

**PATIENTS' SAFETY IN INTENSIVE CARE UNITS IN AN
ACADEMIC HOSPITAL IN GAUTENG**

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A research report submitted to the Faculty of Health Sciences, University of the
Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree

of

Master of Science in Nursing

Johannesburg, 2016

DECLARATION

I, Mphofu Agnes Tlholo, declare that this research report is my own work. It is being submitted for the degree of Master of Science (Nursing) in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Signature.....

This 15th December, 2016

Protocol Number **M140876**

DEDICATION

In loving memory of my mother

‘Maboeang Anna Tlholo

1966-2010

Gone too soon Mama!

ACKNOWLEDGEMENTS

- I am grateful to God Almighty for the gift of life and guidance.
- I am also grateful to my husband Maraisane Ntsekhe and both our families for making this study at Wits University possible through financial and emotional support.
- My supervisors Dr Shelley Schmollgruber and Mrs Andrea Hayward are highly acknowledged for all the assistance and guidance from the beginning to the end of this study. If it was not because of their selfless involvement, I do not know if I would have been able to maintain my sanity.
- I also thank the authorities at the hospital for awarding me with the permission to use their institution for this study and their friendly unit managers and nursing staff.
- Gratitude also goes to the developer Dr Binnekade for giving me the permission to use the Critical Nursing Situation Index as my data collection tool.
- The assistance of the Biomedical Statistician, Dr Steve Olorunju, was so valuable in making sense of the data collected and answering research questions.
- My gratitude goes to the patients and their families for giving me consent for their inclusion in the study.
- All my friends and colleagues for encouragement and constant prayers throughout my study, I have learned a lot from them.

ABSTRACT

The purpose of this study was to assess any deviations from protocols and standards of patients' care in different constructs of nursing care and to compare the deviations with the level of nursing expertise in five ICUs of one Academic hospital in Gauteng in order to make recommendations for nursing practice, education and future research.

The study was conducted at one university-affiliated, public sector tertiary hospital in Johannesburg in Gauteng Province. A quantitative, prospective non-experimental design by random application of Critical Nursing Situation Index (CNSI) was used to assess adherence to nursing protocols. This Instrument was developed and validated by Binnekade in 2001 to assess the rate of occurrence of observable nursing errors in Intensive Care Units in the Netherlands. Data was analysed with the use of descriptive and inferential and results were presented as frequencies, graphs, means and standard deviations. Kruskal-Wallis and Cronbach's reliability coefficient were also used to test the reliability of the tool and relationship between various variables respectively. The statistical significance level was 0.05 ($p < 0.05$).

Regarding the 100 patients whose care was assessed, and out of the eight domains of care, basic ICU nursing care was found to be associated with most deviations in relation to recording of patient's length and body weight (100%, $n=100$), risk of pressure sore assessment (77%, $n=77$) and keeping patient's relatives records (55%, $n=55$). Six hourly fluid assessment (100%, $n=100$) and adequate adjustment of alarms for cardiac rhythm (60%, $n=60$) were also among the areas of care with more than half of the deviations. These two fall under fluid administration and care of the cardiac rhythm and circulation respectively. Moreover, there was a statistically significant difference in occurrence of deviations in fluid administration and nurse's qualifications.

Recommendations were made to address these deviations in relation to patient assessment, risk identification and record keeping all to ensure patient's safety.

TABLE OF CONTENTS

	Page
DECLARATION	ii
ACKNOWLEDGEMENTS	iii
ABSTRACT	iv
TABLE OF CONTENTS	v
LIST OF FIGURES	x
LIST OF TABLES	xi
ABBREVIATIONS	xii
CHAPTER ONE: OVERVIEW OF THE RESEARCH STUDY	
1.0 INTRODUCTION	1
1.1 BACKGROUND OF THE STUDY	1
1.2 PROBLEM STATEMENT	3
1.3 PURPOSE OF THE STUDY	4
1.4 OBJECTIVES	4
1.5 SIGNIFICANCE OF THE STUDY	5
1.6 RESEARCHER ASSUMPTIONS	5
1.6.1 Meta theoretical assumptions	5
1.6.2 Theoretical assumptions	8
1.6.3 Methodological assumptions	12
1.7 OVERVIEW OF RESEARCH METHODOLOGY	13
1.8 VALIDITY AND RELIABILITY OF THE STUDY	14
1.9 ETHICAL CONSIDERATIONS	15
1.10 SUMMARY	16
CHAPTER TWO: LITERATURE REVIEW	
2.1 INTRODUCTION	17
2.2 INTENSIVE CARE NURSING SPECIALITY	17
2.3 PROTOCOLS AND GUIDELINES IN INTENSIVE CARE	18
2.3.1 What Causes Deviations from Protocols?	20
2.4 PATIENT SAFETY	21
2.5 AREAS OF NURSING CARE	23

2.5.1	Basic Intensive Care Nursing	22
2.5.2	Mechanical Ventilation and Related Risks	25
2.5.3	Intravascular Access Lines and Administration of Fluids	29
2.5.4	Cardiac Rhythm and Circulation	31
2.5.5	Medication	32
2.5.6	Nutrition	33
2.5.7	Medical Devices	35
2.6	SUMMARY	35

CHAPTER THREE: RESEARCH DESIGN AND METHOD

3.1	INTRODUCTION	37
3.2	OBJECTIVES	37
3.3	RESEARCH DESIGN	37
3.3.1	Research Design	37
3.3.2	Research Setting	38
3.4	RESEARCH METHODS	39
3.4.1	Population and Sample	39
3.4.2	Data Collection	40
3.4.3	Instrument	41
3.4.4	Validity and Reliability of the Instrument	42
3.4.5	Pre-testing	43
3.4.6	Data Collection Procedure	43
3.4.7	Data Analysis	44
3.5	VALIDITY AND RELIABILITY OF STUDY	45
3.6	ETHICAL CONSIDERATIONS	45
3.7	SUMMARY	47

CHAPTER FOUR: RESULTS AND DISCUSSION OF FINDINGS

4.1	INTRODUCTION	48
4.2	APPROACH TO DATA ANALYSIS	48
4.3	RESULTS AND FINDINGS	49
4.3.1	Section One: Demographic Data of Patients	49
4.3.2	Section Two: Critical Nursing Situation Index (CNSI)	52

4.3.2.1	Basic ICU nursing care	53
4.3.2.2	Care of mechanical ventilation	54
4.3.2.3	Care of intravenous lines	56
4.3.2.4	Administration of fluids	57
4.3.2.5	Monitoring of cardiac rhythm and circulation	58
4.3.2.6	Administration of medication	59
4.3.2.7	Care of enteral nutrition	60
4.3.2.8	Hygienic care and control of devices	61
4.3.3	Incidence Rate of Critical Nursing Situations (Protocol Deviations)	62
4.3.4	Comparative Statistics	63
4.3.4.1	Patient gender and age	64
4.3.4.2	Expertise of nursing categories	67
	Nursing categories	66
4.4	DISCUSSION OF MAIN FINDINGS	69
4.5	SUMMARY	77

CHAPTER FIVE: SUMMARY, CONCLUSIONS AND RECOMMENDATIONS AND LIMITATIONS

5.1	INTRODUCTION	79
5.2	SUMMARY OF THE STUDY	79
5.2.1	Purpose of the Study	79
5.2.2	Objectives of the Study	79
5.2.3	Methodology	79
5.3	SUMMARY OF MAIN FINDINGS	80
5.4	LIMITATIONS OF THE STUDY	82
5.5	RECOMMENDATIONS OF THE STUDY	83
5.5.1	Intensive Care Nursing Practice	83
5.5.2	Intensive Care Nursing Education	83
5.5.3	Further Research	83
5.6	CONCLUSION	84
	REFERENCES	85

APPENDIXES

Appendix A	Data collection sheet	94
Appendix B	Ethical clearance certificate	99
Appendix C	Permission to use instrument	100
Appendix D	Unit managers information letter	101
Appendix D1	Nurse's information letter	102
Appendix D2	Patient's information letter	103
Appendix D3	Patient's relative information letter	104
Appendix E	Unit manager's consent form	105
Appendix E1	Nurse's consent form	106
Appendix E2	Patient's consent form	107
Appendix E3	Patient's relative consent form	108
Appendix F	Hospital permission to conduct research	109

LIST OF FIGURES

	Page
Figure 4.1 Nurses years of experience in ICU	51
Figure 4.2 Incidence rate critical care nursing situations	62

LIST OF TABLES

		Page
Table 4.1	Demographic data for patient participants for the total sample (n=100)	50
Table 4.2	Expertise of nurses assigned to care for patient participants (n=100)	51
Table 4.3	Summary of responses for items in the category of basic ICU nursing care	53
Table 4.4	Summary of responses for items in the category of care of mechanical ventilation	54
Table 4.5	Summary of responses for items in the category of care of intravenous lines	56
Table 4.6	Summary of responses for items in the category of administration of fluids	57
Table 4.7	Summary of responses for items in the category of monitoring cardiac rhythm and circulation	58
Table 4.8	Summary of responses for items in the category of administration of medication	59
Table 4.9	Summary of responses for items in the category of enteral nutrition	60
Table 4.10	Summary of responses for items in the category of hygienic care and control of devices	61
Table 4.11	Summary of scores for frequency of critical incidents by domain	63
Table 4.12	Summary Cronbach's reliability coefficient for the domains	64
Table 4.13	Comparison of scores for domains by gender categories	65
Table 4.14	Summary of Kruskal Wallis test for gender by domains	66
Table 4.15	Summary statistics for comparison of gender categories by age	66
Table 4.16	Comparison of scores for domains by nursing categories	67
Table 4.17	Summary of Kruskal Wallis test for the domains by nursing categories	69
Table 4.18	Summary of Kruskal Wallis test for years of experience by nursing categories	70

ABBREVIATIONS

ARDS:	Acute Respiratory Distress Syndrome
AACCN:	Australian Association of Critical Care Nurses
AACN:	American Association of Critical Care Nurses
CDC:	Centre for Disease Control
ECG:	Electrocardiogram
EN:	Enrolled Nurse
ICN:	Intensive Care Nurse
ICU:	Intensive Care Unit
PN:	Professional Nurse
SANC:	South African Nursing Council
SAPS II:	Simplified Acute Physiological Score version II
SD:	Standard Deviation
WHO:	World Health Organisation

CHAPTER ONE

OVERVIEW OF THE STUDY

1.0 INTRODUCTION

This chapter gives the overview of the study. It describes the background of the study, its purpose, the problem statement, research questions which sought to be addressed and objectives guiding the study. The researcher has also described her paradigmatic perspectives and has provided a brief overview of the methodology employed including the design, data collection methods, the population sample and sampling procedures and a data collection tool. The ethical considerations as well as validity and reliability of the study have also been briefly described.

1.1 BACKGROUND OF THE STUDY

Safety is the fundamental right of every patient that seeks healthcare including the critically ill patients. Intensive care nursing in South Africa was officially introduced in 1966 as a nursing training programme or post registration qualification available to registered nurses at diploma level (one year) and degree level (two years) (Schmollgruber, 2007). It is one of the specialities of nursing that is characterised by a very complex setting and that requires high level of professional autonomy and competence. This implies that not every nurse can be employed in an intensive care setting if quality of care in this setting is to be maintained at its highest level.

The South African Nursing Council as the regulatory body of nursing in South Africa has provided the scope of practice that conveys that nurses with an additional and specialized nursing qualification should offer a high quality patient care and evidence based care. It has however been difficult to recruit and retain adequate numbers of intensive care nurses in South African Intensive Care Units (ICUs) because of the challenges such as high attrition rate, poor working conditions, low salaries, increasing workload and other challenges that are facing human resources for health particularly nurses.

It is not only important to have the adequate number of nurses in ICU, but also to have competent, appropriately experienced and skilled nurses in order to ensure the quality of care they offer. However, South Africa is currently facing an acute shortage of registered intensive care nurses. According to Scribante and Bhangwanjee (2007), only 25% of nurses working in ICU are qualified Intensive Care Nurses and 21% of nurses working in ICU are enrolled nurses who assume responsibilities way beyond their abilities and scope of practice. Moreover, only 28.7% of nurses working in ICU had five to ten years of working experience implying limited level of supervision for the novice nurses.

Employment of general nurses and enrolled nurses in ICU is a short-term solution to this shortage and has its consequences. Even more alarming, it is not unusual in South African ICUs to employ agency staff to help cope with the demands of the intensive care nursing workload. This strategy poses numerous challenges most of which compromise patient safety as the agency staff often display lack of commitment and their work is of questionable quality. Moreover, permanently employed nurses sometimes work overtime or double shift through agencies and will surely be exhausted and unproductive when they report on duty (De Beer, Brysiewicz & Bhengu, 2011).

The introduction of readily available registered nurses who can do basic nursing tasks without specific ICU training also results in overall reduction or dilution in performance level resulting in unexpected and undesirable side effects to the patients (Binnekade, Vroom, De Mol & De Haan, 2003; Valentin, Capuzzo, Guidet, Moreno, Dolanski, Bauer & Metnitz, 2006). This is a problem in ICU considering the range of invasive and potentially dangerous interventions that often prevail in this unit. Since nurses are the healthcare professionals doing the majority of patients' care activities and spend most of their duty time at the bedside, they should stick to evidence based practice and the protocols that guide their practice and should always bear in mind the principles of ethics. This implies that the availability of sufficient specialized nurses in ICU is a major factor in ensuring patients' safety and quality of care. Obtaining a qualification in intensive care is a challenge in South Africa as it is often difficult to obtain study leave due to the shortage of nurses in the workplace (De Beer *et.al.* 2011).

Safety in intensive care is very important considering the morbidity of patients' conditions and mortality of patients in this unit. Valentin *et al.* (2006) have revealed that most of the

errors in ICU can be prevented. Any preventable adverse events by health care professionals can complicate the course of patients' treatment and even prolong hospital stay or even lead to death of the patient, frustration of the family and the health care professionals at large.

Traditionally, nurses' input in monitoring clinical practice has been limited to voluntarily disclosing of the occurrence of errors through voluntary incident reporting in other countries (Te Beest, Van der Starre, Tibboel & Van Dijk, 2012; Morrison, Beckmann, Durie, Carless & Gillies, 2001). In contrary, incident reporting in South Africa is compulsory according to the National Policy to manage Patient Safety Incidents in the Public Health Sector of South Africa. According to this policy document, the health facilities should have a system in place that enable health care professionals to report all patient safety incidents openly but anonymously (only those directly involved should know identities of the party at fault) and these should be dealt with in a just and timely way (The South African Department of Health, 2015).

1.2 PROBLEM STATEMENT

Patients have a right to receive safe care in a safe environment and to be treated by competent healthcare providers. Patients' safety entails a systematic healthcare delivery that ensures that patients receive care that is free from preventable medical or nursing errors that might complicate the course of their treatment and prolong their hospital stay. Safety in Intensive Care Unit is important when considering the morbidity of patients' conditions and mortality of patients in this unit. Studies conducted overseas have indicated that there are observable deviations from protocols and standards of care that may lead to serious adverse events for the patients (Binnekade, de Mol, Kesecioglu & de Haan, 2001; de Neef, Bos & Tol, 2009). These can complicate the course of patients' treatment and prolong hospital stay or lead to death of the patient, frustration of the family and health care professionals at large. In light of South African shortages of qualified intensive care nurses and increasing numbers of placement of professional nurses and sub-professionals without the necessary training or experience to care for critically ill patients, which will impact on the quality of care and patient safety. It is therefore imperative to assess the deviation from standard operating procedures in the ICUs in order to make situation

analyses and formulate strategies to combat errors and to ensure quality of care for safety of patients.

The researcher sought to answer the following questions:

- What are the observable deviations from protocols of safe practice in intensive care nursing?
- Which domains of nursing care in the ICUs are most prone to deviations from nursing care protocols?
- Is there an association between deviations from nursing protocols and level of nursing expertise?

Therefore the study intended to assess nursing protocol deviations with implicit risk to the patients' safety in Intensive Care Units.

1.3 PURPOSE

The purpose of this study was to assess any deviations from protocols and standards of care in different domains of nursing care and to compare the deviations with the level of nursing expertise in five ICUs of one academic hospital in Gauteng, in order to make situation analyses and formulate strategies to prevent errors and to ensure quality of care for safety of patients.

1.4 OBJECTIVES

The objectives for the study were:

- To determine the incidence of protocol deviations that compromise patient safety in five ICUs in three months.
- To compare the incidence of protocol deviations that compromise patient safety in different domains of nursing care in the intensive care units.
- To compare the incidence of protocol deviations that compromise patient safety with the level of nursing expertise.

1.5 SIGNIFICANCE OF THE STUDY

In South Africa there is limited literature with regard to studies on patients' safety. With the shortage of appropriately qualified intensive care nurses, it is imperative in the ICU setting to study patients' safety as adverse events are most likely to occur when staffing challenges like inexperience of nursing staff, staff shortages and inadequate supervision prevail (Morrison *et al.* 2001). In a Delphi study to determine research priorities in adult ICU in Europe, prevalence and prevention of critical incidents in ICU (medical errors and adverse events) were emphasised as a research priority area (Blackwood, Albarran & Latour, 2011). The importance of this study is that the findings will contribute to current baseline knowledge of hospital management, ICU nurse managers and ICU nurses in relation to availability of an objective quantification of protocol deviations from operating standards of care for critically ill patients that comprise patient safety. As recommendations will also be made based on this study findings it is hoped that these will assist in formulating strategies to combat errors to ensure the quality of care for safety of patients in the foreseeable future.

1.6 RESEARCHER ASSUMPTIONS

A paradigm is a world view, a general perspective on the complexities of the real world (Polit & Beck, 2012). The research was based on the following meta-theoretical, theoretical and methodological assumptions:

1.6.1 Meta-theoretical assumptions

Meta-theoretical assumptions are the "statements that describe concepts or connect two concepts that are factual, accepted as true and represent values, beliefs and/or goals of the researcher" (Meleis, 2005:12). They reveal the researcher's view of a person, environment, nursing and health or illness. The researcher's meta-theoretical assumptions with regards to these concepts therefore were as follows:

- **The person**

The critical care patient is believed to be a person in a critical situation of life instability with a precarious physical and psychological balance, subject to continuous clinical or care changes, sometimes difficult to foresee and control in their evolution (Pitacco, Silvestro & Drigo, 2001). In this case, the person is a critically ill patient admitted to ICU, the intensive care nurse at the bedside of the patient and the patients' relatives or family. The patient has some physiological, emotional, psychosocial or spiritual discomforts and the intensive care nurse should have both skills and experience to individualize care and ensure that the healthcare outcomes are in favour of the patient, the family and the nursing profession. The patient should receive quality and safe care and to ensure this, the intensive care nurse uses his or her own critical thinking skills and employs protocols that guide nursing practice in his or her area of speciality.

The intensive care nurse should also take into account the involvement of the patients' family in the care delivered. The family is often devastated by the admission of their loved one and they need psychological and emotional support during the patient's stay in ICU. In order to be able to offer holistic care to the patient while also taking care of the family, the intensive care nurse should work in an environment that has adequate resources like updated and relevant protocols and guidelines, adequate and functional medical devices and other basic resources, the environment that is not stressful to the nurse, has adequate and accessible support system and should foster continued professional development. The nurse also plays a role of advocating for the critically ill patients' rights since most of these patients are on life-support treatment and cannot criticize the kind of treatment they receive in ICU.

- **Environment**

The environment is believed to "include any aspect of the patient, family, or institutional setting that can be manipulated by the nurse, a loved one or the institution to enhance comfort" (Dowd, 2010:711). In this study, environment is the ICU setting that the patient is admitted to. It includes the medical devices used in the care of the critically ill patient and the technological devices that assist in monitoring the patients. These constitute an unnatural environment that can be the source of discomfort and anxiety to the critically ill

patient and family. They are most often believed to be related to the severity of illness and morbidity of the patient's condition. As mentioned above, the nurse is responsible for providing a safe, comfortable environment for the patient and that fosters adaptation. This was also emphasized in Nightingale's Environmental theory in which a conducive environment is believed to enhance recovery. A well ventilated, warm room that is free from noise and adequately light is likely to comfort the patient. The false or true monitoring alarms can be a source of confusion and anxiety for the patient and relatives. Therefore, intensive care nurses should make sure that they set their alarm limits in relation to patient's parameters and that they attend to their patients with urgency. Continuity of care, personal cleanliness of patients, ensuring adequate intake of food and fluids, comfortable bedding, engaging in a conversation that gives hope and advices and observation and recording of patients care are also the canons of environmental theory (Nightingale, 1969). The research tool used in this study assessed the safety of patient environment.

- **Nursing**

Nursing is defined by the International Council of Nurses (<http://www.icn.ch/about-icn/icn-definition-of-nursing/>, 2014) as “autonomous and collaborative care of individuals of all ages, families, groups and communities, sick or well and in all settings. It includes health promotion, prevention of illness, and the care of the ill, disabled and dying people.” This emphasizes the importance of independent decision-making in nursing while working as a team with other health care professionals for the best outcome of care given to patients. It also clarifies the fact that access to health care is a universal right of every person not only the sick. This includes health promotion services, those services aimed at prevention of illnesses, caring for the sick, people with disabilities and those who need end of the life care. The role of the nurses in the stipulated health care services encompasses advocating for the patient especially in Intensive Care Unit where most of the patients are unconscious or have life-threatening illnesses and are vulnerable. The nurse should therefore be competent and provide evidence-based care to ensure safety of patients (International Council of Nurses, 2014).

- **Health**

Health is defined by World Health Organisation (WHO) as the state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity (Official Records of the World Health Organization, 1948). When the person is admitted into ICU, it means that there is alteration in wellbeing, mainly physical. During this period both the mental and social aspects are affected as many of these patients are so physically ill that they are unconscious and require life support for the functioning of vital body systems. The life support equipment is often invasive and requires competent professionals to assess, intervene, monitor and evaluate patient's care. With all the devices used and administration of scheduled drugs, the patients' safety depends on the health care professionals who are directly responsible for patient care. If the professional is competent in what he or she does, the patient is likely to receive quality care which enhances the continuum from illness to health.

1.6.2 Theoretical assumptions

Meleis (2005:12) stated that "A theory is an organised, coherent and systematic articulation of a set of statements related to significant questions in a discipline that are communicated in a meaningful whole". The following theoretical assumptions adapted from the Synergy Model for patient care by the American Association of Critical Care Nurses (Masters, 2012) were applied in this study:

The best patients' outcomes will only become a reality if the competencies of the nurse correspond with the patient and family needs. The Synergy model came into existence in 1993 when the AACCN summoned a group of experts well known nationally with a purpose of developing a new paradigm for clinical practice. The result was the description of 13 characteristics of patient's needs and nine characteristics of the nurse with the capacity to meet those needs. This was however redefined in 1995 to test validity of the concepts in critical care nursing. Thus, only eight patient's characteristics emerged with eight nurse's characteristics. The patients' characteristics that were found relevant in this study included resiliency, predictability, complexity, vulnerability, stability, involvement in the care decisions, resource availability and participation in care. The importance of

involvement of the patient's family where the patient is unable to make care decisions cannot be overlooked.

Nurse's characteristics that were found relevant in this study include clinical judgement, advocacy, caring practices, system thinking, collaboration, facilitation of learning, response to diversity, and clinical inquiry. In this model, the belief is that the synergy that comes from matching of patients' needs with the nurse's characteristics brings the best outcomes of care for the patients as the nurse's characteristics define his or her competencies in terms of integration of skills, knowledge and experience in practice. Considering physical, psychosocial and emotional instability, the vulnerability and the complexity of critically ill patients, it is mandatory that the critical care nurses ensure patients' safety at all times.

The Synergy model outlines the three different levels of outcomes as the outcomes derived from the patient, from the nurse and from the health care system at large. Those associated with the patient are functional changes that lead to attainment of self-care, behavioural changes that lead to independence, trust in the healthcare system, satisfaction with the care received, comfort and quality of life (Hardin, 2005) From the nurse's competency, the patients derive physiologic changes that enhance recovery since such a nurse is able to monitor physiological changes, make nursing care plan and collaborate with other professionals to change the patient's condition for the better. Moreover, it is likely that there will be no complications as competent nurses notice abnormalities once they occur and act according to protocols to reverse the situation and set objectives to measure the nursing care outcomes (Curley, 1998). From the healthcare as a system, the outcomes are measured in terms of readmission rates, length of hospital stay and cost consumption that may be due in part by complications arising from gaps in the systematic patients' care (Hardin, 2005).

The operational definitions consistently used in this study are as follows:

- **Academic hospital**

An academic hospital is a teaching hospital for health care professionals and is affiliated to the university or a training institution. It provides hands-on experience to students from all

health disciplines. In this study, a large academic hospital in Johannesburg was selected because it was easily accessible to the researcher.

- **Intensive Care Unit**

Intensive Care Unit is the specialised area of care in the hospital that is highly technological, requiring the nurses to have a broad knowledge base and a high level of decision-making skills as they care for critically ill patients who require continuous and close monitoring as well as their families who are in vulnerable circumstances (De Beer *et.al.* 2011). Trauma, cardiothoracic, coronary care, neurosurgical and multidisciplinary units were used in this study as they were selected by the researcher because they are the highly specialized ICUs that manage critically ill patients with both medical and surgical problems.

- **Critically ill patient**

Critically ill patient is the patient presenting with multiple and/or severe medical or surgical conditions requiring life support. Critically ill patients are defined by the American Association of Critical-Care Nurses (AACCN) as “those patients who are at high risk for actual or potential life-threatening health problems. The more critically ill the patient is, the more likely he or she is to be highly vulnerable, unstable and complex, thereby requiring intense and vigilant nursing care” (American Association of Critical-Care Nurses, 2014). In this study, only adult patients in the five selected ICUs were considered when sampling since the research instrument was not validated for use in paediatric patients.

- **Intensive care nurse**

A person registered as a professional nurse with the South African Nursing Council, who has undergone an advanced education and training programme in the specialty, and has direct responsibility for caring for patients (and family members) experiencing life-threatening situations in the intensive care unit (Nursing Act, 2005). These nurses are expected to have a high level of skills in critical thinking, problem solving, decision making and multidisciplinary collaboration when providing direct patient care.

- **Protocols /Guidelines**

Protocols / Guidelines are the set of specific written instructions for caregivers to follow when managing patients with specific health problems. They should be evidence-based, up-to-date, appropriate and acceptable to all members of the healthcare team. They guide caregivers on signs and symptoms to look for and when and how to intervene (Morris, 2003). The protocols define a uniform and standard way of nursing patients and reduce errors of deviations that are likely to occur when less experienced staff delivers direct patient care.

- **Patient safety assessment**

Patient safety assessment is the prevention and mitigation of harm caused by errors of omission or commission that are associated with healthcare. It involves establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur (National Quality Forum, 2010). In this study, patients' safety is assessed by using the Critical Nursing Situation Index with 84 items subdivided into eight domains of nursing in ICU as outlined under the research instrument.

- **Protocol deviations /Critical incident situations**

Observable deviations from protocols in nursing care are also known as critical incident situations, which are clearly related to an increased safety risk for the patient (Binnekade *et al.* 2001; Binnekade *et al.* 2003). In this study, detection of these deviations was guided by use of the 84 items in the Critical Nursing Situation Index. The number of all “true” items reflected the number of incidences of nursing protocol deviations. The more the number of protocol deviations, the more unsafe the patients were in the ICUs.

- **Nursing expertise**

This is defined as a hybrid of practical and theoretical knowledge that informs nurses understanding of patients' situations, clinical judgment and decision making (McHugh &

Lake, 2010). It develops from nurses' time in clinical practice and self-reflection that allows pre-conceived notions and expectations to be confirmed, refined or disconfirmed in real circumstances (Benner, 1984; Benner & Tanner, 1987; Simmons, Lanuza, Fonteyn, Hicks & Holm, 2003). For this study, nursing expertise was determined by nurses' professional qualifications and years of experience in intensive care nursing.

- **Professional nurse**

A person registered as a professional nurse with the South African Nursing Council, who is qualified and competent to independently practice comprehensive nursing care in the manner and to the level prescribed by the South African Nursing Council, and who is capable of assuming responsibility and accountability for such practice (Nursing Act, 2005).

- **Enrolled nurse**

An enrolled nurse is an associate to the professional nurse who demonstrates competence in the provision of elementary nursing care in the manner and to the level prescribed by the South African Nursing Council (Nursing Act, 2005).

1.6.3 Methodological assumptions

Methodological assumptions are defined by Polit and Beck (2004:711) as "the basic principles that are accepted as being true based on logic or reason, but without proof or verification". This research was based on the traditional positivism underlying the scientific approach that supports the belief that reality exists in a fixed and orderly manner and can therefore be studied without bias (Polit & Beck, 2004). The study follows the systematic and disciplined way of acquiring the information through the use of a formal research instrument. In this way, the reality of patients' safety in Intensive Care Units is sought non-experimentally by audit that includes record reviews.

The Critical Nursing Situation Index is a formal research instrument that has been tested for validity and reliability in a setting that is similar to the one in this study, thus, the study is expected to be precise, valid and reliable and bias is likely to be minimal. Since the

research is an observational study, the evidence of patients' safety is empirical and as it was obtained through what was observed as opposed to the researcher's own beliefs or values.

The data gathered was quantitative or numeric and was analysed with statistical measures. The results conveyed an understanding of the situation in ICUs with regards to patients' safety and it was hypothesized that the level of expertise of nurses working in those units was directly related to occurrence of adverse events. The assumption is that the results can be generalized to other settings that are similar to the one used in this study in terms of services offered, staffing, resources, location and background.

1.7 OVERVIEW OF RESEARCH METHODOLOGY

This is brief outline of the research methodology, to be discussed in greater detail in Chapter three.

A quantitative, prospective, non-experimental design, by application of the Critical Care Nursing Situation Index (CNSI) for safety assessment was used in assessing the occurrence of deviations from nursing protocols in adult intensive care units. Patients' care was observed and patients' ICU records reviewed with the guidance of this research instrument.

The study setting was a tertiary referral hospital, which is also the main teaching hospital for the University of the Witwatersrand, Faculty of Health Sciences. The study participants were critically ill patients admitted to five ICUs namely: Trauma ICU, Multidisciplinary ICU, Neurosurgical ICU, Cardiothoracic ICU and Coronary Care ICU.

A sample size of 100 (n=100) was decided upon by a biomedical statistician based on good representation of the population and validity of the study. A non-probability convenience sampling method was used.

Permission was sought from the managers of the hospital in the form of a letter. Unit managers' permission was also sought to conduct the study in their unit. After permission was granted by the hospital and ICU managers, consent to include the patient in the study was obtained from the patients' primary nurse and their relatives. The patients' consent to

use the data obtained in the study was obtained in the recovery period in a general ward after discharge from ICU. Participation in the study was voluntary and respondents were free to withdraw at any point in time.

An instrument developed by Binnekade et al. (2001) was used for data collection. This is a validated, published and well known instrument for assessing the safety and quality of nursing care in the ICU. It contains 84 observable situations divided into a set of eight sections namely: “basic ICU nursing care”, “mechanical ventilation”, “care of intravenous lines”, “administration of fluids”, “cardiac rhythm and circulation”, “medication”, “enteral nutrition” and “hygienic care and control of devices”. Each item was observed for any deviation from the protocol and scored as “*true*” (presence of a critical incident), “*false*” (absence of critical situation), or “*not applicable*” to the treatment or care of the patient on the day observations were carried out. Additional data was collected pertaining to the patients’ age, gender, illness severity, length of ICU stay, professional qualifications and years of experience of nurses assigned to their care.

The instrument was developed from the literature and clinical experience (Binnekade *et al.* 2001) and tested on an independent sample of critically ill patients in the Netherlands (Binnekade, Vroom, de Mol & de Haan, 2003).

Descriptive and comparative statistics were used to analyse the results of the study, with statistical software STATA 12 used for analysis purposes. Statistical assistance was obtained from a biomedical statistician from the Medical Research Council in the Pretoria office.

1.8 VALIDITY AND RELIABILITY OF THE STUDY

According to Polit and Beck (2004: 35-36), “Reliability refers to the accuracy and consistency of information obtained in a study and validity is the soundness of the study findings, that is, whether the findings are cogent, convincing and well grounded.” In this study, validity and reliability was maintained by ensuring that the findings were accurate, unbiased and adequately represented the target population. The study was done in accordance with the procedures and protocols of the Human Research Ethics Committee of the University of the Witwatersrand. The instrument, that is, the Critical Nursing Situation

Index used in this study had been used in intensive care unit and had been tested for validity and reliability in assessing adherence to protocols. Moreover, it had been adapted as part of the Patients Safety Management System in the Netherlands since 2005. The researcher was the only one collecting data to ensure consistency of the findings. All the statistical analysis was done with the assistance of a biomedical statistician from the Medical Research Council (MRC) to ensure accurate interpretation and analysis of all data collected.

1.9 ETHICAL CONSIDERATIONS

Permission to undertake the study was sought from the Human Research Ethics Committee and Postgraduate Committee of the University of Witwatersrand (**Appendix B**). The permission to use the Critical Nursing Situation Index was sought from the developer of the instrument in the form of writing and permission was granted through e-mail (**Appendix C**).

The nurses in charge of the selected wards, nurses and patients or relatives were given the information letter (**Appendix D, D1, D2 and D3** respectively) that explains the purpose of the study and the procedure and also the consent forms to sign (**Appendix E, E1, E2 and E3** respectively). The relatives were asked to give permission on behalf of the patient if for any reason the patient was unable to sign. For example, if the patient was unconscious or intubated and sedated.

The letter of request for permission (**Appendix F**) was submitted to the hospital where the study was conducted to give permission to observe the nurse-patient interactions. The hospital permission letter (**Appendix F1**) was received before data collection commenced. Confidentiality and anonymity was maintained throughout the period of the study by not disclosing any real names of the hospital or people. The wards were identified by the use of codes. All electronic data collected was saved on a password protected computer and the other data was kept under the lock and key which was accessed only by the researcher and supervisors

1.10 SUMMARY

The chapter has provided an outline of the study. The problem statement, purpose of the study, research objectives and the significance of the study has been described. The assumptions of the researcher have been discussed and the operational terms defined. A brief overview has been given of the research methodology, validity and reliability of the study and the ethical procedures adhered to during the course of this study.

The following chapters will provide a review of the literature, the methodologies, data analysis, the description and interpretation of research findings. The final chapter will state limitations of the study, summary of the study findings, conclusions and recommendations for future research.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

The previous chapter has provided an overview of the study, its background, the purpose, objectives and significance. The research questions, problem statement and researchers methodological and theoretical assumptions were also discussed. It defined the operational terms frequently used in the study and provided the overview of methodology employed in the study and the ethical considerations applicable.

This chapter provides the summary on the available information about the subject studied in this research.

2.2 INTENSIVE CARE NURSING SPECIALITY

According to Bucher and Melander (1999), intensive care nursing came into existence in the 1950s when nurses and physicians realised that they had to triage patients based on seriousness of their illness or injury. Nurses and physicians then decided that patients who were critically ill or injured but had a chance of survival would be nursed in special units. During that time, the technology that was available in intensive care units was limited and there were not enough physicians to render care hence mortality rates were very high in these units. Nurses were then forced by circumstances related to technological advancement to improve on their skills so that they could manage patients in the absence of the physicians. Knowledge was shared by these healthcare professionals for the good of the patients. Nurses then learned the pathophysiology of diseases, to interpret electrocardiograms and laboratory results and reported to physicians on how patients responded to different interventions (Elliott, Aitken & Chaboyer, 2007).

In 1965, the first coronary care unit was opened in Philadelphia with appropriate technology to assist patients with cardiovascular diseases. Nurses were then trained to diagnose dysrhythmias, initiate emergency pharmacotherapy or even defibrillate patients (Bucher & Melander, 1999). This was just the beginning of speciality ICUs as other units were also established with the advancing technology and the special needs of the critically

ill patients. Neurosurgical, respiratory, surgical, burn, paediatric and neonatal ICUs were then established. Nurses had appropriate advanced training and acquired speciality certifications that were offered by the American Association of Critical Care Nurses (AACCN) at that time.

In South Africa, intensive care nursing was first introduced as a speciality and a training programme or post registration qualification for registered nurses at diploma level (one year) was commenced in 1966 and degree level (two years) introduced later (Schmollgruber, 2007). The scope of practice and professional code of conduct for these nurses is provided by the South African Nursing Council (SANC). Currently, the supply of intensive care nurses is exceeded by the demand, not only in South Africa but also abroad. This is believed to be the result of increase in the complexity of illnesses partly due to the high prevalence of HIV/AIDS, reduction in the enrolment of nurses as women nowadays have various career choices and burn out related to nurses' dissatisfaction with their work (Aiken, 2005).

2.3 PROTOCOLS AND GUIDELINES IN INTENSIVE CARE

In order to develop professional practice, it is imperative to put some guidelines and protocols in place for its members to base their practise on and minimize variations. These are tools that have gained concentration of health care professionals in various health care settings with regards to their development, deployment and evaluation (Hewitt-Taylor, 2006). Although some health care professionals may use protocols and guidelines interchangeably, they are different. A protocol is defined as a model of evidence-based, best-practice methods established, tested and implemented by the multidisciplinary team of an intensive care unit (Plost & Nelson, 2007).

On the other hand guidelines are a written guide for health care professionals to follow for a particular practice aspect in order to ensure effectiveness and efficiency of treatment (Leddy & Wilkinson, 2015). The main difference between the two is the fact that guidelines are an overview of concepts and do not give specific instructions that inform clinical decision-making while protocols have detailed content and specific instructions for clinical decision-making (Morris, 2003). This means that because protocols are rigid and do not allow variation, different healthcare professionals can make the same decision when

following protocols, something that cannot happen when following clinical guidelines. However, both protocols and guidelines are current evidence-based clinical tools that guide health care professionals to standardise care, ensure patient safety by improving outcome of patient's care and reduce cost of health care (Kingston, Krumberger & Peruzzi, 2000).

The fact that they are guidelines clarifies the fact that they should not replace professional autonomy and individualized patient care. According to Perrie, Schmollgruber and Bruce (2014), protocols only provide a base and complement for health care professionals without eliminating their ability to act according to what is best for the individual patient at the time. In ICUs, protocol-directed care has been adapted and has its benefits and challenges.

Considering the nature of the ICU environment, staffing patterns and patients' conditions, it makes sense that health care professionals familiarize themselves with and implement ~~with~~ the available current evidence-based protocols in their various units. This is particularly important for ICU nurses as they are the back-bone of patients' care and have the ability to influence other health care professionals to do the same in the interest of providing quality patient care.

However, protocols are not intended to be basic tools for nurses alone as they do not provide care in isolation n holistic patient care. Kingston *et al.* (2000) have emphasized the importance of accessible protocols in enhancing effective communication and ensuring coordination of health care by the multidisciplinary team. It is therefore clear that it is teamwork rather than individual responsibility to eliminate the habit of using personal experiences, opinions or trial and error in clinical practice and let current research inform practice.

It is also important to consider when or where the protocols can be applied. According to Casey and Balas (2011), protocols can be used in a clinical setting to inform treatment of certain conditions like glycaemic control, sedation, weaning parameters and sepsis and pneumonia management. Another important area where protocols are applied is in management of pain (Perrie *et al.* 2014).The emphasis however is on the fact that these protocols are only a guide. The response of an individual patient to care must be interpreted by nurses and their assessment overrules a protocol.

Moreover, with the complexity of critical illness, one patient may require use of more than one protocol that will potentially challenge nurses and other health care professionals as their components may be in contrast with one another (Perrie *et al.* 2014). Collaboration in the multidisciplinary team will therefore be critical in reaching a solution that will avoid deviations in care and their potential risk to the patient.

In one study (Dijkema, Dieperink, Meurs & Zijlstra, 2012) it is argued that it might be very difficult in ICU to differentiate between the effect of the adverse event and the actual disease progression of the patient. However, whether an adverse event has occurred or not can always be established by assessing the healthcare professional's adherence to the standards of care and the unit and hospital updated protocols and guidelines.

As explained by Plost and Nelson (2007), evidence-based protocols can make procedures and processes easy to do, can standardize care, ensure patient's safety and reduce the cost of health care by reducing the length of ICU stay and reducing unnecessary procedures to correct the errors and the possibility of disability after hospitalization. Protocols should not be used to shift blame to individuals but should be updated, acceptable to the healthcare team, be practical and flexible so as to serve their purpose of guiding professional practice and improving the outcome of health care (Michell, 2011).

2.3.1 What Causes Deviations from Protocols?

There are a number of factors that are attributable to the occurrence of the adverse events as a result of deviation from protocols. In a setting where supervision is mandatory, it is not surprising to discover deviations from protocols and standards of patient care as the workload of the qualified intensive care nurse increases. In this case, the American Association of Critical Care Association (AACCN), (2005) uses the word, "Inappropriate staffing" since care is provided by nursing assistants instead of appropriately qualified nurses. This compromises patient's safety by increasing the likelihood of errors and deviations from standards and protocols. According to Blignaut, Coetzee and Klopper (2014), nurse's qualifications may not affect how they perceive patient's safety but there is significant link between appropriately qualified nurses and positive patient's outcomes.

There is also a belief that the years of experience in ICU impacts on the clinical contribution of nurses. In a study by Acebedo-Urdiales, Medina-Noya and Ferré-Grau (2014), it was identified that the most experienced nurses in ICU had accumulated more implied and perceived knowledge of ICU practice over their years in ICU than the newly deployed ones. This was explored in various areas of patient care including, communication, mechanical ventilation, basic ICU care, transition of care and avoiding occurrence of errors.

The Royal College of Nursing (RCN) 2003 just like AACCN encourages unit managers to think beyond nurse-patient ratios and consider nurse's skills, patients' needs and health care environment when deciding of appropriate staffing. RCN also acknowledges the value of practical experience providing comprehensive care as it complements their professional training. Where there is an appropriate skill and experience, protocols and guidelines will complement decision-making and ensure patient safety. Nurses with skills and experience are more likely to be familiar with clinical guidelines and protocols in their unit as may have applied them during their years of experience in ICU or may have come across them during their studies.

2.4 PATIENT SAFETY

Patients' safety is one of the most important aspects of healthcare that has to be considered at all times during patients' stay in the hospital. Research in the area of patients' safety was not considered as important until 1950s when very few studies were conducted on adverse events (World Health Organisation, 2008). The publications on adverse events studies increased in the 1990s and the study by the Institute of Medicine in 1999 named "*to err is human: building safer health systems*" provided important data and was an eye-opener for healthcare organisations worldwide to prioritize this issue in their policies and debates. This was in line with the International Nurses Council (ICN) guidelines that have clearly demonstrated that nurses would not maintain standards of care and competence if they are not involved in continued education, research and evidence-based practice (ICN, 2012).

The World Health Organisation (WHO) has since urged the member states to consider patients' safety and to put into place all the strategies that ensure safety and improve the

quality of care offered to patients (WHO, 2008). The World Alliance for Patients' safety has been established as the global initiative to improve patients' safety and to encourage research in the area of patients' safety especially in developing countries where such research is highly needed. Quality improvement in healthcare needs evidence based decisions and such decisions are informed by research. Unsafe health care and adverse events are estimated to be affecting tens of millions of patients world-wide and are believed to be higher in developing countries due to lack of basic health care resources (WHO, 2008; Adhikari, 2013).

During the course of patient's stay in hospital, there are a number of things that may unintentionally go wrong and alter the outcome of hospitalization. These are the occurrences other than the patient's disease process that can complicate the course of treatment. In developed countries, the estimation of adverse events in medical and nursing care is around nine%, 44% of which are preventable (Adhikari, 2013). In the same paper, it is also estimated that out of the 43 million adverse events occurring globally, 23 million disabilities that require life adjustment resulted. This means that instead of health care being therapeutic, it can be the opposite if health care professionals do not follow their standards of care and ensure patients' safety at all times.

The World Health Organisation Patient Safety (2012) conducted a record review to assess the nature and frequency of occurrence of adverse events in the developing countries. As compared to the developed countries, the preventable adverse events were higher in developing countries at 83% of the total events recorded and 30% of the events lead to the death of the patient. Even though the results are not specifically for Intensive Care Units (ICUs), it can be anticipated that they are the majority of the contributors considering the complexity of the ICU environment, the number of risky and invasive procedures, technological advances, and shortage of appropriately qualified staff and acuity of the patients.

2.5 AREAS OF NURSING CARE

2.5.1 Basic Intensive care nursing

It is also the role of a critical care nurse to ensure that if the patient is transferred from one hospital to another or from one unit to another, bacterial cultures are taken upon admission into ICU in order to exclude any infectious diseases or infections that may need attention and distinguish between the hospital acquired infections and community acquired ones. There has been a significant increase in the hospital-acquired infections in the ICUs because of the prolonged stay in ICUs, improper use of antibiotics and increased multiple invasive procedures (Michell, 2010). Healthcare workers' failure to adhere to hospital infection control policies and the multiple invasive procedures in these units contribute to hospital-acquired infections. When patients are admitted to ICU, they should be screened for infections like Methicillin Resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococcus (VRE) and other infections prevalent in other wards or facilities transferring patients to ICU (Weinstein & Bonten, 2002)

Poor hand washing technique has been implicated by several studies as the major source of hospital infections as it assists transmission of infections from the patient to healthcare worker and vice-versa and also from patient to patient (Weinstein & Bonten, 2002; du Plessis & Monkoe, 2010). In a study conducted by du Plessis and Monkoe (2010), in one major teaching hospital in South Africa, it was found that compliance with hand hygiene protocol was as low as 50% and that the hands of the adult ICU healthcare workers were the most colonized with pathogenic micro-organisms, 59%, compared with 21% for paediatric ICU and 19.67% for the neonatal ICU. The risk of patients in direct contact with these healthcare workers for acquiring an infection is therefore very high.

Apart from infection prevention and control, the critical care nurse is responsible for ensuring patient's comfort and maintaining dignity. The scope of practice of critical care nurses explains that this role requires skilled professionals that will carefully study the condition of an individual patient and prioritize accordingly. The scope also takes in to account the fact that ensuring physical comfort, rest and sleep may be difficult to achieve in ICU setting but it encourages nurses to reduce the noise levels, communicate with the

patients in order to reduce anxiety and increase tolerance of the uncomfortable interventions (Scribante *et al.* 1995).

Positioning of the critically ill patient should be individualized as it can both ensure comfort and prevent complications and development of pressure sores. Bed sore development reflects inadequate skin assessment, care and evaluation in nursing as they can be prevented by the use of evidence-base guidelines. This is according to Estilo, Angeles, Perez, Hernandez and Valdez, (2012) who state that the skin is often not given the same attention in ICU as other organs that are considered as vital organs.

According to VanGilder, Amlung, Harrison and Meyer, (2009), facility acquired pressure ulcers are mostly prevalent in adult intensive care units with the highest percentage (12.1%) being in medical ICU. This means that critical care nurses should assess patients for the development of pressure ulcers, study all patients' risk factors by means of scales and implement effective measures to reduce this from happening. According to Cox (2011), risk factors that the critical nurse should bear in mind include; patient's immobility, nutritional status, incontinence (both faecal and urinary), age, length of ICU stay, sensory perception, APACHE score, vasopressors administered, blood pressure and other co-morbid conditions such as diabetes mellitus.

Two hourly turning or repositioning of the critically ill patient who cannot turn by himself has been recommended as a strategy to prevent the development of pressure sores since it relieves pressure from the dependent parts (Cox, 2011; Siddiqui, Behrendt, Lafluerand & Craft, 2013). Positioning is also important for postural drainage, mobilization of secretions, preventing ventilator-associated pneumonia, improving oxygenation and patient comfort (Goldhill D., Badacsonyi, Goldhill A. & Waldmann, 2008).

However, these interventions should take in to account the condition of individual patients. For example, it will not be beneficial or safe to position a patient with acute respiratory distress syndrome (ARDS) in the prone position if he or she has an open abdominal or thoracic cavity post-operatively (Murray & Patterson, 2002). Other interventions for avoiding pressure sores include elevating and supporting the heels, monitoring and caring for the incontinent patients, use of an evaluation scale, using skin barriers, evaluating the

skin in contact with assistive devices and ensuring optimal nutrition and hydration (Siddiqui *et al.* 2013).

Intake and output balance is very important in critically ill patients. Since the critical care nurse is responsible for maintenance of elimination by the patient, he or she should monitor the patient's intake and output including the ability to pass stools. The Scope of Practice allows nurses to intervene accordingly to ensure elimination by the patient and adequate hydration (Scribante *et al.* 1995). Once abnormalities are noted and interventions are in place, adequate and accurate recording should be carried out.

Logically, if something is not recorded in the patient's hospital file, it is not considered as done or it never happened. According to the scope of practice of critical care nurses, patient's records are the most important professional and legal tools of communication between the healthcare professionals in the unit. Clear, accurate and complete record keeping is essential for delivery of safe and effective care to patients (Griffiths, Debbage & Smith, 2007). For example, if the nurse administers the prescribed medication but forgets to record in the correct charts, another nurse taking over the same patient may think that it was never given and administer it again putting the patient at risk of drug overdose.

2.5.2 Mechanical Ventilation and Related Risks

Many critically ill patients have secondary respiratory problems that require mechanical ventilation to manage or prevent acid-base imbalances that result from other organ system failure. More commonly, mechanical ventilation in ICU is carried out for primary respiratory disorders and respiratory support. This therapy is very useful in normalizing arterial blood gases and correcting acid-base imbalance by ensuring optimal ventilation and oxygenation in patients while offering respiratory support and promoting rest of the respiratory muscles (Grossbach, Chlan & Tracy, 2011).

Patients on mechanical ventilation should be nursed by highly competent and appropriately qualified nurses who understand the disease pathophysiology and the purpose of the ventilator settings and alarms in order to ensure a positive outcome and to prevent complications related to mechanical ventilation. Mechanical ventilation increases the risk of patients for developing ventilator associated pneumonia (VAP), hypoxemia, barotrauma

and volutrauma which might lead to a longer hospital stay, increased cost of health care or resultant death of the patient.

Ventilator Associated Pneumonia (VAP) is a form of iatrogenic pneumonia that occurs in patients who have been mechanically ventilated for periods longer than 48 hours (Kollef, 1999; Best Care Always, 2012). According to Augustyn, (2007), VAP is the second most prevalent hospital acquired infection in the United States and leads to a 27% mortality rate or even as high as 43% if the causative agent is resistant to antibiotics. In South Africa, the prevalence of VAP is 13% in mechanically ventilated patients and the mortality rate is believed to be around 46% (Best Care Always, 2012).

However, ventilator associated pneumonia (VAP) can be prevented by avoiding colonization of the oropharynx through proper hand washing and practicing aseptic technique while suctioning the patient. Introduction of the VAP bundles has been shown to decrease the risk of VAP (Best Care Always, 2012). Bundles are evidenced based practice actions which when performed as a group will decrease the risk of VAP. The VAP bundles include:

- Elevating the head of the bed to 30 to 45 degrees whenever possible. This can also reduce the risk of aspiration that would otherwise occur when the ventilated patient is nursed flat (Best Care Always, 2012).
- Oral Care. Augustyn, (2007) suggests that oral decontamination be performed at least twice a day. This can be accomplished either by pharmacological means such as the use of chlorhexidine oral rinse or by tooth brushing and rinsing.
- Sedation hold. Although sedation is important in preventing patient-ventilator dyssynchrony and optimizing oxygenation, it should be individualized and continuously assessed to avoid both under and over-sedation. Kalanuria, Zai and Mirski (2014) have recommended that critically ill patients should receive daily sedation holds. This is important since it reduces the risk of VAP that results from the decreased level of consciousness, loss of cough and gag reflexes with resultant aspiration. However, Vincent (2005) has argued that if sedation is titrated according to guidelines and sedation scales and used correctly, there will be no need to discontinue it once a day.

- Suctioning of the oro-pharyngeal and endo-tracheal secretions is essential because intubated patients are unable to clear their airway. This ensures that the airway is patent and oxygenation will be maximized. Endo-tracheal suctioning is a primary role of the critical care nurse and the technique should be carried out in such a way that it prevents complications such as hypoxemia, infections due to contamination of the airway and disturbances of the haemodynamic status of the patient (Jongerden, Rovers, Grypdonck & Bonten, 2007). Jongerden *et al.* (2007) found that the closed suction system is more efficient than the open suction system in avoiding physiological disturbances such as changes in oxygenation and heart rate, as adequate oxygenation is maintained throughout suctioning. However, in the same study, it was found that there was no significant reduction of VAP occurrence between the two systems.
- Frequently changing the suction catheters in the closed suction system is associated with higher incidences of VAP. Schell and Puntillo (2006) have indicated that it is safe to change suction catheters weekly as opposed to daily to avoid contamination. Similarly, normal saline instillation during endo-tracheal suctioning is not recommended as it is believed that the saline does not affect viscosity of the secretions and may not even induce cough reflex. Instead, the same saline might flush micro-organisms deeper into the lower respiratory tract (Schell & Puntillo, 2006). To the contrary, Reeve, (2009) conducted the randomized control trial and found that saline instillation before endo-tracheal suctioning significantly reduces the development of VAP. Although instillation of normal saline during endo-tracheal suctioning is a common practice in some ICUs, it carries several risks to the patient including increasing the partial pressure of carbon dioxide and oxygen saturation minutes after suctioning (Zahran & Abd El-Razik, 2011).

Controversy on the instillation of normal saline during endo-tracheal suctioning has led to several recommendations to mobilize secretions (Schell & Puntillo, 2006; Zahran & Abd El-Razik, 2011; Spears, Cook & Garcia, 2012). Suggestions include the use of mucolytic agents, nebulizers, humidifiers, ensuring adequate systemic hydration and adequate mobilization. If there is any visible condensate in the tubing of the ventilator, it should be drained and discarded and care should be taken that the fluid does not flow towards the patient. Proper hand washing and decontamination together with the use of gloves is encouraged during such a procedure to avoid contamination. The ventilator circuit should

only be changed if it does not function properly and when it is visibly soiled as opposed to every 48 hours (Tablan, Anderson, Besser, Bridges & Hajjeh, 2004).

According to Jordan, van Rooyen and Venter (2012) the endo-tracheal tube cuff pressure should be maintained between 25 and 30 cm H₂O in order to ensure that aspiration and inadequate oxygenation as a result of leakage does not occur. Incidences related to excessive cuff pressure are the occurrence of tracheal stenosis, rupture, laryngeal nerve palsy and sometimes tracheo-oesophageal fistula as a result of excessive compression and resultant ischaemic necrosis of tracheal mucosa due to poor perfusion (Michell, 2014; Jordan *et al.* 2012).

A prolonged intubation period also increases the risk of the patient developing VAP as the presence of the endo-tracheal tube impedes the natural cough reflex and secretion clearance. This means that any colonization in the oro-pharyngeal cavity can be easily aspirated in to the lower respiratory tract leading to development of VAP. In a study by van Aswegen, Richards, Goosen and Becker, (2010) patients that had been ventilated for more than five days had a higher morbidity and were more likely to develop sepsis and multiple organ failure than those who were ventilated for less than five days. They were likely to show severe functional impairment of trachea six months after discharge from the hospital. Best Care Always, (2012) recommends that all mechanically ventilated patients should be frequently assessed for readiness to be extubated.

The assessment of these patients should be comprehensive and individualized in order to ensure that the patient is both haemodynamically stable and has a satisfactory acid-base status. According to Schell and Puntillo (2006), the patient who is ready for extubation should be able to provide adequate spontaneous ventilation, be able to lift their head from the pillow, have enough minute ventilation, a good negative inspiratory pressure and the acid-base status should either be normal or compensated while the patient is on continuous positive airway pressure (CPAP) and a low fraction of inspired oxygen (FiO₂) of less than 50%. If weaning from mechanical ventilation is successful, the risk of re-intubation is low. Kalanuria *et al.* (2014) have indicated that the risk of VAP increases when extubated patients are re-intubated, hence use of protocols when weaning is necessary in order to ensure a positive outcome after mechanical ventilation.

2.5.3 Intravascular Access Lines and Administration of Fluids

Intravascular devices are very common in ICU as they are used for administration of fluids, intravenous medications, blood products, enteral nutrition and also for monitoring haemodynamic parameters such as central venous pressure, arterial blood pressure and pulmonary artery occlusion pressure. According to Baird, Keen and Swearingen (2005), most of the critically ill patients either have cardiovascular illnesses or are at risk of developing cardiovascular diseases, therefore haemodynamic monitoring is essential in ICU. Intravascular devices can either be introduced for short-term or long-term usage and this will determine the technique of insertion.

The break in the natural barrier (skin) during insertion of these lines thus puts the patient at risk of developing infections (local or systemic), bleeding and thrombosis that may lead to ischaemia (Baird *et al.* 2005). It is therefore the critical care nurse's role to monitor the patient for development of these complications. Intravascular catheter-related blood stream infections are among the top three hospital-acquired infections at 25% with the central venous lines accounting for 90% of all catheter-related infections. However, these can be prevented as the majority of these infections result from contamination by the medical or nursing staff while trying to manipulate the devices (Mer, 2006).

In an attempt to prevent catheter-related blood stream infections, Best Care Always (2012); Gillespie (2008) recommended that South Africa should adapt the United States of America's (USA) central venous line care bundle that has been developed and effectively implemented in the USA to prevent catheter-related infections. These are the evidence-based guidelines for interventions that were developed by the Institute for Healthcare Improvement with a recommendation that they should be implemented by the entire critical care team for all the patients with intravascular lines. If correctly implemented, these bundles can improve safety of patients and ensure reduction in the hospital stay and cost of care.

The transparent semi-permeable dressings are preferred as opposed to gauze and tape because they allow continuous visualization of the insertion site, allow skin to 'breathe' by allowing evaporation of the moisture under it and reduce colonization (Schell & Puntillo, 2006). However, Mer (2006) has argued that use of adhesive gauze coupled with a non-

adherent pad centrally is effective in the prevention of catheter related infections as long as chlorhexidine gluconate containing solution has been applied to the insertion site prior to dressing. The dressings should be changed according to the hospital or unit protocol to avoid infections but Centre for Disease Control, (2011) recommends that gauze dressings should be changed every two days while the transparent dressings should be replaced after seven days.

Other recommendations by Mer (2006) to prevent catheter related infections include;

- Consistent use of principles of asepsis during insertion, maintenance and use of the intravascular devices
- For replacement of catheters, it is recommended that standard central venous and haemodialysis catheters be replaced after 14 days while peripheral venous and arterial lines should be replaced after three to four days and 30 days respectively.
- All the lines that have been used for blood transfusion should be replaced after 24 hours
- Lipid-containing parenteral nutrition solutions should be completed within 24 hours.
- It should be infused through only one dedicated port and its line to be replaced 24 hourly.
- Administration sets used for delivery of inotropes and antibiotic to be replaced after 72 hours or before if clinically indicated.
- The day on which the lines were replaced should be clearly recorded on the ICU charts or in the medical records.
- Bridges and their respective lines, transducers and continuous flush devices can be replaced at seven day intervals if there is strict adherence to asepsis.
- Aseptic technique also extends to care of ports and caps attached to intravascular devices, it includes the spraying of a chlorhexidine gluconate-containing solution following manipulation.

The length of time that the intravascular catheter is insitu is also an important variable to be considered. The Centre for Disease Control (2011), recommends that the pulmonary artery catheter should not be insitu for more than three days and that the central venous

catheters be flushed with 0.5 units/kg/hour of heparinized saline to prevent occlusion from thrombus formation and colonization.

According to Schell and Puntillo (2006), positive pressure should be applied to the flush bag to avoid blood backup into the lumen. The recommended pressure for that purpose is 300mmHg to deliver three millimetres per hour according to Elliott *et al.* (2007). CDC (2011) has also identified incorrectly placed or missing caps on the lines as a common error in ICU with 156 breaches per 1000 catheter days; therefore, healthcare professionals in this area should adhere to standards in placement and replacing caps.

Management of the patient with intravascular devices does not only revolve around infection control. It also incorporates fluid balance monitoring and accurate recording. The scope of practice states that critical care nurses are responsible for assessment of fluid status and to intervene as necessary if imbalances occur (Scribante *et al.* 1995). In order to detect the imbalances, nurses should accurately record the volume of all the fluids that the patient is receiving (including the flushed heparinized saline and blood products) as well as the volume of what he or she is eliminating (Diacon & Bell, 2014).

In the study by Diacon and Bell, (2014), 79% of fluid balance totals in one ICU in South Africa were incorrectly calculated by more than 50mL and hence inaccurately recorded. This is a significant deviation since it will be used to guide interventions by both the nursing and the medical teams to ensure patient's fluid balance. Moreover, five of the 103 ICU patient's charts had no record of calculations of fluid balance which raises a question of how fluid in a critically ill patient can be adequately managed without fluid balance calculation. It is therefore not surprising that the same researchers discovered that there was inappropriate diuretic administration that could compromise the patient's safety since it has the potential to lead to haemodynamic instability. Although this study was limited in a sense that it was conducted in one hospital, its findings are significant and warrant similar audits in other hospitals.

2.5.4 Cardiac Rhythm and Circulation

Cardiac monitoring is one of the critical roles of intensive care nurses that require basic knowledge of physiology and pathophysiology of the cardiovascular system. According to

Crimlisk, Johnstone and Winter (2015) health care professionals should be competent in identifying the normal and abnormal heart rhythms. This is possible through education on the interpretation of a 12 lead electrocardiogram (ECG). Identifying cardiac rhythm abnormalities and ischaemic changes on ECG, together with reviewing cardiac monitoring alarms, are essential nursing actions if correct evaluation and interventions are to be carried out. This indicates that nurses as health care professionals at the bedside should have undergone training and competency assessment in order to monitor cardiac parameters recognize abnormalities and choose appropriate interventions.

However, one might argue that intense training in cardiac monitoring is only necessary for those professionals working in cardiac units, but as demonstrated by Crimlisk *et al.* (2015), it is necessary even for healthcare professionals in the medical-surgical units in order to detect abnormalities early and initiate referral processes while the patient's life can still be saved through appropriate therapies.

In the past pulmonary artery catheters (PAC) such as the Swan Ganz catheter was commonly used to diagnose and treat cardiopulmonary illnesses and monitor the fluid status of a patient but through continued clinical trials it was found not to be very useful in improving the morbidity and mortality rate in ICU considering its invasive nature (Richards, Warszawski, Anguel, Deye, Combes, Barnoud, Boulain, Lefort, Fartoukh, Baud, Boyer, Brochard & Teboul, 2003). These investigators discovered that PAC was associated with various complications such as arterial puncture, haemothorax, arrhythmias and conduction disturbances and the catheter frequently developed knots.

2.5.6 Medication

Polypharmacy is not a rare phenomenon in the critically ill and has both its benefits and associated risks that can alter the patient's outcome of hospitalization. In a multinational sentinel events study involving 1913 (n=1913) patients from 205 ICUs in 29 countries, it was discovered that adverse drug events were the second most prevalent category affecting 136 patients after lines, catheters and drains (Valentin, Capuzzo, Guidet, Moreno, Dolanski, Bauer & Metnitz, 2006).

In South Africa, most errors associated with medications are said to occur during prescribing by medical personnel while some are errors in administration of drugs by nurses. Errors of drug administration include giving the right patient the wrong drug at the wrong dose or using the wrong routes (Michell, 2006). Moreover, drugs administered through intravenous routes place the patient more at risk because it is highly likely that incorrect dose calculation, incorrect titration, incorrect settings for the infusion pumps and possible obstructions and accidental disconnections may occur (Burdeu, Crawford, van de Vreede & McCann, 2006).

The competency of the critical care nurse is a major factor in the administration of drugs and monitoring their effects on the patient. Knowledge of drug properties, possible drug to drug interactions, side effects, special precautions and its therapeutic effects is essential in the ICU setting. When the patient receives more than one infusion, care should be taken not to mix incompatible drugs or give intravenous drugs intra-arterially or into the epidural line (Michell, 2006).

2.5.7 Nutrition

In addition to other roles the critical care nurse needs to assess the nutritional status and ensure that all patients receive adequate nutrition. Under normal circumstances, food and drinks are taken orally. However, when illness strikes and people are hospitalized, other methods of feeding may be initiated in order to ensure continued adequate nutrition even during that period. These include enteral nutrition, which is the introduction of nutrients directly into the stomach or small intestines through either gastric, duodenal or jejunal tubes and parenteral nutrition which involves supply of nutrients through intravenous routes (Dieticians Association of Australia, 2011; Smeltzer & Bare, 2004).

According to Vincent (2005), oral or enteral nutrition should be started within 24 to 48 hours of the patient's admission into ICU if not contraindicated (as in gut dysfunction) but Turner (2006), recommends that enteral nutrition should be started as early as within six hours of ICU admission if nutritional goals are to be reached. Parenteral feeding is only encouraged in such cases where enteral nutrition is contraindicated. This is because parenteral feeding is believed to increase the patient's risk of catheter related infections. However, parenteral feeding should be initiated within the same time if enteral and oral

feeding is contraindicated such as in cases of bowel obstruction, rupture or ischaemia of intestines (Turner, 2006). Feeding the patient early prevents bacterial translocation from the gut to the lymphatic system that is a major cause of sepsis and resultant multiple organ dysfunction in ICU (Baird, *et al.* 2005).

The benefits of optimal nutrition in the critically ill patients cannot be over-emphasized. It maintains gut function, provides necessary minerals and vitamins necessary for healing, it ensures supply of adequate energy needed to counteract the increased metabolic needs during illness and helps to boost the immune system. In a study by Khalid, Doshi and DiGiovine (2010), patients who were mechanically ventilated and on inotropic support and who received early enteral nutrition had 5.8% lower mortality rate than those who had late initiation of enteral nutrition (28.3%).

However, enteral nutrition may increase the risk of aspiration of gastric contents depending on its location especially in mechanically ventilated patients who are unconscious and in the supine position. This risk can be reduced by elevating the head of the bed 30 to 45 degrees, avoiding bolus feeding and practicing post pyloric feeding whenever possible (Schell and Puntillo, 2006). The critical care nurse should be able to closely monitor patients this position since it is associated with haemodynamic instabilities and should weigh the benefits against the risks of putting patients in semi fowler position.

Turner (2005) recommends that in order to assess tolerance of enteral nutrition, the nurse should aspirate every four hours and measure the aspirate. If the aspirated volume is less than 200mL, the feeding rate should be increased from 30ml/hour to 60ml/hour and that aspiration should be done every four hours. However, if the aspirate is more than 200ml, in Turner's opinion, it is a sign that a patient is not tolerating the feeding. The rate should be reduced to a minimum of 10ml if the aspirate remains more than 200ml over 24-48 hours and the doctor should be informed in order to prescribe drugs that promote gastric emptying or alternative ways of feeding while the patient is closely monitored for complications related to retention of feeds.

In order to ensure optimal nutrition to the patient, the enteral tube should be flushed to maintain patency. Smaller tubes are at a higher risk for occlusion and therefore should be flushed more frequently than large bore tubes (Dieticians Association of Australia,

2011).Critical care nurses should record feeding under the intake and should include the volume of water used for flushing. The volume of aspirate discarded should be totalled with the output.

2.5.8 Medical Devices

The use of medical equipment in ICU is essential and constitutes part of the daily care because patients in ICU have life threatening illnesses that call for high acuity interventions. However, there is a slight potential to malfunction or fail to work as expected and this may compromise patients' safety. One study carried out in the United Kingdom identified all the adverse events related to equipment that were reported to the National Patient Safety Agency in that country. 8.45% of all the incidents reported from 151 ICU and high dependency units were attributable to medical equipment with the majority (18.1%) of the events relating to infusion pumps (Thomas & Galvin, 2008). In that study, the incidences related to infusion pumps included; failure of the pumps, unavailability of pumps, incorrect use or setting, inadequate training and lack of proper cleaning. The numbers may not look 'worrying' but the effect of these on patients' outcome is significant.

2.6 SUMMARY

We therefore learn from all the above facts that patient's safety is a matter that cannot be overlooked in health care settings. It is in the hands of health care professionals to ensure that the course of a patient's treatment takes a positive route and that the outcome of care is in the best interest of the patient, relatives and profession. While nursing professionals provide the direct patient care and spend their time at the bed-side, some factors may cause them to deviate from their standards of care, guidelines or protocols that are necessary in aiding their patient's everyday care. The common deviations that can compromise patient's safety in ICU are often avoidable but as previously mentioned, inappropriate staffing is highly likely in the South African ICU considering the shortage of appropriately qualified staff.

Different categories of nurses are guided by their scope of practice but sometimes enrolled nurses find themselves allocated to work in ICU to overcome the challenge of staff

shortage. This in itself poses a risk to the patient as these nurses work beyond their scope of practice and require direct supervision from intensive care nurses. While supervision may be offered, circumstances in the ward like number of patients, acuity of patients and available number of nurses available to offer supervision may all affect care that the patient receives. This means that enrolled nurses may find themselves having to carry out certain procedures that require supervision on their own thus putting the patient at risk of errors.

This may also happen if appropriately a qualified nurse is in ICU just after completing the post-basic course without any relevant experience in the unit. With the staffing pattern that is questionable, patient's safety is the concern. Studies on patient's safety should therefore be carried out to gather data that helps in situation analysis and aid decision making towards appropriate staffing.

Patient care should be guided by tools that will eliminate any inconsistencies or trial and error approaches by health care professionals in ICU. These tools are called protocols and are developed to guide practice not to replace critical thinking abilities. In order for them to be relevant, they should be developed based on current evidence through credible research and should remain updated to fit what is latest in managing critical illness. They should also be accessible, acceptable, understandable and easy to apply in clinical practice in order to enhance compliance. Protocols should serve their purpose thus unit managers and clinical facilitators should make sure that protocols are not locked up in their lockers awaiting hospital and unit audits while nurses and other health care professionals know nothing about them.

CHAPTER THREE

RESEARCH DESIGN AND METHODS

3.1 INTRODUCTION

The previous chapter provided the available literature on this research topic. It highlighted what is already known about this topic in different areas. This chapter describes the research methodology. The research design, setting, population, sample and sampling and both the inclusion and exclusion criteria have also been presented. Data collection, the explanation of the research tool, its validity and reliability and ethical procedures followed in this study also form part of this chapter.

3.2 OBJECTIVES

To ensure consistency in the study, the objectives are repeated.

- To determine the incidence of protocol deviations that compromise patient safety in five ICUs in three months.
- To compare the incidence of protocol deviations that compromise patient safety in different domains of nursing care in the intensive care units.
- To compare the incidence of protocol deviations that compromise patient safety with the level of nursing expertise.

3.3 RESEARCH DESIGN

The research methods are defined as the systematic approach to the actual research process and include stages of planning, structuring, execution, population, sampling, data collection and analysis (Polit & Beck, 2012). The design and methods used in this study will be discussed.

3.3.1 Research Design

The research design is referred to as the whole plan for obtaining precise and valid answers to research questions (Polit & Beck, 2004). It determines what type of data will be

collected, how data will be obtained, appropriately tests hypotheses and eventually answers the research questions (Nieswiadomy, 2008). Research design can either be quantitative or qualitative. For this study, a quantitative design was chosen. Quantitative research is the study of phenomena that can be easily and precisely measured and quantified. It is often known for rigor and controlled designs (Polit & Beck, 2004). This research design is positivistic and uses a formal research instrument, that is, in this case, the Critical Nursing Situation Index to gather numeric data that was analysed with statistical tools to estimate the rate of incidence of protocol violations in intensive care units. This instrument is divided into eight subsets of constructs on nursing care and has a total of 84 items to be assessed. This eliminates the problem of including other safety constructs that are otherwise not relevant to critically ill patients.

The traditional positivism uses the scientific approach that supports the belief that reality exists in a fixed and orderly manner and can therefore be studied without bias (Polit & Beck, 2004). The approach was selected in this research because the researcher remains as objective as possible to avoid bias and acquire empirical evidence. This evidence was collected by means of non-experimental prospective design whereby the researcher did not introduce any intervention before or after data collection. The non-experimental research refers to the research design in which the researcher does not manipulate the independent variable but merely observes the relationship between variables (Polit & Beck, 2012). The researcher began with the level of expertise as the presumed cause of protocol violations and then progressed to assessing the occurrence of observable deviations from protocols that can compromise patients' safety. This is referred to as prospective design by Polit and Beck (2004).

Moreover, the study took place in a natural setting where the researcher had not manipulated the environment in any way. It was conducted in five selected ICUs

3.3.2 Research Setting

According to Polit and Beck (2004), a research setting is the 'physical location and conditions in which data collection takes place in a study'. The study was conducted at a tertiary referral hospital in Gauteng. Like other public sector hospitals, it serves the majority of the population. These patients, who are poor and have no medical aid cover,

are mainly non-South African citizens. Because of immigration, both legal and illegal, and disease burden in the country with HIV-related illnesses, the hospital beds are often fully occupied and sometimes patients may be turned away.

It provides highly specialized services with the Provincial government funding through Gauteng Provincial Treasury. This hospital is a tertiary referral hospital and is the main teaching hospital for the local Universities. It is a public sector hospital that has 1200 beds and of these, 39 are ICU beds with a nurse patient ratio of 1:1 (Hatchett, Langley & Schmollgruber, 2009). This amounts to a minimum of 39 nurses assigned to direct patient care per day in the intensive care units (n=5).

In this study, only the adult ICUs were used. These were Trauma ICU, Multidisciplinary ICU, Neurosurgical ICU, Cardiothoracic ICU and Coronary Care ICU. The ICU rooms vary in sizes and some are big rooms divided by curtains or screens in between the beds. Most of these ICUs implement strict visiting hours for patients' family and friends and only allow a certain number of visitors per patient at the time for infection control purposes. They also restrict children by age from visiting the critically ill patients. Data was collected during the weekdays between 07H00 and 16H00 in these ICUs without any intervention or manipulation by the researcher.

3.4 RESEARCH METHODS

3.4.1 Population and sample

Polit and Beck (2012) define population as the total number of people or elements that fit the specific set specifications of the study. The target population included all the patients in the five units who met inclusion criteria. A preliminary record review done in 2013 showed that over a period of three months, there were about 402 patients admitted in all ICUs. This is on average of 134 patients per month.

A sample is described as the subset of the whole population that is chosen to participate in the study (Polit & Beck, 2004), while sampling is the process of selecting a portion of the population to represent the entire population in the study (Polit & Beck, 2012). In research, it is important to carefully select the sampling technique and to decide how big the sample

should be in order to give the adequate, relevant, accurate and true representation of entire population. Sampling is necessary because sometimes it might not be practically possible to include the entire population due to limited resources like money, time and personnel. Sometimes it might just be practically impossible to include every single person in the study even if they meet inclusion criterion since not everybody volunteer to participate in the study. In this study, a non-probability, convenience sampling was used. Convenience sampling is the type of sampling whereby the researcher selects those participants or subjects that are readily available (Nieswiadomy, 2008).

Following discussion with a biomedical statistician, an adjusted sample size of 100 (n=100) was reached with a confidence level of 95% (1.96), margin of error of 5% and prevalence of 80%. This sample size was a representative sample where the results can be generalised to the population.

The sample size was calculated using a statistical formula of:

$$n^* = \frac{z^2 \times p(1-p)}{d^2}$$

Where n*=estimated sample size, z=confidence interval at 95% (1.96), p=estimated prevalence of patient's bed occupancy in selected ICUs 80% (0.8), d=margin of error at 5% (0.5).

This study considered only the five selected ICUs and in those units, only adult patients were included in the population. The inclusion criteria were all adult patients in ICUs who are aged 18 years and above in the units whose unit managers had given permission for researcher to enter. Furthermore, only the patients who had signed a written consent or whose relatives had signed on their behalf where necessary were included in the study.

3.4.2 Data Collection

Data collection is the process of gathering information to answer research questions (Polit & Beck, 2004). It should be done in such a manner that it conforms to the ethical and professional standards. It is one of the crucial steps in research since it provides the information needed to answer research questions. It should be done in an unhurried manner and should take in to account the inclusion and exclusion criteria. In this study, the data

collection was guided by the research instrument since patients' safety is a very broad topic. Data related to the eight constructs outlined in the research instrument as well as the nurses' and patients' demographic data was collected. Demographic information for the patients consisted of age, gender, Simplified Acute Physiological Score (SAPS II) and ICU length of stay while that of nurses assigned to care for the patient on the particular day of observations included the qualification and years of experience in ICU. Research codes were used to separate data from different ICUs. All the information gathered was recorded every day and every time during observations on the CNSI data collection tool created for this purpose.

3.4.3 Instrument

Research instrument is the tool or the device used to gather information that answers research questions (Polit & Beck, 2004). It guides the data collection process as it stipulates exactly what data is relevant in the study. The instrument used in this study consisted of two sections; section one consisted of six items that presented the clinical data on patients' age, gender, ICU length of stay and the Simplified Acute Physiology Score (SAPS II), the assigned nurses' qualifications and years of experience in ICU while section two consisted of 84 items of the Critical Nursing Situation Index.

The Critical Nursing Situation Index (CNSI) safety assessment was applied in the five selected ICUS over a period of three months. The index was developed by Binnekade in 2001 for use in adult intensive care units. It originates in the Netherlands at the Academic Medical Centre in Amsterdam which is a tertiary, university teaching hospital with 1030 beds 30 of which are ICU beds (Binnekade *et al.* 2001). The developer and colleagues assembled all the hospital's electronic standards and protocols and selected all the instructions for the nursing interventions from them. These were then translated into conformities and nonconformities in patients' care. Whenever possible, those deviations or nonconformities which implied risk to the patient were then translated into observable items. Of these observable items created, some were removed because they could not be answered with a 'true' or 'false'. After this step, the CNSI had 100 items formulated.

The 100 items were then evaluated by the selected nursing staff and 16 of the items were removed because they were not clear leaving the CNSI with only 84 items. It has been

adapted as part of the Patient Safety Management System in the Netherlands since 2005. The Critical Nursing Situation Index assesses the rate of occurrence of observable nursing errors, which may potentially lead to adverse events (Binnekade *et al.* 2001; Binnekade *et al.* 2003).

As mentioned earlier, it contains 84 observable situations divided into eight subsets of constructs; basic ICU nursing care (14 items), mechanical ventilation (20 items), intravenous lines (infusion and measurement; 10 items), administration of fluids (5 items), cardiac rhythm and circulation (8 items), medication (10 items), enteral nutrition (6 items) and hygienic care and control of parts and devices (11 items). Each item observed was scored as true (presence of critical situation), false (absence of critical situation) or not applicable in the treatment or care of the patient at the time of observation and review (Binnekade *et al.* 2001; Binnekade *et al.* 2003).

This instrument was selected because it has been used in the setting that is similar to the one in this study considering the number of hospital beds and the number of ICU beds available. Both the hospital where the instrument was first developed and the one in which this study was carried out are the tertiary and university teaching hospitals. The items developed in this instrument cover a wide range of basic nursing areas in ICU in short form and the deviations can be easily observed.

3.4.4 Validity and reliability of the instrument

The instrument has been evaluated for validity and reliability in assessing adherence to nursing protocols by the developer. “Reliability refers to the accuracy and consistency with which an instrument measures the target attribute”. (Polit & Beck, 2004:416). In the original study, the Critical Nursing Situation Index was assessed for inter-observer reliability by comparing two independent observers who simultaneously observed 840 items (10 patients), and there was high overall inter-observer agreement at $K=0.83$ (Binnekade *et al.* 2001).

“Validity is the ability of an instrument to gather the information that it is intended to gather” (Nieswiadomy, 2008:221). In order to test this instrument for validity, the developer and colleagues had hypothesized that CNSI would show that the short time that

the critical care nurse spends at the bedside leads to an increase in occurrence of incidences. Construct validity was derived from correlation between this less available nursing time and critical nursing situations and was considered statistically significant with relative risk of 1.36 and 95% confidence level (Binnekade *et al.* 2001, Binnekade *et al.* 2003).

The pre-testing procedure was carried out to test feasibility of the main study as well as determining any refinements to be considered in the main study (Burns & Grove, 2011).

3.4.5 Pre-testing

This is a small-scale trial that is conducted before the main study (Nieswiadomy, 2008). This was done to determine content and face validity to establish whether the instrument is suitable in the South African setting since it has only been used in the Netherlands. Five cases were randomly selected for the pre-testing procedure, one case from each one of the five selected ICUs. The results from the pre-test were not included in the main study as it was done test the feasibility of the study procedures. The researcher sought to also ensure correct interpretation of the CNSI items and to learn observation techniques in preparation for the main study.

3.4.6 Data collection Procedure

When the permission to undertake the study was granted by the relevant authorities, the researcher reported to the nurse in charge of the ward on a random day before starting the observations. The observations took place during the week days between 07H00 and 16H00. On arrival in the ward, the researcher introduced herself to the nurses and explained the study to be undertaken and asked for permission to observe nursing care. Then, those patients who met the inclusion criteria were identified. The nurses responsible for their care were then given the information about the study together with the consent forms to sign if they give permission to the researcher to observe the care rendered to patients.

The researcher then proceeded to the patient's clinical records. If the patient met the inclusion criteria, the researcher waited for the visiting hour to ask for consent from the

relatives. If the relatives were present during visiting hours, then an informed consent obtained from them but for the next day if the patient would still be in the unit since the visiting hours were only an hour before cut-off time for data collection. Data was then collected and recorded. It took approximately 10 minutes to complete the information on the instrument and on average; five assessments were done per day. Once the patient has been discharged to high-care, then the research followed them to explain the study and how their relatives gave consent on their behalf when they were in ICU. A new information sheet together with a consent form was given to them to sign if they give permission to researcher use their information in the study. Where the patient could not be found in high care unit or does not give consent, the data collected was destroyed and excluded from the study.

Patients' care in the specific ward during that day was observed. At least three record reviews and observations were done in the selected wards over a period of a month. The CNSI items were scored during day shifts based on information acquired from the patients' clinical records and observation of nursing care. If a patient was still in the ICU during the repeat data collection, he or she was observed more than once during stay in ICU but not more than once a day. Consent was sought every time data was collected from the relatives and the nurses.

The observations were made at the bedside and recorded on the data collection sheets. The nurses assigned to care for the patients were not questioned about the observed patients' care or condition. All the data collected was kept under lock and key at the Nursing Education Department to ensure confidentiality.

3.4.7 Data analysis

After collection and organisation, on Microsoft Excel spread sheet, data was analysed by use of STATA version 12. The data was verified by the Statistician at the Medical Research Council to ensure there were no errors. Descriptive tests including frequency, mean, percentages and standard deviations were used to create nurses' and patients' demographic data as well as the total scores from the research tool. Inferential tests used included Kruskal-Wallis and Cronbach's reliability coefficient. The statistical significance level was set at 0.05 ($p < 0.05$).

3.5 VALIDITY AND RELIABILITY OF STUDY

“Reliability refers to the accuracy and consistency of information obtained in a study and validity is the soundness of the study findings, that is, whether the findings are cogent, convincing and well grounded” (Polit & Beck 2004:35-36). In this study, validity and reliability were maintained by ensuring that the findings were accurate, unbiased and adequately represent the target population. Consistency was maintained in the sample selection and the researcher adhered to the inclusion and exclusion criteria predetermined. The study was done in accordance with the procedures and protocols of the Human Research Ethics Committee of the University of the Witwatersrand.

The instrument, that is, the Critical Nursing Situation Index used in this study had been used in intensive care unit and had been tested for validity and reliability in assessing adherence to protocols of nursing care. Moreover, it was adapted as part of the Patients Safety Management System in the Netherlands since 2005. The researcher was the only person collecting data to ensure consistency of the findings and the inclusion and exclusion criteria were adhered to at all times. The statistical analysis was done with the assistance of the biomedical statistician from the Medical Research Council (MRC) to ensure accurate interpretation and analysis of all data collected.

3.5 ETHICAL CONSIDERATIONS

According to Wood and Ross-Kerr (2011) most researchers are guided by the three principles of ethics thus, autonomy, beneficence and non-maleficence. The principle of autonomy has been applied in this research with the understanding that the individual patient has a right and freedom to decide whether to be included in this study or not. The principle of non-maleficence was also followed during this study as the researcher did not cause any harm to anyone in the hospital during the data collection period. The third principle of justice was also applied as the researcher considered all the ICUs as being equal and deserving equal consideration in the study.

- Permission to undertake the study was granted by the Human Research Ethics Committee and Postgraduate Committee of the University of Witwatersrand (**Appendix B**) after assessing the research proposal submitted to them by the researcher.

- The permission to use the Critical Nursing Situation Index was sought from the developer of the instrument in the form of writing and permission was granted through e-mail (**Appendix C**).
- The nurses in charge of the selected wards, nurses, patients and relatives were given the information letter (**Appendix D, D1, D2 and D3** respectively) that explains the purpose of the study and the procedure and also the consent forms (**Appendix E, E1, E2 and E3**) to sign if they accept that their wards be included in the study. The information letter explained clearly that nurses or nurses in charge of the units did not have the active part in the research. It also explained the right of the unit manager to withdraw consent anytime during data collection period without any penalties. The benefits that the research results were likely to bring to the units were also made clear. The steps that were followed to ensure anonymity and confidentiality during the entire period of study and thereafter were also explained.
- The letter of request for permission (**Appendix F**) was submitted to the hospital where the study was conducted to give permission to observe the nurse-patient interactions. The detailed letter explaining the research purpose, data collection procedure and instrument was submitted to the Chief Executive Officer of the hospital and the Director of Nursing Services at the hospital. Permission to undertake the study was granted in response (**Appendix F1**).
- Confidentiality and anonymity was maintained throughout the period of the study by not disclosing any real names of the hospital, the wards or people. The wards were identified by the use of research codes. All electronic data collected was saved on a password protected computer and the other data was kept under the lock and key at the Nursing Education Department and was accessed only by the researcher and supervisors.
- All the principles of ethics were followed during this study as the researcher did not cause any harm to anyone in the hospital during the data collection period. The principle of justice was also applied as the researcher considered all the ICUs as being equal and deserving equal consideration in the study.

3.6 SUMMARY

This chapter presented in detail the research methodology. The research design was carefully selected to appropriately meet the purpose and objectives. The instrument used for data collection has also been described in detail. This instrument successfully met the objectives and was also used for a pre-testing procedure at the main study site. The following chapter presents data analysis and research findings.

CHAPTER FOUR

RESULTS AND DISCUSSION OF FINDINGS

4.1 INTRODUCTION

This chapter describes how data was handled and analysed as well as providing the discussion of the results. After collection, raw data was organised on Microsoft Excel spread sheet. It was analysed by use of the statistical package “STATA” version 12. The data was verified by the Statistician at the Medical Research Council to ensure there were no errors. Descriptive tests including frequency, mean, percentages and standard deviations were used to create nurses’ and patients’ demographic data as well as the total scores from the research tool. Comparative tests used included Kruskal-Wallis and Cronbach’s reliability coefficient. The statistical significance level was 0.05 ($p < 0.05$). Findings will be discussed on construct and item levels.

This chapter provides the analysis of data using both descriptive and comparative statistical tests and how findings were interpreted.

4.2 APPROACH TO DATA ANALYSIS

Descriptive statistics were employed to interpret the demographic data of the patients which included age, gender, and length of stay in ICU and illness severity. Nurses’ demographic data included qualification and years of ICU experience. Frequency distributions and cross tables were used to provide an overall summary of the data. Percentages in these findings were rounded off to one decimal place.

Descriptive statistics were then employed to describe and synthesise the distribution of responses that are inclusive of eight domains of nursing: “basic ICU care (14 items), “care of mechanical ventilation” (20 items), “care of intravenous lines” (10 items), “administration of intravenous fluids” (5 items), “monitoring cardiac rhythm and circulation” (8 items), “administration of medication” (10 items), “enteral nutrition” (6 items) and “hygienic care and control of parts and devices” (11 items)”. The items are scored either “true” (presence of critical situation), “false” (the absence of critical

situation) or “not applicable” (where an item was not relevant in the care of the patient)”. The sum of observed items were added together to form the frequency of “true” (presence of critical situations) and “false” (absence of critical situation). The incidence rate was calculated by following the analytical methods as advocated by Binnekade *et al.* (2003). Frequency distributions and cross tables were used to provide an overall summary of the data.

The Cronbach’s reliability coefficient alpha was applied to assess the reliability of the rating scale composed of total item scores for construct variables. When comparing item scores the Kruskal Wallis test was applied to test for significance of differences in the mean scores of responses for construct variables. Testing was done on this level to further explore the data. When comparing categorical variables the response was like the latter, the Kruskal Wallis test was used to test for significance of differences in the frequencies of critical nursing situation responses (*true*) for eight construct variables and patient demographic (gender and age) and nurse demographic (qualification and years of ICU experience) variables. The application of the Kruskal Wallis one-way analysis of variance to the study was to compare **mean** ranked sum differences between responses of two or more independent variables on a continuous or ordinal dependent variable and used to determine where the differences in groups are occurring. The level of statistical significance was set at the level of $p < 0.05$. A biomedical statistician from the Medical Research Council analysed the data using the statistical package ‘STATA’ version 12.

4.3 RESULTS AND FINDINGS

4.3.1 Section One: Demographic Data of Patients

This section related to the participants demographic data, which comprised of four items. Items included: age, gender, length of ICU stay and severity of illness (SAPS II) score. This information was obtained by the researcher from the record review. A total of 100 (n=100) patients made up the sample size. Results of this process are summarized in **table 4.1**. Items were grouped together to allow ease of discussion.

Table 4.1 Demographic data for patient participants for the total sample (n=100)

Demographic data	Frequency	Percentage
Age		
19 to 29 years	19	19.0%
30 to 39 years	22	22.0%
40 to 49 years	15	15.0%
50 to 59 years	21	21.0%
60 to 69 years	13	13.0%
70 to 79 years	10	10.0%
Gender		
Male	62	62.0%
Female	38	38.0%
Length of ICU stay		
<7 days	78	78.0%
>7 to 14 days	15	15.0%
>14 to 21 days	3	3.0%
>21 days	4	4.0%
Illness severity score (SAPS II)		
4 to 19 points	20	20.0%
20 to 39 points	49	49.0%
40 to 59 points	31	31.0%

Males accounted for 62.0% (n=62) and females 38.0% (n=38) of the total patient sample (n=100). The majority (77.0%; n=77) were between the ages of 19 to 59 years, and 23.0% (n=23) were in the 60 to 79 age categories. A close majority (49.0%; n=49) had an illness severity score (SAPS II score) on admission to ICU between 20 to 39 points, and followed by 31.0% (n=31) and 20.0% (n=20) of patients in the categories of 40 to 59 and 4 to 19 points, respectively. Of the total sample (n=100), three quarters (78.0%; n=78) of patients had an average length of stay in ICU less than 7 days.

Expertise of Nurses

This section related to the expertise of nurses assigned to care for patient participants (n=100), which comprised of two items. Items included: qualification and years of experience in ICU. Results of this process are summarized in **table 4.2**.

Table 4.2 Expertise of nurses assigned to care for patient participants (n=100)

Demographic data	Frequency	Percentage
Qualification		
Intensive care nurse	38	38.0%
Professional nurse	50	50.0%
Enrolled nurse	12	12.0%
Years of experience in ICU		
1 to 5 years	52	52.0%
6 to 10 years	31	31.0%
11 to 15 years	14	14.0%
16 to 20 years	3	3.0%

Of the total sample (n=100) professional nurses accounted for 50.0% (n=50), and followed by 38.0% and 12.0% indicated in the categories of intensive care nurse and enrolled nurse, respectively. The majority (52.0%; n=52) had between one and five (1 to 5) years of experience in the intensive care units, followed by 31.0% (n=31), 14.0% (n=14) and 3.0% (n=3) in the category of 6 to 10, 11 to 15 and 16 to 20 years of intensive care unit experience, respectively. **Figure 4.1 displays** these results.

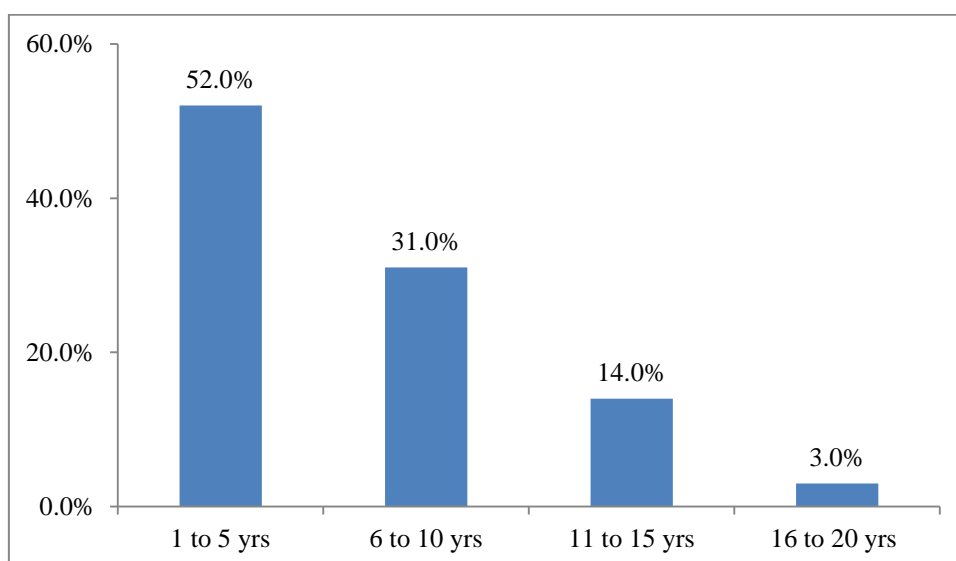


Figure 4.1 Nurses years of experience in ICU

4.3.2 Section Two: Critical Nursing Situation Index (CNSI)

This section comprised of 84 items to which responses were obtained by the researcher based on chart review and direct observation.

The total sample comprised of 100 (n=100) participants who were patients admitted to one of five intensive care units. The instrument used in this study is the Critical Nursing Situation Index (CNSI). The CNSI contains 84 observable situations subdivided into 8 sets (domains) of items: (i) basic ICU nursing care, (ii) care of mechanical ventilation, (iii) care of intravenous lines, (iv) administration of fluids, (v) monitoring of cardiac rhythm and circulation, (vi) administration of medication, (vii) care of enteral nutrition, and (viii) hygienic care and control of devices. The items are scored either “*true*” (presence of critical situation), “*false*” (the absence of critical situation) or “*not applicable*” (where an item was not relevant in the care of the patient)”. An overview of the results is displayed in **tables 4.3 to 4.10** for the total sample (n=100). Items were combined to form coherent groups to facilitate discussion of the data.

4.3.2.1 Basic ICU nursing care

Table 4.3 Summary of responses for items in the category of basic ICU nursing care

Item	Statement	Applicable				Not applicable	
		True		False		f	%
		f	%	f	%		
Q1	“No inventory of bacterial cultures upon transfer from another hospital.	4	4.0%	16	16.0%	80	80.0%
Q2	Bacterial culture delayed for more than 2 hours (despite written arrangement).	-	-	21	21.0%	79	79.0%
Q3	No risk of pressure sore assessment.	71	71.0%	29	29.0%	-	-
Q4	Entrance to the isolation room is not marked as such.	1	1.0%	10	10.0%	89	89.0%
Q5	Patient’s eyes are clearly contaminated.	2	2.0%	98	98.0%	-	-
Q6	Incorrect use of Glasgow Coma scale.	6	6.0%	94	94.0%	-	-
Q7	Patient is not mobilized according to instructions.	1	1.0%	99	99.0%	-	-
Q8	Patient’s position is not in arrangement with instructions.	-	-	100	100.0%	-	-
Q9	No defecation for more than 3 days, no intervention (day 4).	26	26.0%	38	38.0%	36	36.0%
Q10	No collection of urine production for assessment of fluid balance.	3	3.0%	97	97.0%	-	-
Q11	No records of earlier shift (48 hours).	-	-	100	100.0%	-	-
Q12	No records on family or relatives.	55	55.0%	45	45.0%	-	-
Q13	No records on patient’s length and body weight on the ICU chart (all ICU charts).	100	100.0%	-	-	-	-
Q14	No up-to-date temperature list (past 48 hours.”	-	-	100	100.0%	-	-

Out of 14 items in the category of “*basic ICU care*”, nine (9) items were scored as true, implying that a critical nursing situation was considered to be present. Out of these 9 items, the highest (100.0%; n=100) frequency protocol deviations was observed for “*No records on patient’s length and body weight on the ICU charts*” (item Q13), with contrast of 71.0% (n=71) for “*No risk of pressure sore assessment*” (item Q3), 55.0% (n=55) for “*No records on family or relatives*” (item Q12) and 26.0% (n=26) for “*No defecation for more than 3 days and no intervention on day 4*” (item Q9). **Table 4.3** displays these results.

4.3.2.2 Care of mechanical ventilation

Table 4.4 Summary of responses for items in the category of care of mechanical ventilation

Item	Statement	Applicable				Not applicable	
		True		False		f	%
		f	%	f	%		
Q15	“Discrepancy between registration and actual adjustment of mechanical ventilation.	1	1.0%	55	55.0%	44	44.0%
Q16	No hourly intrinsic PEEP during pressure control-led ventilation.	15	15.0%	6	6.0%	79	79.0%
Q17	No manual inflation according to protocol.	38	38.0%	2	2.0%	60	60.0%
Q18	No endotracheal suctioning according to protocol.	2	2.0%	53	53.0%	45	45.0%
Q19	No clear marking of changes in adjustments of mechanical ventilation.	3	3.0%	33	33.0%	64	64.0%
Q20	Relocation of endotracheal tube not according to protocol.	1	1.0%	-	-	99	99.0%
Q21	No blood gas sample taken within 1 hour after removal of endotracheal tube.	3	3.0%	2	2.0%	95	95.0%
Q22	Inhalation therapy during mechanical ventilation not in agreement with instructions.	-	-	1	1.0%	99	99.0%

Table 4.4 continued

Item	Statement	Applicable				Not applicable	
		True		False		f	%
		f	%	f	%		
Q23	Change patient's position not according to protocol.	-	-	53	53.0%	47	47.0%
Q24	Visible condensate between the tubal connection and the endotracheal tube.	16	16.0%	40	40.0%	44	44.0%
Q25	Condensate piled up in tubes.	-	-	56	56.0%	44	44.0%
Q26	Visible condensate in the heated wire (inspiration) tubes.	-	-	56	56.0%	44	44.0%
Q27	Humidifying system does not function (is switched off).	-	-	59	59.0%	41	41.0%
Q28	No pulse-oximetric and capnographic monitoring of patient in prone position.	-	-	-	-	100	100.0%
Q29	No connection to a closed endotracheal suction system of patient in prone position.	-	-	-	-	100	100.0%
Q30	No water set with connected oxygen tubing in basic ICU set-up (back-up in case of malfunctioning ventilator)	-	-	-	-	100	100.0%
Q31	No complete endotracheal suctioning system in basic ICU set-up.	-	-	60	60.0%	40	40.0%
Q32	No sterile solution for endotracheal flush in basic ICU set-up.	-	-	60	60.0%	40	40.0%
Q33	Incorrect flow adjustment during ventilation in assisted spontaneous breathing.	-	-	33	33.0%	67	67.0%
Q34	Maximum pressure adjustment of ventilation exceeds prescribed limits.”	-	-	26	26.0%	74	74.0%

Out of the 20 items in the “*care of mechanical ventilation category*”, eight (8) items were scored as true, implying that a critical care nursing situation was considered to be present. Out of these 8 items, the highest (38.0%; n=38) frequency protocol deviations was observed for “*No manual inflation according to protocol*” (item Q17), with contrast of 16.0% for “*Visible condensate between the tubal connection and the endotracheal tube*” (item Q24) and 15.0% (n=15) for “*No hourly intrinsic PEEP during pressure control-led ventilation*” (item Q16). **Table 4.4** displays these results.

4.3.2.3 Care of intravenous lines

Table 4.5 Summary of responses for items in the category of care of intravenous lines

Item	Statement	Applicable				Not applicable	
		True		False		f	%
		f	%	f	%		
Q35	“No record of introduction of central venous line.	-	-	72	72.0%	28	28.0%
Q36	No record of introduction of arterial line.	-	-	55	55.0%	45	45.0%
Q37	Swan-Ganz catheter in situ for more than 4 days.	-	-	-	-	100	100.0%
Q38	Central venous line in situ for more than 6 days.	16	16.0%	18	18.0%	66	66.0%
Q39	Arterial line in situ for more than 6 days.	7	7.0%	11	11.0%	82	82.0%
Q40	One or more (red) caps missing on arterial access.	2	2.0%	53	53.0%	45	45.0%
Q41	One or more caps missing on Swan Ganz catheter.	-	-	-	-	100	100.0%
Q42	One or more caps missing on peripheral line.	-	-	45	45.0%	55	55.0%
Q43	Empty flush bag in line pressure system.	-	-	56	56.0%	44	44.0%
Q44	Insufficient pressure on flush bag.”	37	37.0%	19	19.0%	44	44.0%

Out of 10 items in the category of “*care of intravenous lines*”, four (4) items were scored as true, implying that a critical care nursing situation is considered to be present. Out of

these 4 items, the highest (37.0%; n=37) frequency protocol deviations was observed for “*Insufficient pressure on flush bag*” (item Q44), with contrast of 16.0% (n=16) for “*Central venous lines in situ for more than 6 days*” (item Q38). **Table 4.5** displays these results.

4.3.2.4 Administration of fluids

Table 4.6 Summary of responses for items in the category of administration of fluids

Item	Statement	Applicable				Not applicable	
		True		False		f	%
		f	%	f	%		
Q45	“No 6-hourly assessment of fluid balance.”	100	100.0%	-	-	-	-
Q46	Packed cell is connected to the patient without PC number registration.	-	-	7	7.0%	93	93.0%
Q47	Packed cell bag is not checked and endorsed by a second nurse.	-	-	7	7.0%	93	93.0%
Q48	Flush system is not or incorrectly measured on the fluid balance of the ICU chart.	55	55.0%	2	2.0%	43	43.0%
Q49	Not all infusions of the patient are recorded on the ICU chart.”	1	1.0%	96	96.0%	3	3.0%

Out of 5 items in the category of “*administration of intravenous fluids*”, three (3) items were scored as true, implying that a critical care nursing situation was considered to be present. Out of the 3 items, the highest (100.0%; n=100) frequency protocol deviations was observed for “*No 6-hourly assessment of fluid*” (item Q45), with contrast of 55.0% (n=55) for “*Flush system is not or incorrectly measured on the fluid balance of the ICU chart*” (item Q48). **Table 4.6** displays these results.

4.3.2.5 Monitoring cardiac rhythm and circulation

Table 4.7 Summary of responses for items in the category of monitoring cardiac rhythm and circulation

Item	Statement	Applicable				Not applicable	
		True		False		f	%
		f	%	f	%		
Q50	“No routine ECG made on admission”	21	21.0%	79	79.0%	-	-
Q51	Arterial blood pressure not checked against sphygmomanometric pressure (past 24h).	49	49.0%	6	6.0%	45	45.0%
Q52	No haemodynamic profile made of a patient with a Swan-Ganz catheter.	-	-	-	-	100	100.0%
Q53	Incorrect monitoring of cardiac rhythm (frequency).	-	-	100	100.0%	-	-
Q54	Sound item for heart rhythm is permanently switched off.	2	2.0%	98	98.0%	-	-
Q55	Sound alarm for pressure curves is permanently switched off.	-	-	6	6.0%	94	94.0%
Q56	Alarm margins of heart rhythm and arterial pressure not adequately adjusted.	60	60.0%	40	40.0%	-	-
Q57	Reference point and pressure device not installed at correct height.”	6	6.0%	50	50.0%	44	44.0%

Out of 8 items in the “*monitoring of cardiac rhythm and circulation*” category, five (5) items were scored as true, implying that a critical care nursing situation was considered to be present. Out of these 5 items, the highest (60.0%; n=60) frequency protocol deviations was observed for “*Alarm margins of heart rhythm and arterial pressure not adequately adjusted*” (item Q56), with contrast of 49.0% (n=49) for “*Arterial blood pressure not*

checked against manual blood pressure (past 24 hours)” (item Q51) and 21.0% (n=21) for “No routine ECG made on admission” (item Q50). **Table 4.7** displays these results.

4.3.2.6 Administration of medication

Table 4.8 Summary of responses for items in the category of administration of medication

Item	Statement	Applicable				Not applicable	
		True		False		f	%
		f	%	f	%		
Q58	“Prescribed medications not administered or endorsed.	1	1.0%	99	99.0%	-	-
Q59	Prescribed IV medication for prolonged administration not connected.	-	-	54	54.0%	46	46.0%
Q60	Discrepancy between arterial and prescribed millilitre/hour for IV medication.	1	1.0%	54	54.0%	45	45.0%
Q61	Connected prolonged medication not recorded on chart.	-	-	55	55.0%	45	45.0%
Q62	Prepared IV medication not double-checked and endorsed according to protocol.	29	29.0%	55	55.0%	16	16.0%
Q63	No supportive continuous flush infusion in patients on cardiogenic medication.	7	7.0%	30	30.0%	63	63.0%
Q64	Unused lumen of infusion lines are not capped.	6	6.0%	41	41.0%	53	53.0%
Q65	Intravenous medication connected with wrong lumen.	-	-	81	81.0%	19	19.0%
Q66	Intravenous medication for solitary infusion combined with other medication.	-	-	-	-	100	100.0%
Q67	Intravenous medication with an intermittent flush instead of a continuous flush”	3	3.0%	60	60.0%	37	37.0%

Out of 10 items in the “*administration of medication*” category, six (6) items were scored as true, implying that a critical care nursing situation was considered to be present. Out of these 6 items, the highest 29.0% (n=29) frequency protocol deviations was observed for “*Prepared IV medication not double-checked and endorsed according to protocol*” (item Q62), with contrast of 7.0% (n=7) for “*No supportive continuous flush infusion on cardiogenic medications*” (item Q63) and 6.0% (n=6) for “*Unused lumen of infusion lines are not capped*” (item Q64). **Table 4.8** displays these results.

4.3.2.7 Enteral nutrition

Table 4.9 Summary of responses for items in the category of enteral nutrition

Item	Statement	Applicable				Not applicable	
		True		False		f	%
		f	%	f	%		
Q68	“No record of introduction of feeding tubes.	-	-	48	48.0%	52	52.0%
Q69	No retention measurement during gastric tube feeding.	3	3.0%	42	42.0%	55	55.0%
Q70	Intake of prescribed tube feeding less than 75% without specific reason.	-	-	45	45.0%	55	55.0%
Q71	Duodenal tube not flushed according to instructions.	-	-	-	-	100	100.0%
Q72	Change of tube feeding exceeds allowed time.	-	-	46	46.0%	54	54.0%
Q73	Patients in horizontal position while receiving gastric tube feeding.”	-	-	45	45.0%	55	55.0%

Out of 6 items in the category of “care of enteral nutrition”, one (1) item was scored as true, implying that a critical care nursing situation was considered to be present. In this study, there was a 3.0% (n=3) frequency protocol deviations for “*No retention measurement during gastric tube feeding*” (item Q69). **Figure 4.9** displays these results.

4.3.2.8 Hygienic care and control of devices

Table 4.10 Summary of responses for items in the category of hygienic care and control of devices

Item	Statement	Applicable				Not applicable	
		True		False		f	%
		f	%	f	%		
Q74	“Vacuum device of thoracic drain leaks air.	-	-	11	11.0%	89	89.0%
Q75	Water seal of thoracic drain device is missing or insufficient.	-	-	11	11.0%	89	89.0%
Q76	Inhalation devices not renewed according to protocol.	-	-	4	4.0%	96	96.0%
Q77	Closed endotracheal suction system not renewed according to protocol.	-	-	21	21.0%	79	79.0%
Q78	Mechanical ventilation equipment not changed according to protocol.	6	6.0%	55	55.0%	39	39.0%
Q79	Infusion system for total parental feeding not renewed according to protocol.	-	-	6	6.0%	94	94.0%
Q80	Bandage of central line not renewed according to protocol.	-	-	73	73.0%	27	27.0%
Q81	Bandage of arterial line not renewed according to protocol.	-	-	56	56.0%	44	44.0%
Q82	Intravenous and intra-arterial pressure lines not renewed according to protocol.	10	10.0%	53	53.0%	37	37.0%
Q83	Standard infusion systems are not renewed according to protocol.	3	3.0%	94	94.0%	3	3.0%
Q84	Bandages of introduction sites for infusion not renewed according to protocol.”	1	1.0%	80	80.0%	19	19.0%

Out of 11 items in the category of “*hygienic care and control of devices*”, four (4) items were scored as true, implying that a critical care nursing situation was considered to be

present. Out of these four items, the highest (10.0%; n=10) frequency protocol deviations was for “*Intravenous and intra-arterial pressure lines not renewed according to protocol*” (items Q82), with contrast of 6.0% (n=6) for “*Mechanical ventilation equipment not changed according to protocol*” (item Q78) and 3.0% (n=3) for “*Standard infusion systems are not renewed according to protocol*” (item Q83). **Table 4.10** displays these results.

4.3.3 Incidence Rate of Critical Nursing Situations (Protocol Deviations)

In this study data was observed from 100 observations. From these (100 x 84 =) 8400 items, 49.3% (n=4147) were at risk for a critical nursing situation (consequently 50.7% were not applicable). Of the 4147 items at risk 774 scored “*true*” resulting in an overall incidence rate of 18.7 critical care nursing situations per 100 items at risk. **Figure 4.1** displays these results.

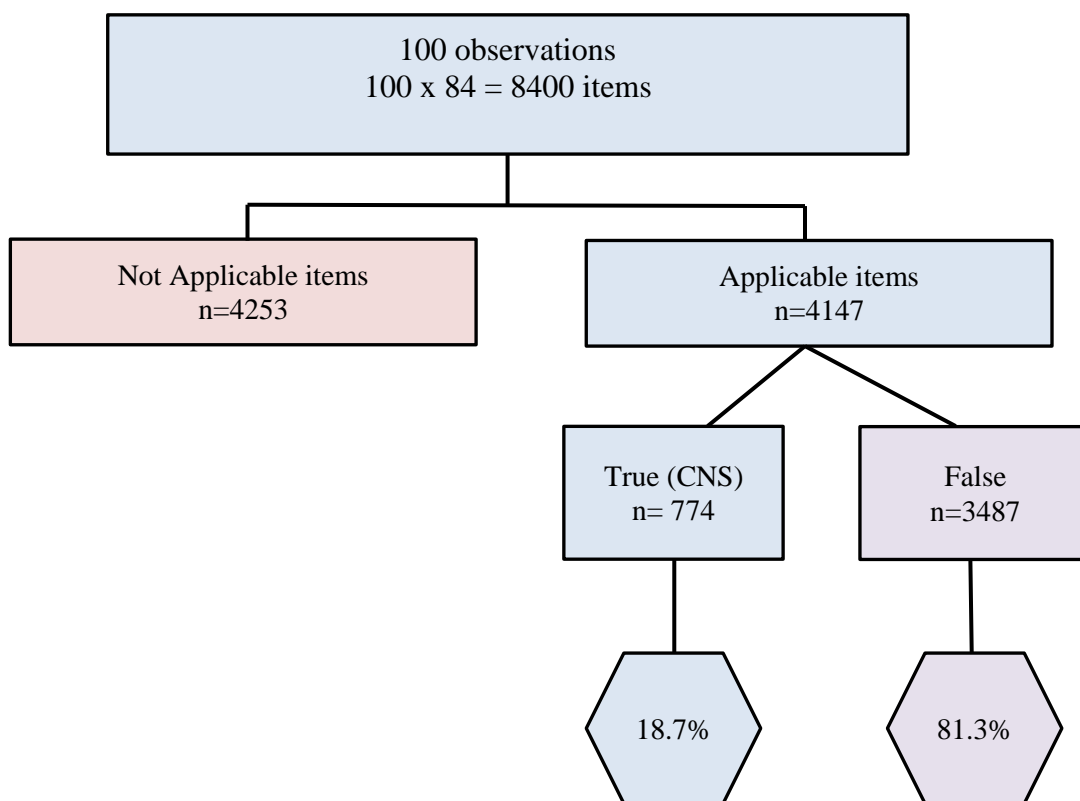


Figure 4.2 Incidence rate critical care nursing situations

The summary of scores for frequency of critical incidents by domains is presented in **table 4.11**.

Table 4.11 Summary of scores for frequency of critical incidents by domains

Domains	Applicable items			
	True	False	Sum true and false	Ratio of Risk
Basic ICU nursing care	269	847	1116	24.1%
Care of mechanical ventilation	79	598	677	11.7%
Care of intravenous lines infusion and measurement	62	329	391	15.9%
Administration of intravenous fluid	156	112	268	58.2%
Cardiac rhythm and circulation	138	379	517	26.7%
Medication	47	529	576	8.2%
Enteral nutrition	3	226	229	1.3%
Hygiene and control of devices	20	464	484	4.1%
Total scores	774	3484	4147	18.7%

Table 4.11 presents a summary of the frequency of critical incidents by domains. Based on computation of the ratio of risk (true/true + false results), a higher 58.2% (156/268) percentage was observed in the domain of “*administration of intravenous fluids*”, followed by 26.7% (138/517) and 24.1% (269/1116) in the cardiac rhythm and circulation and basic ICU care categories respectively.

Further, a low 4.1% (20/484) and 1.3% (3/229) ratio of risk for frequency of nursing errors was observed in the domains of “*hygiene and control of devices*” and “*enteral nutrition*” respectively.

4.3.4 Comparative Statistics

Construct scores and total item scores were of interest for further analysis to compare results with categorical variables. Cronbach’s alpha summative rating scale was used and the sum of construct scores and individual item scores were used. Results of this process are summarised in **table 4.12**.

Table 4.12 Summary Cronbach's reliability coefficient for the domains

Domains	Number of items in scale	Average inter-item correlation	Scale reliability coefficient
Basic ICU nursing care	10	0.0815	0.470
Mechanical ventilation	17	0.4408	0.931
Intravenous lines (infusion and measurement)	9	0.3221	0.811
Administration of fluids	4	0.2978	0.629
Cardiac rhythm and circulation	6	0.0616	0.283
Medication	9	0.2345	0.734
Enteral nutrition	5	0.9544	0.991
Hygienic care and control of parts and devices	10	0.1552	0.648
Scale reliability coefficient	72	0.1340	0.918

Findings were based solely on the reliability coefficient, and 12 items were omitted to maximise reliability of the coefficient alphas. Findings yielded a Cronbach's alpha of 0.918 for the overall CNSI scale. These findings meet the standard 0.80 to 0.85 for reliability (Polit & Beck, 2008), they suggest a positive relationship exists between the variables of the total item scores. Convergent reliability correlations, however were low to moderate, indicating minimal shared variance among the subscales as construct scores ranged from 0.283 to 0.991 with only three (mechanical ventilation, intravenous lines and enteral nutrition) meeting the standard for reliability. Results of this process are summarised in **table 4.12**.

4.3.4.1 Patient age and gender

Measurement of central tendency and variation (mean and standard deviation) were used to summarise the data. Findings for selected patient participant demographic categorical variables are discussed in the next section. Summary of the mean scores for comparison of domain scores with gender sub-categories is provided in **table 4.13**.

Table 4.13 Comparison of scores for domains by gender sub-categories

Domain	Female			Male		
	n	Mean	SD	n	Mean	SD
Basic ICU care	38	17.7	7.4	62	20.2	6.7
Mechanical ventilation	38	3.9	4.5	62	4.0	4.2
Intravenous lines	38	6.3	7.9	62	6.1	7.8
Administration of fluids	38	30.5	10.1	62	31.6	10.6
Cardiac rhythm	38	36.3	17.3	62	36.8	14.1
Medication	38	5.3	7.6	62	4.5	6.4
Enteral nutrition	38	-	-	62	0.8	3.6
Hygiene and device control	38	1.4	3.4	62	2.3	5.9

Table 4.13 presents the summary of scores for comparison of the domains by gender categories (male and female). Of the total sample (n=100) the mean score for “*monitoring cardiac rhythm and circulation*” was a higher 36.8 (SD 14.1; n=62) for males, with contrast of 36.3 (SD 17.3; n=38) in the female group. Similarly, the mean score for “*administration of intravenous fluids*” was a higher 31.6 (SD 10.6; n=62) for males, with contrast of 30.5 (SD 17.3; n=38) in the female group. The mean score for “*basic ICU care*” was a higher 20.2 (SD 6.7; n=62) for males, with contrast of 17.7 (SD 7.4; n=38) in the female group. The mean score for “*hygiene care and device control*” was a higher 2.3 (SD 5.9; n=62) for males, with contrast of 1.4 (SD 3.4; n=38) in the female group. In addition, the mean score for “*care of mechanical ventilation*” was a marginally higher 4.0 (SD 4.2; n=62) for males, with contrast of 3.9 (SD 4.5; n=38) in the female group.

Further the mean score for “*care of intravenous lines*” was a higher 6.3 (SD 7.9; n=38) for females, with contrast of 6.1 (SD 7.8; n=62) in the male group. The mean score for “*medication administration*” was a higher 5.3 (SD 7.6; n=38) for females, with contrast of 4.5 (SD 6.4; n=62) in the male group.

Based on observed difference in the mean scores the sub-groups for gender, the domain scores were then tested to determine whether they were significant or not. The Kruskal Wallis rank test was employed to proportionate the data by categorical variables.

Table 4.14 Summary of Kruskal-Wallis test for gender by the domains

Domains	Female		Male		Kruskal Wallis test p-value
	n	Rank Sum	n	Rank Sum	
Basic ICU care	38	1686.00	62	3364.00	0.084*
Mechanical Ventilation	38	1898.00	62	3152.00	0.872
Intravenous lines	38	1938.00	62	3112.00	0.880
Administration of fluids	38	1864.00	62	3186.00	0.652
Cardiac rhythm	38	1895.00	62	3155.00	0.852
Medication	38	1966.00	62	3084.00	0.698
Enteral Nutrition	38	1862.00	62	3188.00	0.171
Hygiene and device control	38	1900.00	62	3150.00	0.832

Key: * = statistical significance

The relationship between the male and female groups ranked median scores was investigated using the Kruskal Wallis test (**Table 4.14**). Based on the results of this study, there was a statistically significant difference for “basic ICU care” between the male and female groups ($p=0.084$), with a median rank sum of 3364.00 for the male group and 1686.00 for the female group. All other domains show no statistically significant differences, which suggests the groups were similar with respect to these subscales.

Data were then further explored to determine whether there was a difference in mean scores of the domains by age. The Kruskal Wallis test was employed to provide the statistic. Testing was done at the 0.05 level of significance.

Table 4.15 Summary statistics for comparison of gender sub-categories by age

	Female		Male		Kruskal-Wallis test p-value
	n	Rank sum	n	Rank sum	
Age	38	2054.50	62	2995.50	0.336

The relationship between male and female groups ranked median scores was further investigated by age using the Kruskal Wallis test (**Table 4.15**). Based on the results of this study, there was no statistically significant difference in mean scores between groups by age, which suggests the male and female groups were similar with respect to age.

4.3.4.2 Expertise of nurses

Measurement of central tendency and variation (mean and standard deviation) were used to summarise the data. Findings for selected nursing expertise categorical variables are discussed in the next section. Summary of the mean scores for comparison of domain scores with nursing qualification categories is provided in **table 4.16**.

Table 4.16 Comparison of scores for domains by nursing categories

Domains	Nursing Qualifications								
	Enrolled nurse			Intensive care nurse			Professional nurse		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
Basic ICU nursing	11	18.8	8.0	38	19.0	6.3	51	19.5	7.4
Mechanical ventilation	11	4.5	5.7	38	4.7	4.2	51	3.2	4.0
Intravenous lines	11	3.6	9.2	38	7.4	8.9	51	5.5	6.4
Administration of fluids	11	23.6	8.1	38	32.1	9.9	51	32.2	10.6
Cardiac Rhythm	11	43.6	12.1	38	36.8	17.1	51	34.9	14.3
Medication	11	4.5	9.3	38	6.1	6.4	51	3.9	6.7
Enteral nutrition	11	-	-	38	0.4	2.7	51	0.7	3.3
Hygiene and device control	11	-	-	38	1.4	3.4	51	2.9	6.4

Table 4.16 presents the summary of scores for the domains by nursing categories (enrolled nurse, intensive care nurse and professional nurse). Of the total sample (n=100) the mean score for “*basic ICU nursing care*” was a higher 19.5 (SD 7.4; n=51) in the **professional nurse group**, with contrast of 19.0 (SD 6.3; n=38) and 18.8 (SD 8.0; n=11) in the intensive care nurse and enrolled nurse groups, respectively. Similarly, the mean score for “*administration of intravenous fluids*” was a higher 32.2 (SD 10.6; n=51) in the professional nurse group, with contrast of 32.1 (SD 9.9; n=38) and 43.6 (SD 12.1; n=11) in the intensive care nurse and enrolled nurse groups, respectively. The mean score for “*hygiene care and device control*” was a higher 2.9 (SD 6.4; n=51) in the professional nurse group, with contrast of 1.4 (SD 3.4; n=38) in the intensive care nurse group. The

mean score for “*enteral nutrition*” was a higher 0.7 (SD 3.3; n=51) for the professional nurse group, with contrast of 0.4 (SD 2.7; n=38) in the intensive care nurse group.

The mean score for “*care of mechanical ventilation*” was a higher 4.7 (SD 4.2; n=38) in the **intensive care nurse group**, with contrast of 4.5 (SD 5.7; n=11) and 3.2 (SD 4.0; n=51) in the enrolled nurse and professional nurse groups, respectively. Similarly, the mean score for “*care of intravenous lines*” was a higher 7.4 (SD 8.9; n=38) in the intensive care nurse group, with contrast of 5.5 (SD 6.4; n=51) and 3.6 (SD 9.2; n=11) in the professional nurse and enrolled nurse groups, respectively. The mean score for “*medication administration*” was a higher 6.1 (SD 6.4; n=38) for the intensive care nurse group, with contrast of 4.5 (SD 9.3; n=11) and 3.9 (SD 6.7; n=51) in the enrolled nurse and professional nurse groups, respectively.

Further the mean score for “*monitoring cardiac rhythm and circulation*” was a higher 43.6 (SD 12.1; n=11) in the **enrolled nurse group**, with contrast of 36.8 (SD 17.1; n=38) and 34.9 (SD 14.3; n=51) in the intensive care nurse and professional nurse groups, respectively.

Data were analysed to determine whether the difference in the mean scores were statistically significant by nursing categories. The Kruskal Wallis test was employed to proportionate the data by three sub-categories.

The summary of Kruskal Wallis test for the domains by nursing categories is presented in **table 4.17**.

Table 4.17 Summary of Kruskal-Wallis test for the domains by nursing categories

Domain	Nursing Qualifications						Kruskal Wallis test p-value
	Enrolled nurse		Intensive care nurse		Professional nurse		
	n	Rank Sum	n	Rank Sum	n	Rank Sum	
Basic ICU	11	518.50	38	1908.50	51	2623.00	0.897
Mechanical ventilation	11	565.00	38	2139.00	51	2346.00	0.201
Intravenous lines	11	408.50	38	2032.00	51	2609.00	0.179
Administration of fluids	11	352.00	38	2012.00	51	2685.00	0.035*
Cardiac rhythm	11	698.50	38	1904.00	51	2447.00	0.212
Medication	11	502.50	38	2163.50	51	2384.00	0.129
Enteral nutrition	11	539.00	38	1912.00	51	2599.00	0.778
Hygiene and device control	11	467.00	38	1900.00	51	2682.00	0.253

Key: * = statistical significance

The relationship between nursing groups ranked median scores was investigated using the Kruskal Wallis test (**Table 4.17**). Based on the results of this study, **there was a statistically significant difference for “administration of intravenous fluids” between the professional nurse, intensive care nurse and enrolled nurse groups p=0.035**), with a median rank sum of 2685.00 for the professional nurse group, 2012.00 for the intensive care nurse group and 352.00 for the enrolled nurse group. All other domains showed no statistically significant differences, which suggests there is no cause to suggest that the groups were different with respect to these subscales.

Data were then further explored to determine whether there was a difference in mean scores by nursing sub-categories and years of experience. The Kruskal Wallis test was employed to provide the statistic. Testing was done at the 0.05 level of significance.

The summary of Kruskal-Wallis test for years of experience by nursing categories is presented in **table 4.18**.

Table 4.18 Summary of Kruskal-Wallis test for years of experience by nursing categories

Variable	Nursing Qualifications						Kruskal-Wallis test p-value
	Enrolled nurse		Intensive care nurse		Professional nurse		
	n	Rank Sum	n	Rank Sum	n	Rank Sum	
Years of experience	11	296.50	38	2787.00	51	1966.50	0.000*

Key: * = statistical significance

The relationship between nursing groups ranked median scores was further investigated by years of experience using the Kruskal Wallis test (**Table 4.18**). Based on the results of this study, **there was a statistically significant difference between intensive care nurse groups, professional nurse groups and enrolled nurse groups (p=0.000)**, which suggests the groups were different with respect to years of intensive care nursing experience.

4.4 DISCUSSION OF MAIN FINDINGS

The purpose of this study was to assess observable deviations from protocols and standards of care in different domains of nursing care and to compare the deviations with the level of nursing expertise in five ICUs of one academic hospital in Gauteng, in order to make situation analyses and formulate strategies to prevent errors and to ensure quality of care for safety of patients.

The distribution of the patient sample, revealed males accounted for 62.0% (n=62) and females 38.0% (n=38) of the total sample (n=100). More than three-quarters (77.0%; n=79) of the sample were in the 19 to 59 age group, implying in terms of age distribution this is a young ICU patient population. A close majority (49.0%; n=49) of patients had an illness severity level between 20 to 39 points on admission to ICU, followed by 31.0% (n=31) and 20.0% (n=20) of patients in the categories of 40 to 59 and 4 to 19 points, respectively. On average three-quarters (78.0%; n=78) of the patients spent less than 7 days in ICU. The distribution of sample is similar to previously published studies by Binnekade *et al.* (2001), Binnekade *et al.* (2003) and Te Beest *et al.* (2012).

In addition, the majority (50.0%; n=50) of nurses assigned to care for these patients were professional nurses, followed by 38.0% (n=38) and 12.0% (n=12) of nurses in the categories of intensive care nurse and enrolled nurses, respectively. Most (52.0%; n=52) of the nurses had between 1 to 5 years of ICU nursing experience. The distribution of sample is similar to previously published studies locally by Perrie *et al.* (2014), Langley, Kisorio and Schmollgruber (2014) and Klopper, Coetzee, Pretorius and Bester (2012).

In this study, the *first objective* was to determine the incidence of protocol deviations that compromise patient safety in five ICUs in three months.

The data in this study was collected from 100 observations. From these 8400 items, a close majority 49.3% (n=4147) were at risk for a critical nursing situation (consequently 50.7% were not applicable). Out of the 4147 items at risk 774 scored “true” resulting in an overall incidence rate of 19 critical nursing situations per 100 items at risk. This is lower than an incidence rate of 13 and 12 critical nursing situations per 100 items at risk reported in the studies of Binnekade *et al.* (2001) and Te Beest *et al.* (2012), respectively. One other study found an overall incidence of critical nursing situations resulted in 18 per 100 items at risk (De Neef, *et al.* 2009). It would therefore seem that the incidence rate reported in this current study would be considered high in these intensive care settings.

The *second objective* was to compare the incidence rate of protocol deviations that compromise patient safety in different domains of nursing care in the intensive care units.

Findings in this current study revealed the incidence rate of critical nursing situations was not found to be equal for all items. For example, a higher 58.2% safety risk was observed in items related to the domain of “*administration of fluids*”, followed by 26.7% and 24.1% safety risk in the “*cardiac rhythm and circulation*” and “*basic ICU nursing care*” domains, respectively. This is higher than 5%, 14% and 21% reported in the study of Binnekade *et al.* (2003) in items related to the domains of “*administration of fluids*”, “*cardiac rhythm and circulation*” and “*basic ICU nursing care*”, respectively.

Findings from the **individual item analysis revealed the highest frequency of deviation from nursing care protocols** related to the domain of “*basic ICU nursing care*” was indicated as 100%, in item Q13 and, stated as, “*No recording of patients length and body*

weight on the ICU charts". There is a safety risk that tidal volume will be overestimated and lead to loss of protective ventilation when patients' length and weight is not documented on the ICU chart (L'her, Martin-Babau & Lellouche, 2016). In this current study, a high frequency deviation from nursing care protocols was indicated as 71%, in item Q3 and, stated as, "*No risk of pressure sore assessment*". There is a safety risk that pressure sores will not be staged for intervention when skin assessment is not documented according to protocol (Cooper, 2013). Another high frequency of deviation from nursing protocols in this current study was indicated as 55%, in item Q12 and, stated as, "*No records on family or relatives on ICU charts*". There is a safety risk that family members critical care needs (information, reassurance, proximity, comfort and support) will not be achieved through communication (Elliott *et al.*, 2012).

The highest frequency of deviation from nursing care protocols related to the domain of "*mechanical ventilation*" was indicated as 38%, in item Q17 and, stated as, "*No manual inflation according to protocol*". There is a safety risk of airway plugging and may lead to infection when manual hyperinflation is not implemented according to protocol (Paulus, Binnekade, Vroom & Schultz, 2012). In this current study, a high frequency deviation from nursing care protocols was indicated as 16%, in item Q24 and, stated as "*Visible condensate between the tubal connection and the endotracheal tube*". There is a safety risk of infection when visible condensate in the tubing is not removed or discarded and flows towards the patient (Coyer *et al.*, 2007). This plays a major role in the pathogenesis of ventilator-associated pneumonia (Nseir, Zerimech, Jaillette, Artu & Balduyck, 2011). Another high frequency of deviation from nursing care protocols was indicated as 15%, in item Q16 and, stated as "*No hourly intrinsic PEEP during pressure control-led ventilation*". There is a safety risk that tidal volume will be lost and not detected when intrinsic PEEP is not documented during pressure control-led ventilation (Reddy, 2005).

In this current study, the highest frequency of errors related to the domain of "*care of intravenous lines*" was indicated as 37% in item Q44, and stated as, "*Insufficient pressure on arterial flush bag*". There is a safety risk of arterial line blockage when the pressure filled transducer flush system is not adequately inflated (Elliott, *et al.*, 2012). In this current study, a high frequency deviation from nursing care protocols was indicated as 16%, in item Q38 and, stated as, "*Central venous line in situ for more than 6 days*". There is a safety risk of infection when the central venous line is not changed according to

protocol (Centre for Diseases Control, 2011). This plays a major role in central line associated bloodstream infection (CLABSI). Similarly, another high frequency deviation from nursing care protocols was indicated as 7%, in item Q39 and, stated as, “*Arterial line in situ for more than 6 days*”. There is a safety risk of infection when the arterial line is not changed according to protocol (Centre for Diseases Control, 2011).

The highest frequency of deviation from nursing care protocols related to the domain of “*administration of fluids*” was indicated as 100%, in item Q45 and, stated as “*No 6-hourly assessment of fluid balance on ICU chart*”. There is a safety risk of calculation error in fluid balance when 6-hrly fluid balance is not documented (Diacon & Bell, 2014). Another high frequency deviation from nursing protocols was indicated as 55%, in item Q48 and, stated as, “*Flush system is not or incorrectly measured on the fluid balance of the ICU chart*”. There is a safety risk of incorrectly calculated fluid balance that may lead to inappropriate fluid management (Diacon & Bell, 2014).

The highest frequency of deviation from nursing care protocols related to the domain of “*cardiac rhythm and circulation*” was indicated as 60%, in item Q56 and, stated as, “*Alarm margins of heart rhythm and arterial pressure not adequately adjusted*”. There is a safety risk because heart rhythm and arterial pressure limits are not set appropriately and any changes in the patient parameters will occur without being noticed (Binnekade *et al.*, 2001). Similarly, a high frequency deviation from nursing care protocols was indicated as 49%, in item Q51 and, stated as, “*Arterial pressure not checked against manual blood pressure in the past 24 hours*”. There is a safety risk of technology failure when intra-arterial blood pressure is not documented against a manual pressure (Elliott *et al.*, 2012). Another high frequency deviation from nursing care protocols was indicated as 21%, in item Q50 and, stated as, “*No routine ECG made on admission of the patient to ICU*”. There is a safety risk that standard cardiac monitoring is assessed via a limited view (3-leads) when a routine 12-lead ECG is not made on admission of the patient to ICU (Couchman *et al.* 2007; Elliott *et al.*, 2012).

The highest frequency of deviation from nursing care protocols related to the domain of “*administration of medication*” was indicated as 29%, in item Q62 and, stated as, “*Prepared IV medication not double checked and endorsed according to protocol*”. There is a safety risk of medication errors when drug preparations are not double checked and the

dose and rate of the required infusion is not checked against the protocol (Burdeau *et al.*, 2006; Valentin *et al.* 2006). Similarly, a high frequency deviation from nursing care protocols was indicated as 7%, in item Q63 and, stated as “*No supportive continuous flush infusion in patients on cardiogenic medication*”. There is a safety risk of medication error by altering the drug effect when cardiogenic medication is not administered by supportive flush infusion. Dose and rate of administration plays an important role in the pharmacological effect of cardiogenic medication (Elliott *et al.*, 2012). Another high frequency deviation from nursing care protocols was indicated as 6%, in item Q64 and, stated as, “*Unused lumen of infusion lines are not capped*”. There is a safety risk of infection when infusion lines are not capped or protected. This plays a major role in central line associated bloodstream infections (Center for Diseases Control, 2011).

In this study, the highest frequency of deviation from nursing care protocols related to the domain of “*enteral nutrition*” was indicated as 3%, in item Q69 and, stated as, “*No retention measurement during gastric tube feeding*”. There is a safety risk of lack of tolerance when gastric retention is not measured during gastric feeding (Turner, 2005). This plays a major role of malnutrition in critical illness because patients have increased metabolic requirements (Elliott *et al.*, 2012).

In this study, the highest frequency of deviation from nursing care protocols related to the domain of “*hygienic care and control of devices*” was indicated as 10%, in item Q82 and, stated as, “*Intravenous and intra-arterial pressure lines not renewed according to protocol*”. There is a safety risk when lines identified at high risk of central line bloodstream infection (CLABSI) are not renewed and documented according to protocol (Centre for Diseases Control, 2011). Similarly, a high frequency deviation from nursing protocols was indicated as 6%, in item Q78 and, stated as “*Mechanical ventilation equipment not changed according to protocol*”. There is a safety risk of infection (VAP) when ventilator tubing is no changed according to protocol. Another high frequency deviation from nursing care protocols was indicated as 3%, in item Q83 and, stated as, “*Standard infusion systems are not renewed according to protocol*”. There is a safety risk of central line bloodstream infections (CLABSI) when infusion systems are not renewed and documented.

In this current study, a low 4.1% and 1.3% ratio of risk for frequency of errors was found for items related to the domains of “*hygienic care and control of devices*” and “*enteral nutrition*”, respectively. These findings suggest overall lower safety risk for the patient in the present study compared to previous studies. In one study, Binnekade *et al.* (2001) reported the safety risk of 7% and 14% in the domains of “*hygienic care and control of devices*” and “*enteral nutrition*”, respectively.

In this current study, **an individual item analysis revealed the lowest frequency of deviation from nursing care protocols** related to the domain of “*basic ICU nursing care*” was indicated as !%, in item Q7 “*Entrance to the isolation room is not marked as such*”. There is a safety risk of infection and cross infection when entrance to an isolation room is not marked as such. The lowest frequency of deviation from nursing care protocols related to the domain of “*mechanical ventilation*” was indicated as 1%, in item Q15 and, stated as, “*Discrepancy between registration and actual adjustment of mechanical ventilation*”. There is a safety risk of technology failure when mechanical ventilation changes are not documented.

Similarly, the lowest frequency of deviation from nursing care protocols related to the domain of “*care of intravenous lines*” was indicated as 2%, in item Q40 and, stated as, “*One or more (red) caps missing on arterial access*”. There is a safety risk of inadvertent medication administration error when arterial caps are missing. The lowest frequency of deviation from nursing care protocols related to the domain of “*administration of fluids*” was indicated as 1%, in item Q49 and, stated as, “*Not all infusions of the patient are recorded on the ICU charts*”. There is a safety error of miscalculation of fluid balance when infusions are not documented. The lowest frequency of deviation from nursing care protocols related to the domain of “*cardiac rhythm and circulation*” was indicated as 2%, in item Q54 and, stated as, “*Sound item for heart rate is permanently switched off*”. There is a safety risk because a heart rate rhythm disturbance could occur without being noticed.

Further, the lowest frequency of deviation from nursing care protocols related to the domain of “*administration of medication*” was indicated as 1%, in item Q60 and, stated as, “*Prescribed IV medication for prolonged administration not connected*”. There is a safety risk of infection when prescribed prolonged IV medication is not connected. The lowest frequency of deviation from nursing care protocols related to the domain of “*hygienic care*

and control of devices” was indicated as 1%, in item Q84 and, stated as, “*Bandages of introduction sites for infusion not renewed according to protocol*”. There is a safety risk of infection (CLABSI) when infusion sites are not documented for renewal.

When comparing the mean scores between gender of patients’ and inappropriate deviations from nursing care protocols, this study found the mean scores were higher in the category of males (62%; n = 62) than females (38.0%; n= 38) for “*cardiac rhythm and circulation*” (M = 20.2 vs. M = 17.7), “*administration of fluids*” (M = 31.6 vs. M = 30.5), “*basic ICU nursing care*” (M = 36.8 vs. M = 36.3), and “*hygiene care and device control*” (M = 2.3 vs. M = 1.4), respectively. Further, the mean score for “*intravenous lines*” was higher in the category of females than males (M = 6.3 vs. M = 6.1) and “*medication administration*” (M = 5.3 vs. M = 4.5).

When testing for significance between these groups the Kruskal Wallis test was used to provide the test statistic. The study found **a statistically significant difference for items related to the domain of “*basic ICU nursing care*” between male and female patient groups (p=0.084)**, with a high median rank of 3364 for the male group and a low 1684 for the female group, which suggests the groups median rank scores were different with respect to items related to “*basic ICU nursing care*”. **This means the male group had higher scores for inappropriate deviations in items related to the domain of “*basic ICU nursing care*”, when compared to, lower scores in the female patient group.**

In this study, the *third objective* was to compare the incidence of inappropriate deviations from nursing protocols with the level of nursing expertise.

When considering the level of nursing qualifications, this study found the mean score for inappropriate deviations from the nursing protocols was **higher in the category of professional nurse** (52.0%; n = 52) than intensive care nurse (38.0%; n = 38) and enrolled nurse (12.0%; n = 12) groups for items related to the domains of “*basic ICU nursing care*” (M = 19.5 vs. M = 19.0 and M = 18.8), “*administration of fluids*” (M = 32.2 vs. M = 32.1 and M = 23.6), “*hygienic care and control of devices*” (M = 2.9 vs. M = 1.4) and “*enteral nutrition*” (M = 0.7 vs. M = 0.4), respectively.

Similarly, the mean score for inappropriate deviations from the nursing protocols was **higher in the category of intensive care nurse** (38.0%; n = 38) than enrolled nurse (12.0%; n = 12) and professional nurse (52.0%; n = 52) groups for items related to domains of “*care of mechanical ventilation*” (M = 4.7 vs. M = 4.5 and M = 3.2), “*care of intravenous lines*” (M = 7.4 vs. M = 3.6 and M = 5.5) and “*medication administration*” (M = 6.1 vs. M = 4.5 and M = 3.9) , respectively.

Further, the mean score for inappropriate deviations from the nursing protocols was **higher in the category of enrolled nurse** (12.0%; n = 12) than intensive care nurse (38.0%; n = 38) and professional nurse (52.0%; n = 52) groups in the items related to the domain of “*cardiac rhythm and circulation*” (M = 43.6 vs. M = 36.8 and M = 34.9), respectively.

When testing for significance between these groups the Kruskal Wallis test was used to provide the test statistic. The study found a **statistically significant difference for items related to the domain of “administration of intravenous fluids” between the professional nurse, intensive care nurse and enrolled nurse groups (p=0.035)**, with a higher median rank sum of 2685.00 for the professional nurse group, when compared to low 2012.00 and 352.00 for the intensive care nurse and enrolled nurse groups, respectively, which suggests the groups median rank scores were different with respect to items related to the domain of “*administration of intravenous fluids*”. **This means the professional nurse group had higher scores for inappropriate deviations in items related to the domain of “administration of intravenous fluids”,** when compared to lower scores in the intensive care nurse and enrolled nurse groups.

When testing for significance between these groups the Kruskal Wallis test was used to provide the test statistic. The study found a **statistically significant difference in number of years of ICU nursing experience between intensive care nurse, professional nurse and enrolled nurse groups (p=0.000)**, with a higher median rank sum of 2787.00 for the intensive care nurse group, when compared to a low 1966.50 and 296.50 for the professional nurse and enrolled nurse groups, respectively, which suggests the groups median rank scores were different with respect to years of ICU nursing experience. **This means the intensive care nurse group had a higher number of years of ICU nursing experience,** when compared to, a low number in professional nurse and enrolled nurse groups.

4.5 SUMMARY

This chapter has presented the results of the study and the different statistical tests that were used. Tables were used to present the results in order to assist interpretation. Main findings were discussed in details. The following chapter will conclude the study by providing the summary of the study and the findings, as well as revealing limitations and making recommendations.

CHAPTER FIVE

SUMMARY, CONCLUSIONS, RECOMMENDATIONS AND LIMITATIONS

5.1 INTRODUCTION

This last chapter concludes the study by giving a brief summary of the study, the discussion of the main findings of the study, the recommendations for nursing clinical practice, nursing education, nursing management, further research and conclusions.

5.2 SUMMARY OF THE STUDY

5.2.1 Purpose of the study

The purpose of this study was to assess any observable deviations from protocols and standards of patients' care in different domains of nursing care and to compare the deviations with the level of nursing expertise in five ICUs of one Academic hospital in Gauteng in order to make recommendations for nursing practice, education and future research.

5.2.2 Objectives of the study

The objectives of the study were;

- To determine the incidence of protocol deviations from nursing protocols that compromise patients' safety in five ICUs in three months.
- To compare the incidence of protocol deviations that compromise patient safety in different domains of nursing care in the intensive care units.
- To compare the incidence of protocol deviations that compromise patient safety with the level of nursing expertise.

5.2.3 Methodology

Ethical clearance (M140876) was granted by Human Research Ethics Committee of the University of Witwatersrand (Appendix B) before data collection could commence. The

Chief Executive Officer and the Nursing Services Manager of the hospital also gave permission for the researcher to collect data at the hospital (Appendix F1). The five adult Intensive Care Units namely; Coronary care, Trauma, Neurosurgery, Cardiothoracic and Multidisciplinary ICUs were included in the study.

A pilot study was conducted in August 2015 consisting of five cases each from each ICU in order to test if the instrument would work in South African ICU setting. Data was collected between September and November 2015 by the use of the Critical Nursing Situation Index (**Appendix A**) developed by Binnekade (Binnekade *et al.*, 2001). It has 84 items that are divided into eight constructs of nursing care in ICU namely; Basic ICU nursing care (14 items), mechanical ventilation (20 items), intravenous lines (infusion and measurement; 10 items), administration of fluids (5 items), cardiac rhythm and circulation (8 items), medications (10 items), enteral nutrition (6 items) and hygienic care and control of parts and devices (11 items). The instrument was used with no alterations after a small pre-testing procedure and discussion with the experts in ICU in South African setting. The researcher used the quantitative non-experimental prospective design in order to answer research questions.

Data was analysed with the assistance of the Biostatistician from Medical Research Council and descriptive and comparative statistics were used. Statistical tests used included Kruskal-Wallis and Cronbach's reliability coefficient. The statistical significance level was 0.05 ($p < 0.05$).

5.3 SUMMARY OF RESEARCH FINDINGS

The purpose of this study was to assess any deviations from protocols and standards of patients' care in different constructs of nursing care and to compare the deviations with the level of nursing expertise in five ICUs of one Academic hospital in Gauteng. This was achieved by use of a Critical Nursing Situation Index. Demographic data of the patients (n=100) was collected.

The first and second objectives were to determine the incidence of protocol deviations that compromise patient safety and to compare the incidence of nursing protocol deviations in different domains of nursing care in intensive care units. The study's findings revealed out

of 4147 items at risk 774 scored “*true*” resulting in an overall incidence rate of 19 protocol deviations per 100 items at risk. A higher 58.2% safety risk was observed in items related to **administration of fluids**, followed by 26.7% and 24.1% safety risk for **cardiac rhythm and circulation** and basic ICU nursing care, respectively.

With regard to basic ICU nursing care, more than half of the deviations from protocols and standard care were in relation to recording patients’ length and body weight (100%, n=100), risk of pressure sore assessment (71%; n=71) and records of patient’s family or relatives (55%, n=55). These demonstrate that there was poor nursing care with regards to these areas.

This was followed by administration of fluids with more than half of the deviations observed in six hourly assessment of fluid balance (100%, n=100) and flush system omitted from fluid balance chart. The results demonstrate that while it is a possibility of variation in practice in relation to frequency of practice, the accuracy of the fluid balance was questionable as some fluids were omitted. Monitoring cardiac rhythm and circulation also showed 60% (n=60) of deviations with regards to adequately adjusting alarm margins of heart rhythm.

On the other hand, mechanical ventilation was associated with less frequent deviations (<50%) ranging from no manual inflation (38%, n=38) and visible condensate in the tubal connection and endotracheal tube. Nursing care was therefore better under this domain as compared to basic nursing care and administration of fluids. Similarly, there were less frequent deviations (<50%) in care of intravenous lines ranging from 37% (n=37) in relation to insufficient pressure on the flush bag to 16% (n=16) for central lines in situ for more than 6 days.

Medication administration were associated with even less deviations as lack of double-checking and endorsing demonstrated 29% (n=29) of the deviations. Hygienic care and control of devices and parts was the second last area with deviations demonstrated by 10% (n=10) of deviations observed in relation to failure to renew intravenous and intra-arterial lines. Enteral nutrition had the least frequent deviations as only 3% (n=3) of the deviations were observed for failure to measure retention.

Although the frequencies were not high in some of the areas of care, the effects of the deviation may have a great impact on the outcomes of care and therefore should be taken seriously.

The last objective was to compare the incidence of deviations with the level of nursing expertise and years of ICU nursing experience. The results revealed that there was a statistically significant relationship ($p=0.035$) in administration of fluids when the median rank scores were compared between three categories of nurses, whereby the professional nurse group had a higher (2685.00) score for protocol deviations in items related to administration of fluid, when compared to, lower score of 2012.00 and 352.00 for intensive care and enrolled nurse groups, respectively. In addition, the study found a statistically significant difference in years of ICU nursing experience between three categories of nurses ($p=0.000$), whereby the intensive care nurse group had a higher (2787.00) number of years of ICU nursing experience when compared to lower 1966.50 and 296.50 for professional nurse and enrolled nurse groups, respectively.

These results conveyed an understanding of the situation in ICUs with regards to patients' safety whereby it was hypothesized in this study that the level of expertise of nurses working in these units was directly related to occurrence of adverse events.

5.4 LIMITATIONS OF THE STUDY

The following are the limitations that are acknowledged by the researcher;

- The study was conducted at one public sector institution in five ICUs with a sample size of only 100 patients; therefore, the results cannot be generalized to other setting.
- Although the contents of the research tool were unknown to the nurses, the presence of the researcher may have influenced their nursing care. Moreover, for patient's safety, the unit managers were notified of the deviations that could be life threatening to the patient and such deviations were corrected thus affecting the results as the study was carried out over a long period of time.
- Only those nurses who were working during a day shift had their care observed.

- Although the Critical Nursing Situation Index was tested for reliability and validity, some of its items may not resemble the actual nursing care in the South African ICU setting.

5.5 RECOMMENDATIONS OF THE STUDY

5.5.1 Recommendations for Intensive Care Nursing Practice

The following recommendations for practice are made;

- There should be in-service training on regular basis that focuses on the basics of ICU nursing care such as patient assessment in order to keep nurses informed on the importance and components this practice.
- There should be up-to-date and evidence-based protocols and guidelines with regard to cardiovascular monitoring and alarm management and unit managers should ensure that nurses have access to them.
- There should be assessment of the accuracy and completeness of the patients' records in ICU to ensure that basic and much needed patient information is not omitted by the authorities.

5.5.2 Recommendations for Intensive Care Nursing Education

The following recommendations were made for education:

- Clinical facilitators should include the back to basics program in their in-service training which will include basic concepts such as patients assessment and risk identification, basic medications dispensing procedures, basic care of equipment and infection control in ICU
- Continued professional development programs should be in place and easily accessible to nurses to ensure that they have evidence-based knowledge.

5.5.3 Recommendations for Further Research

Further research is encouraged in the following areas;

- This study can be conducted in other hospital settings different from this one, either in private hospital or other public hospitals in the different regions.
- Further research is also recommended in the form of psychometric testing and a factor analysis with a larger sample, more diverse groups of critically ill patients are necessary, to further characterize the generalizability of the CNSI scale.
- Further research is also recommended determining what factors may affect nurse's adherence to the protocols and guidelines in this areas of patient care.

5.6 CONCLUSION

Basic ICU nursing care was the area of nursing care that was prone to deviations from standard care in this study. Most of the items here were related to patients and their immediate environment assessment and accurate and complete recording of patient information. Failure to assess patients holistically may lead to inefficient and inefficient care that may pose a risk to patient's safety. Nursing care in relation to administration was also found to be non-adherent to protocols as frequency and accuracy of fluid balance was not totally adhered to.

Alarm management was also found to be prone to deviations when it comes to their adequate adjustment. The importance of alarms in cardiovascular monitoring cannot be ignored if safety of patients is considered. The results may mean that the alarms were not set based on individual patient parameters for that time or that they were left on default values.

There was a statistically significant difference found between nursing qualifications their performance in administering fluids. This is believed to be a result of enrolled nurses showing lower mean scores under this domain of care. The results were not anticipated to show the difference only in this domain. It was expected that intensive care nurses and professional nurses will perform differently from enrolled nurses in all the domains in this highly specialised area of care.

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**PATIENTS SAFETY IN INTENSIVE CARE UNITS IN AN ACADEMIC HOSPITAL
IN GAUTENG**

DATA COLLECTION SHEET

SECTION A: PATIENT CLINICAL DATA

1.0 Code Number

2.0 Age of patient

3.0 Gender

4.0 Severity of illness (SAPS II Score)

5.0 Length of stay in ICU

6.0 Qualifications of primary nurse assigned to care

7.0 Years of ICU experience of assigned primary nurse

SECTION B: CRITICAL NURSING SITUATION INDEX

Item	Domain details	Critical Nursing Situation Index			Comments
		Applicable item		Non-applicable item	
		True	False		
	Basic ICU nursing care (14 items)				
1	No inventory of bacterial cultures upon transfer from another hospital				
2	Bacteria culture delayed for more than 2 hours (despite written arrangement)				
3	No risk of pressure sores assessment				
4	Entrance of the isolation room is not marked as such				
5	Patient's eyes are clearly contaminated				
6	Incorrect use of Glasgow Coma scale				
7	Patient is not mobilized according to instructions				
8	Patient's position is not in arrangement with instructions				
9	No defecation for more than 3 days, no intervention (day 4)				
10	No collection of urine production for assessment of fluid balance				
11	No records of earlier shift (48 hours)				
12	No records on family or relatives				
13	No records on patient's length and body weight on the ICU chart (all ICU charts)				
14	No up-to-date temperature list (past 48 hours)				
	Mechanical ventilation (20 Items)				
15	Discrepancy between registration and actual adjustment of mechanical ventilation				
16	No hourly intrinsic PEEP during pressure-control-led ventilation				
17	No manual inflation according to protocol				
18	No endotracheal suction according to protocol				
19	No clear marking of changes in adjustment of mechanical ventilation				
20	Relocation of endotracheal tube not according to protocol				
21	No blood gas sample taken within 1 h after removal of endotracheal tube				
22	Inhalation therapy during mechanical ventilation not in agreement with instructions				

23	Change patient's position not according to protocol				
24	Visible condensate between the tubal connection and the endotracheal tube				
25	Condensate piled up in tubes				
26	Visible condensate in the heated wire (inspiration) tubes				
27	Humidifying system does not function (is switched off)				
28	No pulse-oximetric and capnographic monitoring of patient in prone position				
29	No connection to a closed endotracheal suction system of patient in prone position				
30	No water set with connected oxygen tubing in basic ICU set-up (back-up in case of malfunctioning ventilator)				
31	No complete (and functioning) endotracheal suction system in basic ICU set-up				
32	No sterile NaCl solution for endotracheal flush in basic ICU set-up				
33	Incorrect flow adjustment during mechanical ventilation in assisted spontaneous breathing				
34	Maximum pressure adjustment of mechanical ventilation exceeds prescribed limits				
	Intravenous lines (infusion and measurement: 10 Items)				
35	No record of introduction of central venous line				
36	No record of introduction of arterial line				
37	Swan-Ganz catheter in situ for more than 4 days				
38	Central venous line in situ for more than 6 days				
39	Arterial line in situ for more than 6 days				
40	One or more (red) caps missing on arterial access				
41	One or more caps missing on Swan-Ganz catheter				
42	One or more caps missing on peripheral line				
43	Empty flush bag in line pressure system				
44	Insufficient pressure on flush bag				
	Administration of Fluids (5 Items)				
45	No 6-hourly assessment of fluid balance				

46	Packed cell bag is connected to the patient without PC number registration				
47	Packed cell bag is not checked and endorsed by a second nurse				
48	Flush system is not, or incorrectly, measured on the fluid balance of the ICU chart				
49	Not all infusions of the patient are recorded on the ICU chart				
	Cardiac Rhythm and Circulation (8 Items)				
50	No routine ECG made on admission				
51	Arterial blood pressure not checked against sphygmomanometric pressure (past 24h)				
52	No haemodynamic profile made of a patient with a Swan-Ganz catheter				
53	Incorrect monitoring of cardiac rhythm (frequency)				
54	Sound alarm for heart rhythm is permanently switched off				
55	Sound alarm for pressure curves is permanently switched off				
56	Alarm margins of heart rhythm and arterial pressure not adequately adjusted				
57	Reference point and pressure device not installed at correct height				
	Medication (10 Items)				
58	Prescribed medications not administered or endorsed				
59	Prescribed IV medication for prolonged administration not connected				
60	Discrepancy between actual and prescribed millilitre/hour for IV medication				
61	Connected prolonged IV medication not recorded on ICU chart				
62	Prepared IV medication not double-checked and endorsed according to protocol				
63	No supportive continuous flush infusion in patients on cardiogenic medication				
64	Unused lumina of infusion lines are not capped				
65	Intravenous medication connected with wrong lumen				
66	Intravenous medication for solitary infusion combined with other medication				

67	Intravenous medication combined with an intermittent flush instead of a continuous flush				
	Enteral nutrition (6 Items)				
68	No record of introduction of feeding tubes				
69	No retention measurement during gastric tube feeding				
70	Intake of prescribed tube feeding less than 75% without specific reason				
71	Duodenal tube not flushed according to instructions				
72	Change of tube feeding exceeds allowed time				
73	Patients in horizontal position while receiving gastric tube feeding				
	Hygienic care and control of devices (11 Items)				
74	Vacuum device of thoracic drain leaks air				
75	Water-seal of thoracic drain device is missing or insufficient				
76	Inhalation devices not renewed according to protocol				
77	Closed endotracheal suction system not renewed according to protocol				
78	Mechanical ventilation equipment not changed according to protocol				
79	Infusion system for total parenteral feeding not renewed according to protocol				
80	Bandage of central line not renewed according to protocol				
81	Bandage of arterial line not renewed according to protocol				
82	Intravenous and intra-arterial pressure lines not renewed according to protocol				
83	Standard infusion systems are not renewed according to protocol				
84	Bandages of introduction sites for infusion not renewed according to protocol				
	TOTAL				



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DEPARTMENT: Nursing Education
 Charlotte Maxeke Johannesburg Academic Hospital

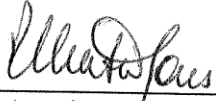
PROJECT TITLE: Patients' Safety in Intensive Care Units in an
 Academic Hospital in Gauteng

DATE CONSIDERED: 29/08/2014

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Shelley Schmollgruber

APPROVED BY: 
 Professor P Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 24/07/2015

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.
 I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.**

Principal Investigator Signature _____

Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

THE PERMISSION TO USE THE CRITICAL NURSING SITUATION INDEX

From: "J.M. Binnekade" <j.m.binnekade@amc.uva.nl>

To: "Mphofu Tlholah" <Mphofu.Tlholah@students.wits.ac.za>

Sent: Thursday, 10 October, 2013 2:06:12 PM

Subject: RE: Request for a Permission to use Critical Nursing Situation Index for my study

Dear Mphofu Tlholah,

I believe that we should share all knowledge that people can benefit from. So, yes you can use the CNSI, even better may be you can improve it. I hope that you also will be able to publish your study results so that other people can benefit from your effort.

Success with your work and study.

Greetings

Dr. J.M. Binnekade

Onderzoeker

Intensive care volwassenen C3-323

Academisch Medisch Centrum

Universiteit van Amsterdam

Postbus 22660

1100DD Amsterdam

Tel: 020 5664412 / 020 5662509

Email: j.m.binnekade@amc.uva.nl

-----Oorspronkelijk bericht-----

Van: Mphofu Tlholah [mailto:Mphofu.Tlholah@students.wits.ac.za]

Verzonden: donderdag 10 oktober 2013 13:57

Aan: J.M. Binnekade

Onderwerp: Request for a Permission to use Critical Nursing Situation Index for my study

Urgentie: Hoog

Dear Mr Jan Binnekade,

I am a post-graduate student at the University of Witwatersrand in South Africa and am doing research as a requirement for completion of masters degree. I am interested in patients' safety and have found Critical Nursing Situation Index as a very useful and relevant Instrument for my study. It is for this reason that I am humbly requesting permission to use this Instrument for my data collection.

I am intending to use it only for the purposes of this research and would like you to clarify if there are any additional requirements before I can get permission to use it.

Thank you for your time and consideration.

Yours Sincerely

Mphofu Tlholah (Ms)

**PATIENTS' SAFETY IN INTENSIVE CARE UNITS IN AN ACADEMIC
HOSPITAL IN GAUTENG**

UNIT MANAGER'S INFORMATION LETTER

Dear _____
(Name of the Unit Manager)

My name is Mphofu Tlhola. I am a registered student in the Nursing Education Department, at the University of Witwatersrand. I am studying for Masters of Science in Nursing. I would like to conduct a research study at Charlotte Maxeke Johannesburg Academic Hospital as a requirement for the programme. The title of the study is: "Patients' safety in intensive care units in an academic hospital in Gauteng." I would like to include your unit in the sample in this research study.

The purpose of this study is to observe any deviations from protocols and standards of nursing care in intensive care units. This will be done by direct observation of nurse-patient interactions and record review. Critical Nursing Situation Index will be used as a research instrument to assess the adherence to nursing protocols. This is a very useful instrument that has been used in the Netherlands to assess any deviations from protocols that may compromise patients' safety and has been adapted as part of the Patients' Safety Management System.

If you agree that your ward will be part of the sample in this study, you will be asked to sign consent form to confirm that you understand the study and are willing to be included. I will pop-in from time to time and will report to you every time before starting data collection. I will be reviewing the patients' records and sometimes observing nurse-patient interactions. There are no special tasks or activities that you will be asked to do for purposes of this study. There are no questions that you will be expected to answer in relation to this study. Code numbers instead of personal names will be used to ensure anonymity and the information given will be treated with confidentiality. No names or personal details will be reported in the study. All the electronic data collected will be saved on the password protected computer and the other data recorded on papers will be stored at the Faculty office in a locked cupboard where only I and my supervisors will have access to the records.

There are no benefits for participating in the study but the results obtained from this research may assist in making situation analysis in relation to patients' safety. This will be used as part of patients' safety management system and in quality management programs in ICUs. There are no anticipated risks.

The appropriate authorities and Human Research Ethics Committee of the University of Witwatersrand, Gauteng Department of Health, and your healthcare institution have been consulted for approval. Should you need further clarification, do not hesitate to contact me on the following cell number 0734223028 or email address mamoketentsekhe@gmail.com.

Thank you very much for your time and consideration.

Mphofu Tlhola
MSc Nursing Student

**PATIENTS' SAFETY IN INTENSIVE CARE UNITS IN AN ACADEMIC
HOSPITAL IN GAUTENG**

NURSE'S INFORMATION LETTER

Dear _____
(Name of the Nurse)

My name is Mphofu Tlholo. I am a registered student in the Nursing Education Department, at the University of Witwatersrand. I am studying for Masters of Science in Nursing. I would like to conduct a research study at Charlotte Maxeke Johannesburg Academic Hospital as a requirement for the programme. The title of the study is: "Patients' safety in intensive care units in an academic hospital in Gauteng." I would like to include the patients under your care in the sample in this research study.

The purpose of this study is to observe any deviations from protocols and standards of nursing care in intensive care units. This will be done by direct observation of nurse-patient interactions and record review. Critical Nursing Situation Index will be used as a research instrument to assess the adherence to nursing protocols. This is a very useful instrument that has been used in the Netherlands to assess any deviations from protocols that may compromise patients' safety and has been adapted as part of the Patients' Safety Management System.

If you agree that your patients will be part of the sample in this study, you will be asked to sign consent form to confirm that you understand the study and are willing to be included. I will pop-in from time to time and will report to you every time before starting data collection. I will be reviewing the patients' records and sometimes observing nurse-patient interactions. There are no special tasks or activities that you will be asked to do for purposes of this study. There are no questions that you will be expected to answer in relation to this study. Code numbers instead of personal names will be used to ensure anonymity and the information given will be treated with confidentiality. No names or personal details will be reported in the study. All the electronic data collected will be saved on the password protected computer and the other data recorded on papers will be stored at the Faculty office in a locked cupboard where only I and my supervisors will have access to the records.

There are no benefits for participating in the study but the results obtained from this research may assist in making situation analysis in relation to patients' safety. This will be used as part of patients' safety management system and in quality management programs in ICUs. There are no anticipated risks.

The appropriate authorities and Human Research Ethics Committee of the University of Witwatersrand, Gauteng Department of Health, and your healthcare institution have been consulted for approval. Should you need further clarification, do not hesitate to contact me on the following cell number 0734223028 or email address mamoketentsekhe@gmail.com or Mphofu.Tlholo@students.wits.ac.za.

Thank you very much for your time and consideration.

Mphofu Tlholo
MSc Nursing Student

**PATIENTS' SAFETY IN INTENSIVE CARE UNITS IN AN ACADEMIC
HOSPITAL IN GAUTENG**

PATIENT'S INFORMATION LETTER

Dear _____
(Name of the Patient)

My name is Mphofu Tlholo. I am a registered student in the Nursing Education Department, at the University of Witwatersrand. I am studying for Masters of Science in Nursing. I would like to conduct a research study at Charlotte Maxeke Johannesburg Academic Hospital as a requirement for the programme. The title of the study is: "Patients' safety in intensive care units in an academic hospital in Gauteng." I would like to include you in the sample in this research study.

The purpose of this study is to observe any deviations from protocols and standards of nursing care in intensive care units. This will be done by direct observation of nurse-patient interactions and record review. Critical Nursing Situation Index will be used as a research instrument to assess the adherence to nursing protocols. This is a very useful instrument that has been used in the Netherlands to assess any deviations from protocols that may compromise patients' safety and has been adapted as part of the Patients' Safety Management System.

If you agree that you will be part of the sample in this study, you will be asked to sign consent form to confirm that you understand the study and are willing to be included. I will be reviewing the patients' records and sometimes observing nurse-patient interactions. There are no special tasks or activities that you will be asked to do for purposes of this study. There are no questions that you will be expected to answer in relation to this study. Code numbers instead of personal names will be used to ensure anonymity and the information given will be treated with confidentiality. No names or personal details will be reported in the study. All the electronic data collected will be saved on the password protected computer and the other data recorded on papers will be stored at the Faculty office in a locked cupboard where only I and my supervisors will have access to the records.

There are no benefits for participating in the study but the results obtained from this research may assist in making situation analysis in relation to patients' safety. This will be used as part of patients' safety management system and in quality management programs in ICUs. There are no anticipated risks.

The appropriate authorities and Human Research Ethics Committee of the University of Witwatersrand, Gauteng Department of Health, and healthcare institution have been consulted for approval. Should you need further clarification, do not hesitate to contact me on the following cell number 0734223028 or email address mamoketentsekhe@gmail.com or Mphofu.Tlholo@students.wits.ac.za.

Thank you very much for your time and consideration.

Mphofu Tlholo
MSc Nursing Student

**PATIENTS' SAFETY IN INTENSIVE CARE UNITS IN AN ACADEMIC
HOSPITAL IN GAUTENG**

PATIENT'S RELATIVE INFORMATION LETTER

Dear _____
(Name of the Relative)

My name is Mphofu Tlholo. I am a registered student in the Nursing Education Department, at the University of Witwatersrand. I am studying for Masters of Science in Nursing. I would like to conduct a research study at Charlotte Maxeke Johannesburg Academic Hospital as a requirement for the programme. The title of the study is: "Patients' safety in intensive care units in an academic hospital in Gauteng." I would like to include your relative who is in ICU in the sample in this research study.

The purpose of this study is to observe any deviations from protocols and standards of nursing care in intensive care units. This will be done by direct observation of nurse-patient interactions and record review. Critical Nursing Situation Index will be used as a research instrument to assess the adherence to nursing protocols. This is a very useful instrument that has been used in the Netherlands to assess any deviations from protocols that may compromise patients' safety and has been adapted as part of the Patients' Safety Management System.

If you agree that your relative will be part of the sample in this study, you will be asked to sign consent form to confirm that you understand the study and are willing to give permission for your relative to be included. I will be reviewing the patients' records and sometimes observing nurse-patient interactions. There are no special tasks or activities that you will be asked to do for purposes of this study. There are no questions that you will be expected to answer in relation to this study. Code numbers instead of personal names will be used to ensure anonymity and the information given will be treated with confidentiality. No names or personal details will be reported in the study. All the electronic data collected will be saved on the password protected computer and the other data recorded on papers will be stored at the Faculty office in a locked cupboard where only I and my supervisors will have access to the records.

There are no benefits for participating in the study but the results obtained from this research may assist in making situation analysis in relation to patients' safety. This will be used as part of patients' safety management system and in quality management programs in ICUs. There are no anticipated risks. In a case where your relative regains capacity to give consent for him or herself, he or she will be given an information sheet and a consent form different from yours to give the researcher permission.

The appropriate authorities and Ethics Committee of the University of Witwatersrand, Gauteng Department of Health, and healthcare institution have been consulted for approval. Should you need further clarification, do not hesitate to contact me on the following cell number 0734223028 or email address mamoketentsekhe@gmail.com or Mphofu.Tlholo@students.wits.ac.za.

Thank you very much for your time and consideration.

Mphofu Tlholo
MSc Nursing Student

**PATIENTS' SAFETY IN INTENSIVE CARE UNITS IN AN ACADEMIC
HOSPITAL IN GAUTENG**

UNIT MANAGER'S CONSENT FORM

I _____ (Name of the Unit Manager) give permission for my ward to be included in the study. I have read and understood the content of the information letter. I have been given the opportunity to ask questions or voice the concerns that I may have regarding the study and my consent to my ward being included in the study. I also understand that I may, at any stage and without any consequences withdraw my consent and participation in the study.

I hereby give permission, voluntarily for my unit to be included in the study by my signature below:

Unit Manager's Signature

Date

Witness

**PATIENTS' SAFETY IN INTENSIVE CARE UNITS IN AN ACADEMIC
HOSPITAL IN GAUTENG**

NURSE'S CONSENT FORM

I _____ (Name of the nurse) give permission for patients under my care to be included in the study. I have read and understood the content of the information letter. I have been given the opportunity to ask questions or voice the concerns that I may have regarding the study and my consent to my patients being included in the study. I also understand that I may, at any stage and without any consequences withdraw my consent and participation in the study.

I hereby give permission, voluntarily for my patients to be included in the study by my signature below:

Nurse's Signature

Date

Witness

**PATIENTS' SAFETY IN INTENSIVE CARE UNITS IN AN ACADEMIC HOSPITAL
IN GAUTENG**

PATIENT'S CONSENT FORM

I _____ (Name of the patient) give permission to be included in the study. I have read and understood the content of the information letter.

I have been given the opportunity to ask questions or voice the concerns that I may have regarding the study and my consent to my inclusion in the study. I also understand that I may, at any stage and without any consequences withdraw my consent and participation in the study.

I hereby give permission, voluntarily to be included in the study by my signature below:

Patient's Signature

Date

Witness

**PATIENTS' SAFETY IN INTENSIVE CARE UNITS IN AN ACADEMIC HOSPITAL
IN GAUTENG**

PATIENT'S RELATIVE CONSENT FORM

I _____ (Name of the patient's relative) give permission for
_____ (Name of the patient) to be included in the study.

I have read and understood the content of the information letter. I have been given the opportunity to ask questions or voice the concerns that I may have regarding the study and my consent to my relative's inclusion in the study. I also understand that I may, at any stage and without any consequences withdraw my consent and participation in the study.

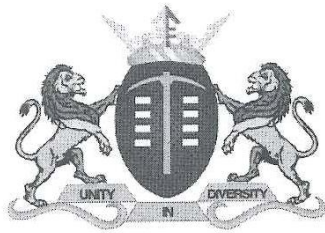
I hereby give permission, voluntarily for my relative to be included in the study by my signature below:

Relative's Signature

Date

Relationship with the patient

Witness



GAUTENG PROVINCE

HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Ms. G. Ngwenya
Office of the Nursing Director
Tell: (011): 488-4558
Fax: (011): 488-3786
14 July 2015

Ms. Mphofu Tlhola
Department of Nursing Education
Faculty of Health Sciences
University of Witwatersrand

Dear. Ms. Mphofu Tlhola

RE: "Patients Safety in Intensive Care Units in one Academic hospital in Gauteng"


Permission is granted for you to conduct the above recruitment activities as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic hospital will not in anyway incur or inherit costs as a result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.
- 5.


Please liaise with the Head of Department and Unit Manager or Sister in Charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

~~Supported / not supported~~


Ms. M.M Pule
Nursing Director
Date: 14/07/2015

~~Approved / not approved~~


Ms. G. Bogoshi
Chief Executive Officer
16.07.2015