.
- iv) All legal requirements with regards to participants' rights and confidentiality will be complied with.
- v) The Company must be furnished with a STATUS REPORT on the progress of the study at least annually on 30th September irrespective of the date of approval from the Committee as well as a FINAL REPORT with reference to intention to publish and probable journals for publication, on completion of the study.
- vi) A copy of the research report will be provided to the Committee once it is finally approved by the relevant primary party or tertiary institution, or once complete or if discontinued for any reason whatsoever prior to the expected completion date..
- vii) The Company has the right to implement any recommendations from the research.



- viii) The Company reserves the right to withdraw the approval for research at any time during the process, should the research prove to be detrimental to the subjects/ Company or should the researcher not comply with the conditions of approval.
- ix) APPROVAL IS VALID FOR A PERIOD OF 36 MONTHS FROM DATE OF THIS LETTER OR COMPLETION OR DISCONTINUATION OF THE STUDY, WHICHEVER IS THE FIRST.

We wish you success in your research.


Yours faithfully

 21/9/2015.

Prof Doreen Plessis

Full member: Research Operations Committee & Medical Practitioner evaluating research applications as per Management and Governance Policy

Shannon Neil


Chairperson: Research Operations Committee

Date:

6/10/2015

This letter has been anonymised to ensure confidentiality in the research report. The original letter is available with author of research