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Evaluation of adherence to the glucose control protocol in a Cardiothoracic ICU

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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 Medicine

in the branch of Anaesthesiology

2015

DECLARATION

I, Dr Dyuti Maharaj declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

Signature

Signed at: University of the Witwatersrand, Johannesburg

On this date: 2015

Presentations arising from this study

1. Poster presentation at the World Federation of Societies of Intensive and Critical Care Medicine Congress 2013, Durban, South Africa.
2. Poster presentation at the University of Witwatersrand Research Day.

ABSTRACT

Background: Glucose control in critically ill patients poses a challenge for all health care workers involved in patient management. To avoid glucose variability and to maintain normoglycaemia, evidence based protocols are implemented to guide clinical care. However, adherence to such protocols needs to be evaluated on a regular basis in order to ensure efficiency of care and to improve outcomes. Available literature suggests that glucose control protocol compliance is generally poor.

Aim of the study: The aim of the study was to evaluate adherence to the glucose control protocol by nurses in the cardiothoracic ICU at CMJAH.

Objectives of the study: The research objectives were to:

1. Describe the number of abnormal glucose readings recorded.
2. Describe the proportion of protocol violations in relation to the glucose control protocol.
3. Compare the differences in glucose protocol violations between day nursing staff and night nursing staff.
4. Compare the level of training of nurses involved with glucose protocol violations.

Method: A retrospective study reviewing the ICU charts of adult patients post cardiac surgery, who were admitted to the cardiothoracic ICU at Charlotte Maxeke Johannesburg Academic Hospital, Gauteng, during March 2011. The data was analysed using STATA 11 statistical software.

Results: A total of 741 glucose readings were evaluated [22 patients: 13 (59.1%) male and 9 (40.9%) female]. The mean age of patients was 48.5 years with an age range of 17-76 years. The surgical procedures were categorised as: valvular 17 (77.3%); coronary artery bypass grafts 3 (13.6%) and other 2 (9.1%). The median glucose reading was 7.8 mmol/l (6.7-9.3 mmol/l). Overall, 411 (55.5%) protocol violations were recorded if the glucose control protocol was not adhered to. Of the readings 629 (84.9%) were abnormal. Protocol violations were similar between the day and night staff; 188 (54.7%) and 223 (58.5%) respectively (p =0.256). Of the readings, 464 (62.6%) were done by ICU trained nurses and 246 (33.2%) by non-ICU trained nurses. There were fewer protocol violations recorded by the ICU trained nurses compared to the non-ICU trained nurses, i.e. 53.3% and 63.7% respectively ($p<0.05$).

Conclusion: It is concluded that adherence to the glucose control protocol in the ICU was sub-optimal. Despite a high percentage of protocol violations, the median glucose level was 7.8 mmol/l. The number of violations committed by the day and night staff was similar. ICU trained nurses committed fewer violations than non-ICU trained nurses.

These results suggest that the training and education of healthcare workers in implementing protocols is an ongoing and dynamic process and that there is a need for evaluation on a regular basis.

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LIST OF ABBREVIATIONS

BG	Blood glucose
CEO	Chief executive officer
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
CT	Cardiothoracic
EBP	Evidence Based Practice
HCW	Health Care Worker
ICU	Intensive Care Unit
IIT	Intensive insulin therapy
MDT	Multi-Disciplinary Team
SEGC	Safe and Effective Glucose Control
TGC	Tight glucose control

CHAPTER ONE

OVERVIEW OF THE STUDY

1.1 INTRODUCTION

In this chapter a brief overview of the study is provided. This includes; background to the study, problem statement, aim and objectives of the study, relevant definitions, location of the study, ethical considerations, research assumptions and definitions, significance, and validity and reliability of the study. Lastly, a summary of the chapter is provided. A more in-depth review of these topics will be presented in subsequent chapters.

1.2 BACKGROUND TO THE STUDY

Glucose control in critically ill patients poses a challenge for both doctors and nurses working in ICUs. Critically ill patients are particularly prone to hyperglycaemia because of metabolic and hormonal changes associated with the stress response (1, 2). They are also predisposed to hyperglycaemia due to certain clinical interventions such as the administration of corticosteroids, ionotropes, dextrose-containing intravenous fluids and enteral or parental nutrition (3). Increased blood glucose (BG) levels, even a single reading, have been associated with adverse outcomes in the critical care setting (4, 5).

The Van den Berghe studies (6, 7) have shown the benefit of tight glucose control (TGC) using intensive insulin therapy (IIT) with respect to morbidity and mortality

in critically ill patients. However, further studies questioned the benefits of TGC, due to the increased risk of hypoglycaemia (8-11). Hypoglycaemia has been associated with an increased risk of hospital mortality (12-15).

From an anaesthetic perspective, glucose control is particularly important during the peri-operative period. Surgical stress results in a hyperglycaemic response characterised by: “an increased production of catecholamines, growth hormone, glucagon and cortisol; as well as a concomitant depression in insulin levels. Elevated hepatic glycogenolysis and gluconeogenesis, along with reduced insulin secretion and tissue insulin resistance, also contribute to the hyperglycaemia (16-18)”.

Hypoglycaemia may also occur. Surgical patients are not uncommonly fasted for prolonged periods of time pre-operatively or, alternatively are administered insulin intra-operatively. This is especially problematic when the hypoglycaemia symptoms are masked by anaesthesia during the peri-operative period (19). Also, the brain is an obligate glucose metaboliser and severe hypoglycaemia can cause neuronal necrosis (20).

Maintaining an adequate glucose level intra-operatively, by an anaesthetist, is of particular importance in certain patients. Patients with traumatic brain injury (TBI) require strict glucose control as hyperglycaemia in this group of patients has been associated with higher intracranial pressures, longer hospital stays, poorer

neurological outcomes and reduced survival (21). As part of the intra-operative anaesthetic goals of neuroprotection in such patients, glucose control is imperative.

ICU admission hyperglycaemia has been shown to be an independent marker of mortality and morbidity (22). One study demonstrated that for every 1.1 mmol/l increase in the mean intra-operative glucose, the adverse outcome risk increased by more than 30% (23).

ICUs provide ongoing care for post-operative patients when required. Most of the intra-operative management goals, like glucose control, are continued in ICU. In doing so, continuity of care can be maintained, glucose targets safely reached and overall patient outcome improved.

In order to ensure that glucose control is achieved in critically ill patients, evidence-based glucose protocols are provided in ICUs. Adherence to these protocols is expected, however, there may be deviations from the protocol for various reasons. Both organisational and individual factors contribute to the occurrence of violations of the protocol (24).

According to international literature on adherence to glucose control protocols in ICU, Taylor et al. (25) reported a 53% adherence and Rood et al. (26) found a 56% adherence to the paper-based glucose protocol. This poses a problem in the

critical care setting where morbidity and mortality may be influenced by glucose control.

There is a school of thought that says that “clinical protocols, which assist in critical care decision-making, may reduce the quality of care by replacing clinical judgement, breeding complacency or stifling learning (27). However, despite these beliefs, evidence shows that protocols can potentially reduce harmful variations in care, enhance efficiency and improve outcomes (28, 29)”.
More protocols are being introduced in ICUs to improve patient care and achieve clinical targets. Currently, there is no literature documenting the evaluation of glucose protocol adherence in South African ICUs.

1.3 PROBLEM STATEMENT

The literature suggests that glucose control in ICUs has important morbidity and mortality implications. Achieving normoglycaemia during this hypermetabolic state, while avoiding hypoglycaemia, is a challenging task. Protocols are in place to help achieve glucose targets, however, they may not always be followed. “The use of protocols simplifies processes, standardises care, facilitates patient safety and reduces costs, but lack of compliance can hinder the success of any protocol (30)”. Protocols for glucose control are in place in the ICUs at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) but adherence to these protocols has not been evaluated in the cardiothoracic ICU at this institution.

Health care workers (HCWs) working in the ICU are from various academic backgrounds. Additionally, the nurses are not all ICU trained and many are agency nurses, who are employed due to permanent staff shortages. In a national audit of critical care resources in South Africa, it was found that the majority (49%) of nurses working in critical care units in South Africa, were registered nurses without critical care training and with less than 5 years' experience (31). Specifically, the cardiothoracic ICU at CMJAH was found to be staffed by more than 50% with non-permanent staff, who were employed via agencies on a temporary basis (32).

1.4 AIM OF THE STUDY

The aim of the study was to evaluate adherence to the glucose control protocol by nurses in the cardiothoracic ICU at CMJAH.

1.5 OBJECTIVES

The research objectives were to:

- Describe the number of abnormal glucose readings recorded.
- Describe the proportion of protocol violations in relation to the glucose control protocol.
- Compare the differences in glucose protocol violations between day nursing staff and night nursing staff.
- Compare the level of training of nurses involved with glucose protocol violations.

1.6 RESEARCH ASSUMPTIONS AND DEFINITIONS

The following definitions were used in this study.

Intensive Care Unit (ICU) – "A hospital unit where patients require close monitoring, which contains highly technical, sophisticated monitoring devices and equipment and which is staffed by personnel who deliver critical care (33)".

Adult patients - Patients who are 16 years and older.

Glucose protocol – **"**Protocols are a means of formalising how to perform a specific procedure (34)". Glucose protocols are specific, prescribed instructions for ICU staff regarding glucose control. The protocols can be either a sliding scale or infusion instructions (Appendix F and G respectively)

Adherence - For the purpose of this study, adherence is defined as the correct action being performed in accordance with the protocol.

Violation - Any treatment or non-treatment action in terms of the glucose level that is not in accordance with the glucose control protocol.

Hypoglycaemia - A blood glucose reading less than 3.5 mmol/l.

Hyperglycaemia – A blood glucose reading of more than 10 mmol/l.

Normoglycaemia – A blood glucose reading in the range 3.6 - 9.9 mmol/l.

1.7 LOCATION OF STUDY

The study took place at the cardiothoracic ICU at CMJAH, Gauteng Province, South Africa. This is a quaternary, academic hospital associated with the

University of Witwatersrand. It is the only public sector cardiothoracic ICU in Johannesburg. On average 21 operations are performed every month with a nurse: patient ratio of 1:1 in this unit.

1.8 ETHICAL CONSIDERATIONS

The proposal for this study was submitted to the Postgraduate Committee of the University of the Witwatersrand for approval (Appendix A).

Ethical approval for this study was obtained from the Human Research Ethics Committee (Medical) of the University of Witwatersrand (Appendix B).

Approval for this study was received from the HOD of critical care at CMJAH. (Appendix D)

In addition, a written informed consent was obtained from the Chief Executive Officer of CMJAH to conduct the research in the hospital and specifically to gain access to, and utilize, patients' records (Appendix C).

The researcher only worked with the numbers allocated to patients and not with the file numbers or patient names (data collection sheet-appendix E). This ensured confidentiality, privacy and anonymity of patient information.

Furthermore, anonymity of HCWs working in ICU during the month of March 2011 was maintained as numbers were allocated to them. The numbers, not the names, were used when cross-checking ICU charts and the researcher only knew the identity of the health care workers (data collection sheet-appendix F). The researcher and supervisor were the only people who had access to raw data for this study.

Data will be stored for a minimum of 2 years after publication of this study or for 6 years in the absence of publication of the results of this study.

The retrospective nature of the study does not allow the researcher to intervene with any patient treatment.

The study was conducted in adherence with the principles of the Declaration of Helsinki (35).

1.9 RESEARCH METHODOLOGY

1.9.1 Study Design

A retrospective, contextual, single-centre, descriptive research design was followed in this study.

1.9.2 Study population and study sample

The ICU flow charts of all adult patients admitted to the cardiothoracic ICU at CMJAH during the month of March 2011 and the demographics of the nurses working in the unit during that period constituted the study sample.

1.9.3 Study sample

A convenience consecutive sampling method was used.

1.9.4 Inclusion and exclusion criteria

Inclusion criteria were the ICU flow charts of all adult patients, 16 years and older, who were admitted to the CT ICU during the month of March 2011. The demographic data of nurses looking after those patients were also collected. There were no exclusion criteria.

1.9.5 Data collection procedures

Two data collection sheets were used; one for the collection of data from the ICU flow charts of patients admitted to the CT ICU during March 2011; and one to

capture the demographics of the nurses looking after those patients during the research period (Appendix I and F respectively).

Protocols utilised in the ICU during the research period are defined in Appendix G and H.

1.9.6 Statistical Analysis

The researcher collected the raw data, personally, and entered it onto a Microsoft Excel spreadsheet. The data was then analysed with the aid of a biostatistician using the software programme STATA 11 (STATA Corporation, College Station, TX USA).

1.10 SIGNIFICANCE OF THE STUDY

Hyperglycaemia at the time of admission to ICU is an independent risk factor for in-hospital mortality (36). Adequate glucose control has been associated with improved patient outcome. However, despite the adoption of protocols by ICUs, questions about the adherence to such protocols remain unanswered.

Identifying the shortcomings of a protocol that has already been implemented, would be beneficial in the development and implementation of future protocols for that unit.

1.11 VALIDITY AND RELIABILITY OF THE STUDY

Validity is the extent to which an instrument actually reflects or measures what it is supposed to measure (37). Content validity was secured by literature review, experts in intensive care, a biostatistician and a research methodologist.

Reliability is concerned with how consistently the measurement technique measures a variable or concept (37). The data was collected, from patient records, by a single researcher only. This ensured that the data was collected in a standardised manner and that it was reliable.

1.12 POTENTIAL LIMITATIONS OF THE STUDY

The results from this study's population were contextual and may not be applicable to other ICUs.

The accuracy of bedside glucometers, i.e. point-of-care instruments, for measuring lower blood glucose levels has been questioned (38). Ideally, to prevent disparities caused by different glucose-measuring methods, a single standardised method should have been used.

Also, one needs to consider the limitations of a retrospective study, which relies on the accuracy of written record or the recall of individuals (recall bias), as well as

legibility and availability of records. Determining the nursing demographic data posed a challenge, as data were obtained from poorly kept shift records. Therefore there was possibly a loss of important data and a possibility of inaccurate data being collected.

1.13 PROJECT OUTLINE

Chapter one presents an overview of this research report. Chapter two includes an in-depth literature review of the research topic. Chapter three contains a comprehensive discussion of the research methodology. Chapter four includes a presentation of results and discussion thereof. The final chapter provides the conclusion of the study as well as further recommendations.

1.14 SUMMARY

This chapter provided a brief overview and summary of this research report. Topics covered included introduction and background, problem statement, aim and objectives, research assumptions, location of the study, ethical considerations, research methodology, significance of the study, validity and reliability, potential limitations and the project outline. A more comprehensive review of the topics is presented in subsequent chapters.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

In this chapter, various concepts relating to glucose control in ICU are reviewed. First evidence-based practice (EBP) is described. Secondly, protocols and the different aspects of their development and implementation are provided. Next, a review is provided of: glucose control, glucose control in critically ill patients, glucose targets, measuring glucose in critically ill patients, insulin administration versus glucose control, glucose control protocols and lastly from tight glucose control (TGC) to Safe effective glucose control (SEGC).

Medicine and the practise thereof, is not an exact science and is an ever-evolving discipline. The ultimate aim of health care practitioners' is good patient outcome. In order to achieve desired clinical goals, the use of EBP is being advocated in most medical disciplines.

2.2 EVIDENCE-BASED PRACTICE

The most widely used definition for EBP is that of Sackett et al. (39). EBP is defined as: "The conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients." The definition further indicates that: "The practice of evidence-based medicine requires the integration

of individual clinical expertise with the best available external clinical evidence from systematic research and our patient's unique values and circumstances".

"EBP requires a shift from the traditional paradigm of clinical practice grounded in intuition, clinical experience and pathophysiological rationale (40)". There is now a shift from "authority" or "opinion" based practice to EBP.

Multi-disciplinary teams are now more involved in patient care. EBP can therefore be used, with evidence as the levelling factor amongst the various teams, with care discussions centring around the evidence - rather than "this is the way we do things around here" or "that is the way the surgeon prefers to do things" (40).

Reliance on experience or the opinion of colleagues is not likely to guarantee that the "best science" or "current evidence" is integrated into practice (40). Recommendations, based solely on clinical judgement and experience, are likely to be more susceptible to bias and self-interest (41). When healthcare is delivered with an organisational culture that supports best practice, EBP is linked to a higher quality of care and with better patient outcomes than care that is heavily weighted in tradition (42).

A common observation when reviewing healthcare services is the gap between evidence and practice (43). Despite healthcare organisations advocating that the use of EBP should be the standard of practice of care, most clinicians in do not

consistently implement evidence-based care (42, 44). Approximately less than 20% of medical practice is backed up by solid evidence (45).

EBP involves doing a literature search relevant to the patient condition, evaluating the literature for its credibility and finally applying the findings to assist with your decision making. It is by going through this systematic process that the quality of patient care can be enhanced (46).

“Multiple barriers have contributed to the slow uptake of EBP across healthcare systems, including: (a) inadequate knowledge and EBP skills of healthcare professionals; (b) misperceptions about EBP; (c) lack of informatics competencies; (d) insufficient administrative support and resources at the point of care; (e) lack of EBP mentors in healthcare systems and; (f) traditional approaches to teaching healthcare students, i.e. the rigorous process of how to do research, rather than how to use research to guide best practice (47-49)”.

Some studies have found that EBP improves the quality of care of patients and their outcome, enhances practitioner skills, decreases practice variation and healthcare costs (50-52). “Other outcomes that can be derived from the EBP process include clinical practice guidelines; protocols; and standards (53); all of which may lead to; (a) greater consistency in the care provided; (b) greater patient satisfaction due to improved outcomes and; (c) a higher quality of care and healthcare provider satisfaction (54)”.

Protocols can be an effective method of introducing EBP into ICUs and evidence shows a decline morbidity and mortality and decrease the cost of critical illness when implemented (28, 55).

2.3 PROTOCOLS - DEFINITIONS, ADVANTAGES, DISADVANTAGES AND ADHERENCE

The terms algorithms, protocols, clinical guidelines and care or clinical pathways are sometimes used interchangeably therefore it is important to clarify the differences and similarities between them. Clinical care processes help to standardise and simplify care for patients and their conditions (56).

- "Algorithms provide a step-by-step procedure and instructions for clinical decision-making or problems (57, 58).
- Protocols are a means of formalising how to perform a specific procedure (34).
- Clinical guidelines have been defined as systematically developed statements that assist practitioner and client decisions about appropriate health care for specific clinical circumstances (59).
- Care pathways are a way of organising care for a well defined group of patients during a well defined period of time (60, 61)".

Whilst standardisation and organisation are common to all these care processes, the degree of specificity between them varies.

“Algorithms provide very detailed information, usually presented in a flow chart, of what to do at each step of the decision making process (62). Protocols also provide detailed information about a particular process or procedure, but do not usually have the same degree of detail as algorithms (63)”.

Clinical guidelines contain more “operational detail than algorithms, as they are made up of recommendations that describe different aspects of the patient’s condition and appropriate management options” (64). “A care pathway, however, may be described as a hybrid of an algorithm, protocol or guideline”. This will generally cover the whole patient journey for a specified period of time and may also contain protocols, algorithms and standards (34, 65).

Swinglehurst (66) implores that a delineation be made as protocols are more rigid and provides little room for individual judgement than guidelines. Protocols tend to be clear rules which must be followed, compared to guidelines which aim assist with clinical decisions being made.

Evidence-based protocols are used in the critical care environment to address multiple aspects of care and to guide the treatment of many conditions (67), for example, glucose control protocols. Health care delivery may to be too dependent on the individual clinician’s knowledge, motivation and skills, with the result that only approximately half of the patients receive the recommended care (68). The high cost of intensive care medicine, along with the significant morbidity and

mortality of specific, high volume admissions and diagnoses, have prompted governmental institutions, researchers and intensive care societies to seek standardised diagnostic and treatment protocols in order to reduce practice variation and improve the quality of care (29, 69, 70).

Currently, in order to assess the delivery of the quality and consistency of care in the critical care setting and other medical disciplines, surrogate markers such as checklists, protocols and integrated care pathways are used (71).

Several investigators have proven that protocol driven therapeutic action beneficially impacts patient outcome in the ICU (72-75). However, one also needs to take into consideration that a standard care pathway/protocol is ideal for many, yet should not be viewed as “tablets of stone” (71). The pathophysiology of critically ill patients is complex, with inter-individual differences (including age, disease processes, co-morbidities, drug responses, etc.) making standard care unsuitable for everyone.

Roffey et al. discuss overuse of protocols in ICU and suggest that protocols may result in the simplification of patient care on a large scale. They are of the opinion that each patient will respond differently to each situation and that even drugs used routinely may not have a place in the care of certain patients on specific occasions. Patients may respond better or worse than expected to a specific pharmacological intervention, be it an ionotrope or sedative medication.

Furthermore, they put forward the concept of the increased use of protocols impacting on the traditional practice of the doctor–patient relationship and there being less hands-on physician interaction with critically ill patients (76).
Many physicians would agree with this school of thought and are wary of a standardised approach and some feel that protocol-driven care may jeopardise the decision-making skills of the profession, especially in a highly technological era in which physician bedside skills may have already reached a peak (27). According to Considine et al. (77), clinical guidelines and protocols intend to facilitate and guide, but not completely replace, clinical decision making.

Many clinicians want to improve their quality of patient care but often lack an understanding on the process of how to initiate change in order to implement change. This knowledge deficit has been termed 'change-process illiteracy' (78). Although most ICU physicians have a good knowledge of patient pathology, few of them possess the formalised training in systems thinking, the process of quality improvement regarding the change of practice and outcomes measurement (78-82). Therefore it is important to identify and understand the non-physiological factors that affect protocol compliance.

A recent study by Chase et al. (83), looked at the role of human factors and how individuals relate to technological protocols in clinical settings. It was found that most issues that affect adherence are often unrelated to the patient or treatment;

instead they are a function of the protocol design and its ability to integrate into a given clinical setting.

There are four specific human factors or issues have been identified that can affect adherence and/or performance i.e.:

- “Management and collaboration. The relationship amongst nursing staff, doctors, pharmacists and hospital management can affect collaboration, especially if there is not a multi-disciplinary approach or no clinical leader (84-87).
- Clinical burden, i.e. the time and effort needed to administer a protocol. Complex protocols or those needing many interruptions, trips from the bedside, extensive data management or outside input can affect adherence directly (85-90).
- Transparency. Complex protocols, difficult interfaces and frequent protocol violations or changes serve to: reduce consistency, remove insight into how the protocol works, and decrease trust in the protocol. These are important for good adherence to the guideline and reducing working outside the protocol (85,87-91).
- Training and education. The level of training and education affects both transparency and the clinical effort required. Regular in-service training can also improve the efficiency of care and adherence to a protocol in longer term use (84,92-96)”.

There are a few theoretical frameworks that could be applied to describe procedural non-adherence in health care. These frameworks have different origins and consequentially lead to different types of analyses of the origins of violations (24).

In 1997 Reason (97) described a framework and distinguished non-adherent behaviour as being either intentional or non-intentional. In an intentional case, non-adherence defines a violation, whereas non-intentional, non-adherent behaviour is an expression of human error (97). Both organisational and individual factors contribute to the occurrence of violations (98).

The types of violations include routine violations, corporate violations, exceptional violations, necessary violations and optimising violations (99). Reason (97) explained that routine and optimising violations were related to personal characteristics and necessary violations were related to organisational failure. “Routine violations are violations that occur when a person perceives an alternative, more efficient way of dealing with a task than the way a policy or a protocol requires”. He stated that these violations are common and often tolerated.

“Corporate violations result from administration creating a situation that supports the violation of procedures (e.g. excessive working hours)”. “Exceptional violations occur in unusual or exceptional circumstances in which a routine cannot be followed”. Optimisation violations are those where additional motives are

involved. This category involves a person being motivated by personal goals, performing experimental treatment and performing unnecessary procedures (97-99).

Violations are an important part of a model of human behaviour and a breakdown in performance (24). By applying Reason's systems approach to protocol violations (rather than the more common "person" approach of placing blame), it is possible to understand the overall picture of the cause of the violation in question (97).

Carthey, (a human factors consultant), Walker (an anaesthetic registrar), and other colleagues from the Imperial College of London, were concerned about the burgeoning number of protocols and guidelines used to standardise and clarify care. They subsequently published an analysis into understanding non-compliance with protocols and guidelines (100). It was found that there was a reduction in adherence to protocols and guidelines due to various factors. Staff may: break the rules if the protocol is complex and lengthy; not follow the protocol because they are unaware of it because of it was held in an unknown place or inadequate distribution of the protocol.

There may be multiple versions of the same protocol which could be the reason for following the wrong protocol. Protocols often need to be updated according to the latest evidence-based literature however previous versions may remain in

circulation. Sometimes there are multiple protocols on the same topic, which leaves healthcare professionals unsure about which protocol to follow (100).

According to Carthey et al (100), sometimes new protocols are introduced as a reflex to a specific incident. As a result, insignificant protocols may be developed that can affect staff morale and willingness to comply with other important protocols (100). Human factors research across several industries has shown that if more rigid protocols are imposed on healthcare workers, the less likely they are to comply with them (101, 102). Humans are also naturally adaptable and tend to improvise, which makes some non-adherence inevitable (103).

Importantly, in our local context, the shortage of skilled nurses poses a problem in the critical care setting. In 2007 a national audit of critical care resources in South Africa was conducted and it was found that only 14.5% of nurses working in ICU were actually ICU trained (31). A large portion of nurses (43%) had 0-5 years of ICU experience (31). A suggestion by Bhagwanjee et al (104), to reduce the impact of the shortage of nursing skills, is the implementation of protocols and guidelines in ICUs .

A study by Perrie (105) in 2006 looked at the level of knowledge of intensive care nurses, working in South African ICUs, with regards to specific care protocols commonly used. Results showed that the level of knowledge was well below the

competency indicator of 70% determined by ICU experts. With regards to knowledge about glucose control, the average score was 48.7%.
Evaluation of the knowledge of doctors working in ICU has not been researched but is an important area that needs to be explored.

These are pertinent aspects to consider when looking at protocol adherence. If one does not understand a protocol, how then can it be effectively adhered to? Furthermore, how does it influence the development and implementation of protocols?

2.4 PROTOCOLS - DEVELOPMENT AND IMPLEMENTATION

Human factors play a significant role in protocol adherence therefore human factors science should be applied to the development and design, implementation, testing and evaluation of policies and guidelines (100).

Despite the methods of guideline development being complex (106), it must be ensured that when implemented, desired patient outcomes may be achieved. There are different recommendations to protocol and guideline development but the salient points remain common throughout.

“Shekelle et al (107) presented five initial steps in the development of an evidence-based guideline:

- identification and refinement of the subject area
- convening and running guideline development groups
- assessment of the evidence about the clinical question or condition
- translation into a recommendation within a clinical practice guideline
- external review of the guideline".

At the start of any development process it is imperative that a multi-disciplinary team is utilised. This ensures that all stakeholders involved with implementing the protocol are also part of its development. Chan et al (108) commented on their staff's perception of increased autonomy and desire to assist with protocol compliance. This was attributed to them being incorporated into the multi-disciplinary which was an integral part of the development and implementation of the protocol. It appears that health care professional involvement in the development process is imperative for the uptake and compliance of the protocol being implemented. Some literature provided evidence that guidelines will only be utilised by healthcare workers if they felt that they had been part of its develpoment (109, 110). Rees et al (111) puts forward that one of the reasons for the lack implementation of a protocol was that the staff felt that they were not involved in the development process.

Equally important in the protocol or guideline development process is taking into account the local context into which the guideline will be implemented (112). Also

to be considered are the available resources and the feasibility of implementing such a protocol or guideline.

“The development of good guidelines does not ensure their use in practice (113). Systematic reviews of strategies for changing professional behaviour show that relatively passive methods of disseminating and implementing guidelines, by publication in professional journals or mailing to targeted healthcare professionals, rarely lead to changes in practitioners’ behaviour (114, 115). Lomas et al (116) observed that the failure of passive dissemination strategies is unsurprising given that many factors influence healthcare professionals' behaviour”.

Research shows that the implementation of clinical guidelines requires time, effort and resources (113). Most healthcare organisations do not have the resources and skills to develop valid guidelines from scratch (41, 117). They should try to identify previously developed guidelines and adapt these for local use (41). Furthermore, when an organisation has identified relevant guidelines in the literature, the validity should be appraised before deciding to adopt the recommendations (113).

There is no one, efficient way to ensure the implementation of new guidelines in clinical practice (118, 119) therefore, a multifaceted approach should be used. The choice of strategies should be informed by the available resources, perceived barriers to care and research evidence about the effectiveness and efficiency of each of the different strategies (120).

The developed protocol or guideline should be externally reviewed to ensure content validity, clarity and applicability (41). Thereafter, there should be appropriate revision of the guidelines on a regular basis (121).

Protocols are commonly used to guide care in ICUs e.g. glucose control protocols.

2.5 GLUCOSE CONTROL

Numerous protocols have been implemented in ICUs worldwide. Whether these protocols are adhered to as prescribed is not always clear. Glucose control protocols, whether paper or computer based, and the range of glucose control that they target has been controversial.

Up until the late 1990's, clinicians viewed stress hyperglycaemia as a beneficial defence mechanism of the body (122). It was accepted for many decades as an adaptive response to physiological stress i.e. a compensatory mechanism to provide fuel to vital organs (123). The importance of glucose control in postoperative patients was first demonstrated by Furnary and associates (124) and later confirmed by Van den Berghe et al (7).

The large, landmark study by Van den Berghe et al in 2001 (7), a single centre randomised control trial involving 1548 patients, most of whom had undergone cardiac surgery, was instrumental in questioning the acceptance of

hyperglycaemia in critically ill patients. TGC between 4.4 and 6.1 mmol/L was targeted by IIT (intensive insulin therapy) using a paper-based protocol for insulin infusion. This represented a huge change in mindset regarding glucose control.

The impact of IIT showed:

- an absolute mortality reduction in ICU from 8% to 4.6%
- a significant reduction in the incidence of multi-organ failure and the need for renal replacement therapy
- less ventilator dependence
- less liver impairment
- a 44% reduction in critical illness polyneuropathy
- a 41% reduction in renal failure
- reduced sepsis related morbidity
- reduced blood transfusions (7).

In a subsequent study involving 1200 patients, Van den Berghe et al (6) reported:

- reduced morbidity in patients admitted to a medical ICU
- mortality benefits were only seen in patients treated with IIT for 3 days or longer
- 18.7% risk of hypoglycaemia.

Confirmation of the mortality benefit of TGC was confirmed in a mixed medical-surgical ICU setting by Krinsley et al (125, 126). Furnary et al (127) and Lazar et

al (128) both showed improved patient outcomes with TGC in patients undergoing cardiac surgery.

An era of TGC then began where centres around the world targeted tighter glucose ranges. In addition, numerous organisations and societies published protocols that promote the attainment of normoglycaemia or near-normoglycaemia in the ICU setting (129-132).

Attempts to replicate the results of the early studies raised concerns about the safety of TGC. Similarly, two smaller single centre studies from Saudi Arabia and Colombia failed to demonstrate benefit from IIT (133, 134). The debate was further fuelled by the premature cessation of two large randomised control trials, VISEP and GLUCOCONTROL due to unacceptably high rates of severe hypoglycaemia (8, 9).

Adding to the controversy were the results from the most recently published NICE-SUGAR trial, the largest randomised control trial to date. They showed that TGC was associated with a 14-fold increase in hypoglycaemia compared with the moderate glucose control group. Subsequently, two meta-analyses also demonstrated that severe hypoglycaemia increased the likelihood of mortality six-fold (135, 136). The evidence could not be ignored and the concern for hypoglycaemia resulted in guidelines suggesting more measured, less aggressive glucose control and higher glucose target ranges (135-137).

In order to understand the benefits of glucose control, the dynamics of glucose and insulin interactions in critically ill patients need to be understood.

2.6 GLUCOSE AND INSULIN INTERACTIONS WITH CRITICAL ILLNESS

"Critical illness promotes a state of insulin resistance which is characterized by increased hepatic gluconeogenesis and glycogenolysis, impaired peripheral glucose uptake and higher circulating concentrations of insulin (138). Elevated levels of cytokines and counter-regulatory hormones such as glucagon, cortisol, growth hormone and catecholamines trigger upregulation of hepatic glucose production (139-141). Exercise-stimulated glucose uptake in skeletal muscle plummets as patients become bedbound (142). Impairments in glycogen synthase activity limit glucose uptake by heart, skeletal muscle, and adipose tissue. Furthermore, insulin stimulated glucose uptake by carriers such as GLUT- 4 is diminished (143, 144)".

These pathophysiological processes serve to elevate glucose levels during critical illness. However, this has been found to be to the detriment of these patients.

2.7 DELETERIOUS EFFECTS OF HYPERGLYCAEMIA

"Hyperglycaemia has immunomodulatory effects including increased production of anti-inflammatory cytokines like interleukin 10 (IL-10), promotion of mitochondrial

dysfunction (145) and impairment of polymorphonuclear neutrophil function resulting in decreased intracellular bactericidal activity, opsonic activity, and innate immunity are examples of these (124, 146-148)".

"Hyperglycaemia promotes inflammation by increasing pro-inflammatory cytokines such as TNF-alpha, interleukins (149), increasing leucocyte adhesion molecules, inducing nuclear factor kappa B (150) and promoting the procoagulant state (124, 146-148)".

Hyperglycaemia can lead to significant oxidative stress (151-153). A recent study showed that hyperglycaemia exacerbates lung injury when using intravenous lipopolysaccharides rat model of acute lung injury (154).

Hyperglycaemia also "induces the formation of advanced glycation end products which are now recognised to promote inflammation and endothelial dysfunction (155). The interaction of AGE and receptors for AGE (RAGE) have been implicated in endotoxin-induced ALI (156) and shown to modulate outcomes in septic shock (157). Although AGEs can be difficult to measure experimentally, RAGE appears to be a marker of Type I cell injury in ALI (158) and a recent acute respiratory distress syndrome (ARDS) network study demonstrated that higher circulating levels of RAGE was associated with severity of lung injury and clinical outcomes (159). These experimental and clinical data provide biologic plausibility

for why glucose control and insulin treatment may be important in improving morbidity and mortality in diverse states of critical illness (123)".

Not only are there benefits of maintaining normoglycaemia in critically ill patients, but there are also benefits of insulin administration.

2.8 Insulin effects

Insulin has a number of non-glucose metabolic effects that may be important in critical illness:

- "modulates inflammation
- reduces free fatty acids and reverses the state of dyslipidaemia in critical illness
- regulates apoptosis
- prevents endothelial dysfunction and hypercoagulation
- decreases neutrophil chemotaxis and leukocyte adhesion via reduction of ICAM-1 and macrophage inhibiting factor
- attenuates the catabolic state of critical illness
- prevents excessive nitric oxide which may help regulate oxidative stress (123, 160-167)".

In order for the correct insulin dose to be administered, the correct glucose level needs to be measured.

2.9 MEASURING GLUCOSE IN CRITICAL ILLNESS

There are various methods of measuring blood glucose. The most common being the point-of-care glucose meter readings from a capillary "fingerstick", but arterial and venous samples are also used, especially when invasive lines are in place (123).

It is important as physicians looking at glucose levels to know the site from which the sample was taken and the device used to measure the glucose level (eg. blood gas analyser versus central hospital laboratory versus glucose meter machines) as the readings may not all correlate. Sometimes the values may be of such significance that clinically relevant changes in insulin titration may occur. Research by Kanji et al (168) provided more confirmatory evidence that clinically relevant differences exist between different methods of glucose measurements.

Bedside capillary glucose meter readings "tended to systematically overestimate blood glucose (BG) values, which is important to note, as this may lead to delayed recognition of hypoglycaemia in clinical practice (123). This tendency for systematic overestimation of capillary readings has been noted in other studies as well (169-171)". A number of factors that are commonly encountered during critical illness can affect point-of-care blood glucose measurements which include:

- "blood source: serum, plasma, whole blood
- blood sampling site (capillary blood differ from venous by as much as 3.8 mmol/l)

- amount of blood on glucometer strip
    - Too much results in spuriously high levels
    - Too little results in spuriously low levels
- haematocrit (progressive anaemia results in spuriously high levels in whole blood assays)
- peripheral hypoperfusion: shock states, vasoconstriction, dehydration, vasospastic disorders
- sample processing delay
- substances reported to interfere with glucose measurements e.g. dopamine, mannitol, acetaminophen, severe lipaemia etc (172)".

It has been well validated that glucose control be achieved in critically ill patients but within what range should it be maintained?

2.10 GLUCOSE TARGETS

It is challenging to develop EBP guidelines when the results from various clinical trials are conflicting. There is agreement in the literature that very high glucose values are not acceptable but to what degree the glucose should be controlled is still debated.

After appraising the various studies that had emerged the American Association of Clinical Endocrinologists and the American Diabetic Association revised their

recommendations for glucose targets. A summary of their recommendations in the critically ill are:

- insulin infusion preferred
- starting threshold not higher than 10 mmol/l
- maintain BG 7.8-10 mmol/l (greater benefit likely at lower end of this range)
- lower targets may be appropriate in selected patients if already being successfully achieved
- < 6 mmol/l NOT recommended (not safe) (137).

The 2009 online update from the Surviving Sepsis Campaign committee closely resemble these recommendations with a goal BG approximating 8 mmol/l (173).

However, due to different pathologies and the pathophysiology of critical illness being so dynamic, the same glucose targets cannot be standard for every critically ill patient.

Griesdale et al (135) suggested surgical ICU patients, especially those undergoing elective surgery, can still benefit from tighter glucose control as opposed to medical ICU patients. The literature also suggests the benefits of strict glucose control post cardiac surgery (6, 124, 127, 174).

Locally, the Nesibopho Best Practice Guidelines (175) on glucose control in ICU, which is endorsed by the Critical Care Society of Southern Africa, recommends

the maintenance of glucose to be < 8.1 mmol/l but if monitoring is inadequate and /or hypoglycaemia occurs, maintenance should be between 7-9 mmol/l.

Despite obtaining optimal BG levels and maintaining them, avoidance of large variations should also be achieved.

2.11 GLUCOSE VARIABILITY

Glucose variability is a way of characterising the fluctuations of glucose values and has been identified as a prognostic indicator of worse outcomes in known diabetic patients (176). Glucose variability has been associated with increased mortality especially in critically ill patients (177). Glucose control should also incorporate glucose variability and not only single readings (176).

Much controversy surrounds the question of which is more beneficial; the amount of insulin administered or the level of glucose control achieved?

2.12 INSULIN ADMINISTRATION VERSUS GLUCOSE CONTROL

"Van den Berghe et al (178) performed a multivariate logistic regression analysis on the data derived from their series of postoperative patients undergoing mechanical ventilation and determined that the degree of glucose control, rather than the quantity of insulin administered, was associated with the decrease in mortality and organ system dysfunction". The issue of whether increased insulin

administration or glucose control per se is responsible for Van den Berghe's highly positive outcomes has however been debated (180-182).

Finney et al (179) conducted a study involving a cohort of 523 patients, predominantly undergoing cardiac surgery, and found that there was a positive correlation between mortality and the amount of insulin given irrespective of the blood glucose level.

2.13 GLUCOSE PROTOCOLS

In recent years, a large number and variety of protocols have been formulated, each adapted to local practices and need. The development and implementation of glucose control protocols demonstrate huge variance across different sites and therefore need to be assessed closely when interpreting results of studies (176). "Heterogeneity of patient populations and therapeutic regimens impede universal adoption of one protocol" (183) . A few of the differences amongst existing protocols include: route of administration, computerised versus written glucose control protocols and various healthcare providers determining the appropriate titration (183).

Protocols that adjust insulin dose, taking into account the degree of hyperglycaemia as well as the direction and rate of change from the previous measurement, are favoured (123). Analysis of available protocols and their performance led Meijering et al (183) to conclude that 'dynamic protocols' had better efficacy and safety when compared to 'static sliding scale protocols'. Also,

fewer hypoglycaemic episodes have been reported when IIT protocols were managed by nurses rather than adjusted by the prescriber (176).

Computerised protocols are potentially beneficial in comparison to written protocols as complex calculations can be performed rapidly by computerised models and many computerised insulin algorithms factor velocity of glucose change into consideration (176). Characteristics of an evidence-based, safe insulin administration protocol include a nursing-managed, computerised dynamic system (176).

Protocols which are changed to apply to local practices need to follow the data to ensure that hypoglycaemia rates are reduced, adverse events found and analysed, and that glucose targets are being met. Also it is important to review feedback from nursing staff regarding obstacles that may inhibit smooth running, lead to frustration, and add to many protocol violations (123).

Important variations to glucose protocols include nutrition and concurrent medications. These need to be considered when assessing a protocol's success and equally important, when the protocol is implemented. For example, in the Van den Berghe et al. trial (6, 7) patients were mostly fed by the parenteral route and received large doses of intravenous glucose. In comparison, many patients in further trials received nutrition mostly via the enteral route.

Corticosteroids also influence blood sugar. In the medical ICU study by Van den Berghe et al (6), approximately half the patients in each arm of the study received corticosteroids while this number was closer to a third in the NICE-SUGAR trial (184).

There is now a move away from TGC. Safe Effective Glucose Control (SEGC) has been suggested as an alternative.

2.14 FROM TGC TO SEGC

Krinsley and Preiser (185), two health care practitioners at the forefront of ongoing glucose studies, are concerned about the clinical burden of TGC. “TGC demands a complex application of monitoring and dynamic treatment throughout the course of the patient’s ICU stay; deficiencies in any number of institutional factors may doom the intervention to failure (185). Krinsley suggests that the need for frequent glucose level assessments with TGC, responding to the adjustments in the administered treatment, the experience and skill of the nursing staff in the use of protocols may affect the probability that the treatment goals are achieved”. Moreover, “the structural and organisational characteristics of the ICU may have a strong impact on the functioning of the protocol especially in view of the high work burden imposed by TGC-estimated to consume two hours out of a 24-hour working day for the ICU nurse (186, 187)”.

Instead of TGC, “Krinsley proposed the use of a stepwise approach SEGC. SEGC involves the adoption of safe glucose targets appropriate to the skills, experience and available tools of the ICU that does not result in a significant risk of hypoglycaemia. The use of appropriate data monitoring tools, both for glucose results and relevant clinical outcomes is essential for SEGC. Lastly, the utilisation of existing monitoring technologies is mandatory for SEGC”.

“Preliminary clinical evaluations of the accuracy of continuous or near-continuous glucose monitors have been published recently from 2005-2010 (23-25). These devices offer the promise of a reduction in severe hypoglycaemia, glucose variability, the nursing work burden, and will probably become a cornerstone of SEGC (188-190)”.

2.15 CONCLUSION

Hyperglycaemia in the critically ill patients, and the adverse outcomes thereof, has been well established. Protocols are in place in ICUs worldwide to assist with glucose control. The overall adherence to glucose control protocols is low. “Reality is that deep and dangerous gaps exist between the care that patients should receive and care they actually do receive.” A thought provoking quote by Lavizzo-Mourey and Berwick (191).

2.16 SUMMARY

An in depth discussion on various aspects of glucose control and protocols in ICU has been presented in this chapter. The following chapter will review the research methodology of this study.

CHAPTER THREE

RESEARCH DESIGN AND METHODOLOGY

3.1 INTRODUCTION

A detailed explanation of the research methodology is discussed under the headings: study design, study population and study sample (including sample size, sampling method, inclusion and exclusion criteria), description of data collection procedures and statistical analysis of the data.

3.2 PROBLEM STATEMENT

The literature suggests that glucose control in the critical care setting has important morbidity and mortality implications. Achieving normoglycaemia during this hypermetabolic state, while avoiding hypoglycaemia, is a challenging task. Protocols are in place to help achieve glucose targets, however, they may not always be followed. The use of protocols simplifies processes, standardises care, facilitates patient safety and reduces costs, but lack of adherence can hinder the success of any protocol (30). Protocols for glucose control are in place in the ICUs at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) but adherence to these protocols has not yet been evaluated in the cardiothoracic ICU at this institute.

The health care workers (HCWs) working in the ICU are from varying academic backgrounds. The nurses are not all ICU trained and some are agency nurses whom are employed due to staff shortages. "An audit of all critical care resources in South Africa revealed that the majority (49%) of nurses working in critical care units in South Africa were registered nurses without critical care training and with less than 5 years experience (31). Specifically, the cardiothoracic ICU at CMJAH was found to be staffed, on average, with more than 50% of non-permanent staff who were employed on a temporary basis via agencies (32)".

3.3 AIM OF THE STUDY

The aim of the study was to evaluate adherence to the glucose control protocol by nurses in the cardiothoracic ICU at CMJAH.

3.4 OBJECTIVES OF THE STUDY

The research objectives were to:

- Describe the number of abnormal glucose readings recorded.
- Describe the proportion of protocol violations in relation to the glucose control protocol.
- Compare the differences in glucose protocol violations between day nursing staff and night nursing staff.
- Compare the level of training of nurses involved with glucose protocol violations.

3.5 LOCATION OF STUDY

The study took place at the cardiothoracic ICU at CMJAH, Gauteng Province, South Africa. This is a quaternary, academic hospital associated with the University of Witwatersrand. It is the only public sector cardiothoracic ICU in Johannesburg.

3.6 ETHICAL CONSIDERATIONS

Approval to conduct this study was obtained from the Postgraduate Committee (Appendix A), the Humans Ethics Committee (medical) of the University of the Witwatersrand (Appendix B) and the head of critical care at CMJAH (Appendix D).

In addition, a written informed consent was obtained from the Chief Executive Officer (CEO) of CMJAH to conduct the research in the hospital and specifically to gain access to, and utilize, patients' records and nurses' demographics.

The researcher only worked with numbers allocated to patients and not the file numbers or patients' names. This ensured confidentiality, privacy and anonymity of patient information.

Furthermore, anonymity of the nurses working in ICU during the month of March 2011 was maintained as numbers were allocated to them. The allocated numbers of the nurses, not names, was used when reviewing the ICU charts and the

researcher only knew the identities of the nurses looking after the patients included in the study. The researcher and supervisor were the only people who had access to raw data for this study. Data will be kept for a period of 5 years in a locked cupboard allowing access only by the researcher.

The retrospective nature of the study did not allow for the researcher to be able to intervene with any patient treatment.

The study will be conducted in adherence to the principles of the Declaration of Helsinki (35).

3.7 RESEARCH METHODOLOGY

3.7.1 Study design

A retrospective, contextual, single-centre descriptive research design will be followed in this study**.**

Retrospective

“A retrospective study investigates a phenomenon, situation, problem or issue that has happened in the past, conducted on the basis that data are available for that period (192)”. Retrospective research often requires the analysis of data that were originally collected for reasons other than research (193, 194). This study is

retrospective in nature as it will involve the analyses of recorded data from patients' ICU records from a past period of time i.e. March 2011.

Contextual

This study will not involve all inpatients but rather a select group of inpatients with specific pathophysiological processes i.e. the critically ill patients in a cardiothoracic ICU.

De Vos (195) describes context as a "small-scale world" of, amongst others, gangs, clinics, hospital wards or critical care units. This study is contextual in nature as it will be conducted within a specific context. It will be conducted in a public sector academic, Cardiothoracic ICU in Gauteng.

Descriptive

"A descriptive design is to gain more information about characteristics within a particular field of study (37)".

This study is descriptive in nature as it aims to gain information about adherence to the glucose control protocols, as well as the violations thereof, in a cardiothoracic ICU.

3.7.2 Study population and study sample

A retrospective review of all ICU charts of adult patients, post cardiac surgery, admitted to the CT ICU during the month of March 2011 at CMJAH and the demographics of the nurses looking after those patients during that time constituted the study sample.

3.7.3 Sample Size

During this study period, 22 patients were admitted and 741 glucose readings were obtained.

3.7.4 Sampling Method

The reason for choosing this month was that it had the most ICU admissions therefore a convenience sampling method was used. This sampling method was also chosen due to the scope of the study as well as ease of access to patients' records. This method of sampling is accepted in descriptive research design (196).

3.7.5 Inclusion and exclusion criteria

Inclusion criteria included the ICU records of all adult patients, 16 years and older, admitted to the CT ICU during the month of March 2011 and the demographic data of the nurses looking after these patients at the time.

There were no exclusion criteria.

3.7.6 Data collection procedure

Data collection is the specific, systematic gathering of information relevant to the research purpose or the specific objectives and questions of the study (37).

After approval was obtained from the head of the CT ICU at CMJAH, Wits University Human Research Ethics Committee (medical), University of Witwatersrand and the Chief Executive Officer of CMJAH, the ICU records of all adult patients admitted post cardiac surgery during March 2011 admissions was reviewed. The data was collected by the researcher personally, from the daily ICU charts used both by nurses and physicians in the unit. A data capture record was completed using the daily ICU records of patients' previously admitted to the cardiothoracic ICU in March 2011. The data was then entered onto a Microsoft Excel spreadsheet.

Data collected included:

a) Patient data

- demographic data (age, gender& race)
- admitting diagnoses
- insulin dosage according to protocol including insulin infusion adjustments
- blood glucose
- time of glucose administration
- length of ICU stay.

b) Nursing Data

- Nurse shift - day shift (07h00-19h00) or night shift (19h00-0700)
- ICU trained or not ICU trained

3.7.7 Statistical Analysis

Raw data was captured using an Excel data spreadsheet and analysed using the software programme STATA 11 statistical software (STATA Corporation, College Station, TX USA).

The following variables were included in the analysis:
Age (in years), gender, ICU admission procedure, protocol violations, nurse shift (day/night), nurse ICU trained (yes/no), length of stay in ICU (days) and glucose values.

The results of the study were described and analysed using descriptive and inferential statistics. Frequencies and percentages were used summarise the categorical data. Mean (age of patients), median IQR and ranges were used to summarise the continuous data. Comparisons were made using the chi-square test and P-values of <0.05 were considered statistically significant. Missing data was still included in the analysis and was charted as ‘’unknown”.

3.8 Validity and Reliability

Validity

"Validity is the extent to which the instrument actually reflects or measures what it is supposed to measure (37)". Content validity was secured by literature review, experts in intensive care, a biostatistician and research methodologist.

Reliability

"Reliability is concerned with how consistently the measurement technique measures a variable or concept (37)". The data was collected, from patients' records, by a single researcher only. This ensured that the data is collected in a standardised manner and is reliable.

3.9 SUMMARY

In this chapter, a detailed explanation of the research methodology has been presented under the headings of study design, study population and study sample (including sample size, sampling method, inclusion and exclusion criteria), description of data collection procedure and the planned statistical analysis of the data.

The following chapter details the data analysis and discussion of the results of this study.

CHAPTER FOUR

DATA PRESENTATION AND DISCUSSION OF RESULTS

4.1 INTRODUCTION

In this chapter, the results of this study are presented and discussed, in accordance with the research objectives.

The research objectives were to:

- Describe the number of abnormal glucose readings recorded;
- Describe the proportion of protocol violations in relation to the glucose control protocol;
- Compare the glucose protocol violations of the day nursing staff and night nursing staff;
- Compare the level of training of nurses involved in protocol violation.

4.2 SAMPLE REALISATION AND APPROACH TO DATA ANALYSIS

The data was collected through a retrospective review of the ICU charts of adult patients, post cardiac surgery, who were admitted to the CT ICU at CMJAH during the month of March 2011.

During this study period, 22 patients were admitted and 741 glucose readings were taken.

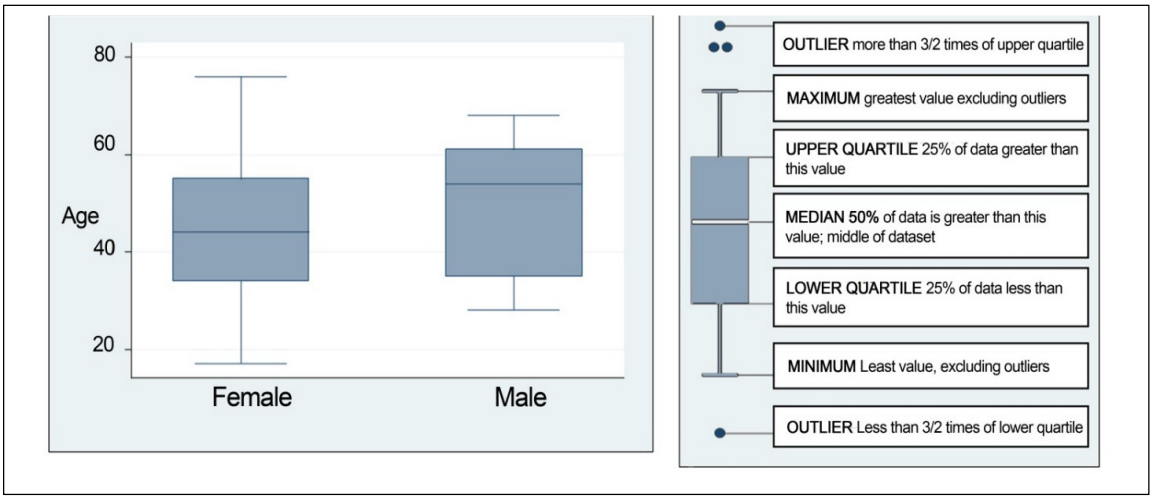
The results of the study are described and analysed using descriptive and inferential statistics. Data that was not available, i.e. information missing from charts or unavailable demographic data of nurses were included in the study, but charted as “unknown”. All results were rounded to 2 decimal places. An abnormal glucose value was defined as a glucose value < 4.1 and > 6 mmol/l according to the glucose control protocol in place during March 2011 (Appendix G).

4.3 RESULTS

4.3.1 Demographic Data

During the data collection period, 22 patients were admitted: 13 (59.1%) male and 9 (40.9%) female. The mean age of patients was 48.5 years; the age range was 17 - 76 years. Figure 4.1 shows the median age and the IQR by gender.

Figure 4.1 Median age and IQR by gender



The median (IQR) length of stay in ICU was 4 (3-5) days, with two patients staying in ICU for more than 20 days.

The demographic data of the nursing staff was as follows:
ICU trained versus non-ICU trained

- Day shift versus night shift

62.6% (n=464) of the glucose readings were obtained by ICU trained nurses, 33.2% (n=245) of the readings were obtained by non-ICU trained nurses, and it was unknown who obtained 4.2% (n=31) of the readings.

The day shift obtained 46.6% (n=345) of the glucose readings; the night shift obtained 51.3% (n=380) of the glucose readings; and it was unknown who obtained 2.1% (n=16) of the readings.

The surgical procedures were categorised as: valvular - 77.3% (n=17); coronary - 13.6% (n=3); and other - 9.1% (n=2). Table 4.1 shows the specific surgical procedures performed during the research period.

Table 4.1 Specific type and number of surgical procedures performed

Variable	N	(%)
Surgical procedure		
MVR+TA+MAZE	4	18.2%
DVR	2	9.1%
MVR	3	13.6%
AVR	1	4.5%
CABG 2 vessel	1	4.5%
CABG 3 vessel	1	4.5%
CABG 4 vessel	1	4.5%
AVR+TA	1	4.5%
DVR+TA+MAZE	1	4.5%
AVR+TA+MV REPAIR	1	4.5%
MVR+TA	2	9.1%
Redo DSAS+AVR	1	4.5%
Submitral aneurysm+MVR	1	4.5%
Other	2	9.1%

Key: MVR=Mitral Valve Replacement; TA=Tricuspid Annuloplasty; MAZE=Ablation of Conduction System of Atria; DVR=Double Valve Replacement; AVR=Aortic Valve Replacement; CABG= Coronary Artery Bypass Graft; Mitral Valve Repair; DSAS=Discrete Sub-aortic Membrane Stenosis.

4.3.2 Number of abnormal glucose readings recorded

The first objective of the study was to describe the number of abnormal glucose readings recorded in adult patients post cardiac surgery in a CT ICU.

An abnormal glucose value was defined as a glucose value < 4.1 and > 6 mmol/l, as per glucose control protocol in place during March 2011 (Appendix G).

A total of 741 glucose readings were taken. The median blood glucose concentration was 7. 8 mmol/l (IQR 6.7 - 9.3 mmol/l). The median and IQR for each patient is shown in Figure 4.2; the range of glucose readings (3.1-17.8 mmol/l) is shown in Figure 4.3.

Figure 4.2 Median & IQR for glucose values per patient

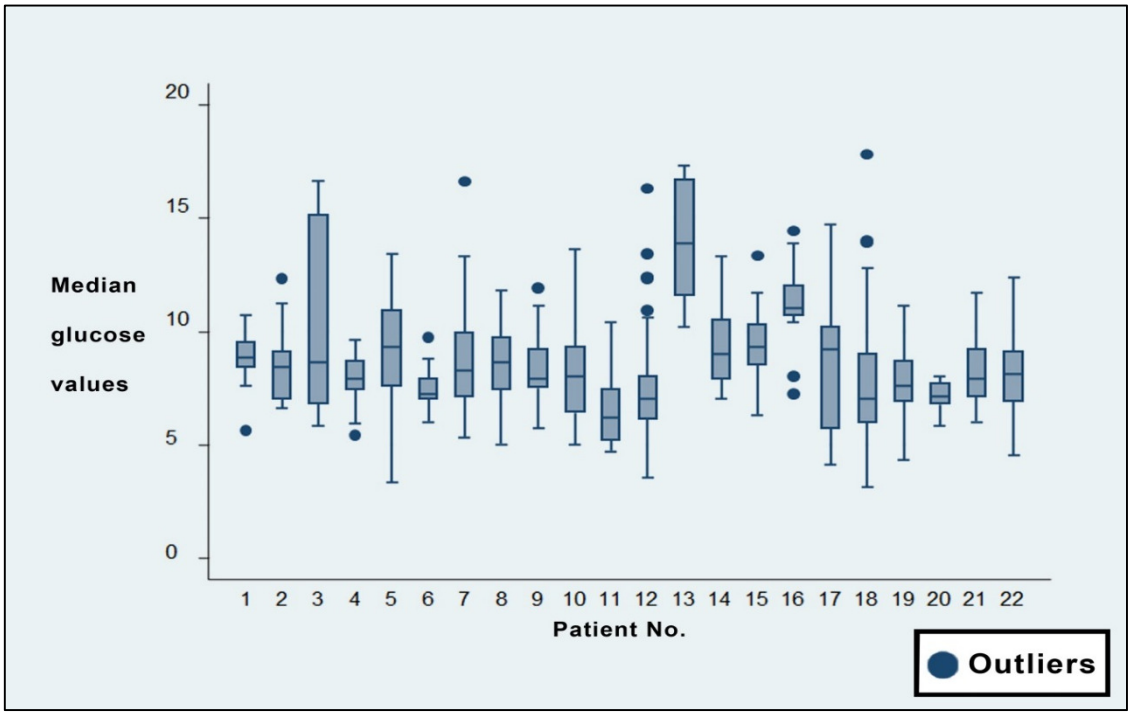


Figure 4.3 Range of glucose readings



Table 4.2 shows the number of glucose readings obtained in the different glucose ranges. According to the glucose control protocol in place during March 2011, 629 (84.9%) of the readings were abnormal, i.e. outside the required glucose range. The target range of 4.1-6 mmol/l was only seen in 112 (15.1%) of the glucose readings.

Hypoglycaemia (defined in this as a glucose value of less than 4 mmol/l) was evident in 7 (0.9%) glucose readings. If the results were analysed according to the new glucose protocol currently in place, the target range of 6.1-8 mmol/l would have been seen in 279 (37.7%) readings.

Table 4.2 Glucose results by category

Glucose category	Number	%	Normal Range
<4	7	0.9	No
4.1 – 6	112	15.1	Yes
6.1 – 8	279	37.7	No
8.1 – 12	300	40.5	No
12.1 – 14	26	3.5	No
14.1 – 16	6	0.8	No
16.1 – 18	11	1.5	No
>18	0	0	No

4.3.3 To describe the proportion of protocol violations in relation to the glucose control protocol

The next objective of the study was to describe the proportion of protocol violations in relation to the glucose control protocol.

During the study period, a total of 741 glucose readings were taken. Overall, 411 (55.5%) protocol violations were recorded and 18 (2.4%) were unknown.

Figure 4.4 demonstrates the number of glucose readings obtained for each patient and the proportion of violations from the glucose control protocol per patient. The unknown values are not shown on this figure.

Figure 4.4 Protocol violations with respect to glucose readings per patient

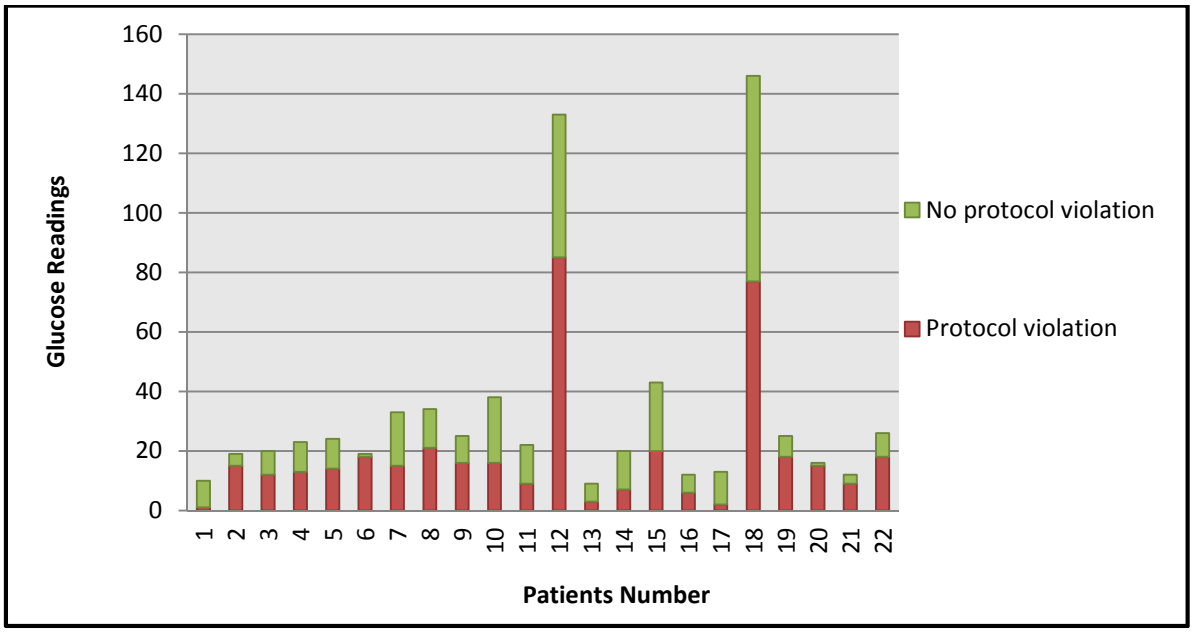


Table 4.3 depicts the total number of glucose readings and the number of protocol violations for each patient. This table includes the unknown values per patient.

Table 4.3 Number of glucose readings and protocol violations per patient

Patient number	Protocol violation	No protocol violation	Unknown	Total glucose readings per patient
1	1	9	0	10
2	15	4	0	19
3	12	8	6	26
4	13	10	0	23
5	15	10	0	25
6	18	1	0	19
7	15	18	1	34
8	21	13	0	34
9	16	9	0	25
10	16	22	1	39
11	9	13	2	24
12	85	48	0	133
13	3	6	1	10
14	7	13	1	21
15	20	23	2	45
16	6	6	1	13
17	2	11	0	13
18	77	69	0	146
19	18	7	1	26
20	15	1	0	16
21	9	3	1	13
22	18	8	1	27
	411	**312**	**18**	**741**

4.3.4 To compare the differences in glucose protocol violations between the day nursing staff and night nursing staff

The next objective of this study was to compare the differences in glucose protocol violations between the day nursing staff and night nursing staff.

Day staff work a 07h00-19h00 shift and night staff work from 19h00-07h00. No statistically significant difference was found between day nursing staff and night nursing staff - $X^2(1) = 1.29$, p=0.26. This is shown in Table 4.4.

Table 4.4 Association between day staff and night staff and protocol violations

Variable	Glucose readings n (%)	Protocol violations n (%)	Protocol violation	P value
Nurse shift				
- Day	345 (46.6%)	156 (45.4%)	188 (54.7%)	
- Night	380 (51.2%)	156 (41.2%)	223 (58.5%)	0.26

4.3.5 To compare the level of training of nurses involved with glucose control violations

The last objective of the study was to compare the level of training of nurses involved with glucose control violations.

A statistically significant difference was found in protocol violations between ICU trained and non-ICU trained nursing staff - X^2 (1) =6.97, p=0.008. The non-ICU trained staff violated the protocol more often. This is shown in Table 4.5.

Table 4.5: Association between ICU training and protocol violations

Variable	**Glucose Readings n (%)**	**No Protocol Violation n (%)**	**Protocol Violation**	**P value**
Training				
- ICU trained	464 (62.6%)	216 (46.7%)	247 (53.3%)	
- non-ICU trained	245 (33.2%)	89 (36.3%)	156 (63.7%)	
				0.008

4.4 Discussion

In this study, the proportion of glucose protocol violations was found to be 55.5%. This value is higher than that reported by Taylor et al. (25) and Rood et al. (26), with glucose protocol violations reported as 47% and 44% respectively. Oeyen et al. (3), reported 29% violations to an insulin protocol. The NICE-SUGAR trial reported a 29% violation rate to a glucose control protocol. Possible reasons for the lower proportion of violations are that these were large trials conducted in developed countries that have adequate resources compared to our local setting.

Shift work, and in particular working night shifts, is recognised as a source of stress for nurses (197). In a study of 23 Australian nurses, getting less sleep was significantly related to an increased likelihood of patient error and a decreased likelihood of finding someone else's error (198). It was this understanding of the night nursing staff probably committing more protocol violations than the day staff that motivated us to review the timing of protocol violations. However, there was no statistical significance between day staff and night staff violations with a p–value of 0.26. It is beyond the scope of this study to identify reasons for similar proportion of violations between day staff and night staff in this study sample.

According to the South African National Audit of Critical Care Resources in 2007, there is a national shortage of critical care nurses (31). As a result, there is over-stretching of the active critical care nurse and a risk of increased workload and burnout (31). The workload burden of protocols in the ICU is an important factor to consider. In a prospective single-centre study, it was shown that the time required for a glucose control protocol to be implemented was 2 hours per day, that is, approximately 20% of a nurse's working day (186). Together with staff shortages and highly protocolised ICUs, critical care nurses are under constant pressure to deliver safe and effective care to critically ill patients, as well as to impart their skills and knowledge to non-ICU trained nurses. In this study, we looked at protocol violations between ICU trained and non-ICU trained nurses and, after reviewing the literature were not surprised to find that in our study there were more protocol violations by the non-ICU trained nurses; a p-value of 0.008.

For a protocol to be efficiently developed and implemented, its feasibility should be tailored according to resource availability in that setting. All health care workers involved in patient care (nurses, doctors, nutritionists, etc,) need to work together in order to facilitate this process. Other health care workers involved with implementation of the glucose control protocol were not evaluated in this study, but are equally responsible, as nurses, in implementing protocols.

Protocol violation may or may not compromise patient care. Conducting an audit of practice in ICUs assists in identifying the reasons for violations. In 2008, Gupta et al. (199) reported a case of accidental severe hypoglycaemia and neuroglycopaenia caused by an arterial line flush error. The fluid used as the arterial line flush was normal saline with dextrose, instead of plain normal saline. As a result, falsely high glucose readings were taken from blood samples from the arterial line as a saline/glucose flush had been used. Insulin was used to treat these erroneously high glucose readings, according to the glucose control protocol in place in that ICU at that time. This resulted in the patient suffering severe hypoglycaemia and neuroglycopaenia.

This is just one of several examples in which even though the action was not strictly a protocol violation, it did demonstrate how a simple error can lead to an adverse patient outcome.

According to Wong et al. (200), “one of the cardinal concepts, (borrowed from industry), in patient safety, is systems analysis. This is the concept that system failure, not individual human failure, is to blame for many of the adverse events occurring in health care. An important part of moving beyond the blame and punishment often associated with medical error is recognizing that the human factor is only one aspect of today’s complicated medical system”. “Preventing errors and improving safety for patients require a systems approach in order to modify the conditions that contribute to errors. People working in health care are among the most educated and dedicated work force in any industry. The problem is not bad people; the problem is that the system needs to be made safer.” A saying which also needs to be kept in mind is “To err is human” (201).

Other possible causes for protocol violations include:

- “interaction with technology
- the large number of health care staff involved in the provision of care, resulting in multiple hand-overs
- poor communication between patients and staff and poor staff-staff communication
- stress and fatigue
- human factor design flaws
- lack of appropriate education and training
- higher acuity of illness
- the need for rapid decision-making
- reduction in staffing

- a lack of redundancies to prevent error (201)".

Cabana et al. (202) identified barriers to adherence to practice guidelines. In their model, "barriers to knowledge include lack of awareness and familiarity with guidelines. Barriers to attitude include lack of agreement with guidelines, lack of self-efficacy, lack of outcome expectancy and lack of motivation. Barriers to behaviour include factors related to patients (e.g. patient expectation), the practice environment (e.g. lack of time; or resources) and the guidelines themselves (e.g. conflicting recommendations). These categories are indicated in Table 4.6.

Table 4.6 Summary of Cabana's barriers to using guidelines (202)

Physician Attribute	**Barriers**
Knowledge	Lack of awareness Lack of familiarity
Attitude	Lack of agreement Lack of self-efficacy* Lack of outcome expectancy** Inertia of previous practice
Behaviour	External barriers • Patient related barriers • Environmental related barriers • Guideline related barriers

* Lack of self-efficacy: self-efficacy is the belief that one can perform a task.

** Lack of outcome expectancy: outcome expectancy is the belief that if one carries out the task it will make a difference to patient outcomes".

Although adherence to the protocol was poor, the median (IQR) glucose reading was 7.8 mmol/l. Locally, the Nesibopho Best Practice Guidelines (175) on glucose control in ICU, (which is endorsed by the Critical Care Society of Southern Africa), recommends the maintenance of glucose to be <8.1 mmol/l; but if monitoring is inadequate or hypoglycaemia occurs, maintenance should be between 7-9 mmol/l. Therefore the glucose value being obtained in the CT ICU, despite resource constraints and protocol violations, was found to still be within a reasonable range.

The benefits and risks of TGC has been an ongoing debate, but there seems to be a move towards SEGC rather than TGC (185). Despite the morbidity and mortality implications of TGC, the work burden of implementing TGC is difficult in the local setting, as highlighted by a national audit of resources in the critical care setting, which showed a shortage of skilled nursing staff (31). Therefore, the finding of a statistically significant proportion of protocol violations by non-ICU trained nursing staff in this study bears further evidence of the shortage of skilled nursing staff in ICUs, which then impacts on patient safety. An important point to note from the landmark Leuven 1 trial (7) was that TGC in the ICU was possible due to adequacy of nursing staff- hence hypoglycaemic episodes were reduced. However, this is not feasible in most critical care settings.

Glucose control is difficult in critically ill patients and the target glucose range is not always met. The exact incidence of hospital hyperglycaemia is not known, but it varies based on study populations and definitions utilised in previous reports. Two observational studies, which used 7.8 mmol/ as hyperglycaemia, found hyperglycaemia in 80% of critically ill patients after cardiac surgery (12, 13). The occurrence of hyperglycaemia is even more evident in critically ill patients; 31% of the population will have at least one BG reading >11.1 mmol/l and nearly 100% will have a BG > 6.1 mmol/l during their ICU stay (7, 10, 14).

"Based on the results of recent trials, the American Association of Clinical Endocrinologist and American Diabetes Association task force on inpatient glucose control, it was recommended that targeting a BG level between 7.8 and 10.0 mmol/l for the majority of ICU patients and a lower glucose target between 6.1 and 7.8 mmol/l in selected ICU patients (i.e. centres with extensive experience and appropriate nursing support, cardiac surgical patients and patients with stable glucose control without hypoglycaemia) (203). Glucose targets >10 mmol/l or < 6.1 mmol/l are not recommended in ICU patients (74, 79)".

In this study, the target glucose range during March 2011 in the CT ICU was 4.1-6 mmol/l. This target range was only seen in 15.1% of glucose readings with the number of abnormal readings being 84.9% (n=629). According to the new glucose control protocol that is now implemented in the CT ICU, the target range is 6.1-8 mmol/l. This target range would therefore be seen in 37.7% of the readings.

4.5 CONCLUSION

“One of the most consistent findings in research on health services is the gap between evidence and practice (43)”. Evidence-based protocols and guidelines are utilised to assist not only with patient clinical management and to reduce the guess work from patient care, but to also reduce the work load on nursing staff as a short term solution to skilled staff shortages (104). The finding of a substantial proportion of protocol violations in the ICU highlights the necessity of further education and ongoing assessments of implemented protocols by all health care workers involved with patient care.

4.6 SUMMARY

In this chapter the results of the study were presented, as per the research objectives, and discussed. The data presented included: the sample realisation; the demographic data of the study sample; the number of abnormal glucose readings recorded from adult patients post cardiac surgery in a CT ICU; the proportion of protocol violations from the glucose control protocol used in ICU, the differences in glucose protocol violations between day nursing staff and night nursing staff and the level of training of ICU nursing staff involved with protocol violation. The findings were described and analysed using descriptive and inferential statistics.

In the final chapter a summary is presented, together with the limitations, recommendations and a conclusion of the study.

CHAPTER 5

SUMMARY, LIMITATIONS, RECOMMENDATIONS AND CONCLUSION

5.1 INTRODUCTION

In this chapter, the aim, objectives, study design and results of the study will be reviewed briefly. The limitations of the study will be addressed, recommendations made to improve clinical practice and suggestions provided for areas of further research. Finally, a conclusion is presented.

5.2 SUMMARY OF THE STUDY

5.2.1 Aim of the study

The aim of the study was to evaluate adherence to the glucose control protocol by nurses in the cardiothoracic ICU at CMJAH.

5.2.2 Objectives of the study

The research objectives were to:

- Describe the number of abnormal glucose readings recorded.

- Describe the proportion of protocol violations in relation to the glucose control protocol.
- Compare the differences in glucose protocol violations between day nursing staff and night nursing staff.
- Compare the level of training of nurses involved with glucose protocol violations.

5.2.3 Summary of methodology used in the study

A retrospective, contextual, single-centre descriptive research design was used in this study. The ICU charts of all adult patients, post cardiac surgery, admitted to the CT ICU during March 2011 at CMJAH and the demographics of the nurses working in the unit for that period of time were reviewed and this constituted the study sample. The reason for choosing this month was that it had the highest number of ICU admissions during the research period. A convenience sampling method was employed.

The glucose control protocol in place in ICU at the time of conducting the study was defined.

Inclusion and exclusion criteria were also defined. The data collected was analysed using STATA 11 statistical software.

The results of the study were described and analysed using descriptive and inferential statistics. Frequencies and percentages were used summarise the categorical data. Mean (age of patients), median IQR and ranges were used to summarise the continuous data. Comparisons were made using the chi-square test and P-values of <0.05 were considered statistically significant.

5.2.4 Main findings of the study

Twenty-two patients' ICU charts were entered in the study and a total of 741 glucose readings evaluated. The median glucose reading was 7.8 mmol/l (6.7- 9.3 mmol/l). Of the 741 readings, 629 (84.9%) were abnormal (i.e. outside the required target range) according to the glucose control protocol at the time. Overall, the proportion of protocol violations was 55.5%.

Protocol violations were similar between day and night staff, i.e.188 (54.7%) and 223 (58.5%) respectively (p =0.256).

Of the total glucose readings, 463 (65.4%) were done by ICU trained nurses and 245 (34.6%) by non-ICU trained nurses.

There were fewer protocol violations recorded by ICU trained nurses as opposed to non-ICU trained nurses, i.e. 53.3% and 63.7% respectively (p<0.05).

5.3 LIMITATIONS OF THE STUDY

This study has the following limitations.

This study was done contextually at CMJAH and the results may not be generalisable to other ICUs.

It was unknown what the sample size would be until the data was collected (as we did not know how many blood glucose readings would be done in one month) and therefore were unable to calculate the sample size necessary to find this difference so the results should be interpreted with caution as they may be underpowered.

A study by Kanji et al. (168) confirmed that there may be clinically relevant disparities between different methods of glucose measurement. The “gold standard” of blood glucose measurement involves a blood sample being sent to the laboratory for the most accurate result; however, this was not feasible in this study. Most glucose values in this study were identified by blood gas analysis; however it was not distinguished on the chart when a point of care machine was used or when an arterial blood sample and a venous blood sample were used. Using arterial blood sample compared to venous blood sample being more accurate for glucose measurement. A single standardised method of glucose measurement should ideally be used; however, this study is a reflection of day to day practice in the ICU.

Lastly other limitations of a retrospective study are that it relies on the accuracy of written record or recall by individuals (recall bias), as well as legibility and availability of records. In this study, determining nursing demographic data posed a challenge, as data was obtained from poorly kept shift records and via word of mouth. Therefore, it is possible that there was a loss of important data and that inaccurate data was collected.

5.4 RECOMMENDATIONS FROM THE STUDY

5.4.1 Recommendations for clinical practice

The workload burden of implementing a glucose control protocol in our ICU setting is notable. A trend towards SEGC, rather than TGC is a more manageable approach to glucose control.

Due to the severity of illness in critically ill patients, the rapid advancement in technology and the emergence of new information, all health care workers need to be up to date and well acquainted with the literature in order to provide safe, quality care to patients. Educational programmes need to be implemented, for all health care workers in ICU. All programmes should be updated and presented regularly to new health care workers in the CT ICU.

There is a gap between research and practice. There should be regular audits of clinical practice to ensure that what is prescribed for the patient is actually the care given.

5.4.2 Recommendations for further research

Education of health care workers and follow up questionnaires on the understanding and implementation of local protocols.

Evaluate and identify factors responsible for protocol violation and target those factors in order to improve adherence to any protocol implemented in ICU. As proposed by Cabana et al. (202) mentioned in the previous chapter where the knowledge, attitudes and behaviour of health care workers should be evaluated when implementing a protocol. Furthermore, a systems analysis approach should be considered for implementation of future protocols (200).

The literature has revealed a large number of studies involving computerised and closed-loop protocol implementation with improved adherence to the protocol. These types of protocols will be used in future for further research into protocol implementation.

5.5 CONCLUSION

Adherence to the glucose control protocol in the CT ICU was poor. Despite a high percentage of protocol violations, the median blood glucose level was 7.8 mmol/l. The number of violations committed by day staff and night staff were similar and not statistically significant. ICU trained nurses committed fewer violations than non-ICU trained nurses and this was statistically significant.

These results suggest that the training and education of healthcare workers in implementing protocols is an ongoing and dynamic process and evaluation is needed on a regular basis.

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Appendix A

Postgraduate Permission Letter

Faculty of Health Sciences
Medical School, 7 York Road, Parktown, 2193
Fax: (011) 717-2119
Tel: (011)717-2075/6

Reference: Ms Salamina Segole
E-mail: Salamina.segole@wits.ac.za
06 June 2012
Person No: 0108344E
PAG

Dr D Maharaj
Suit No 7
P/Bag X2
Pinegowrie
2123

South Africa

Dear Dr Maharaj

Master of Medicine (in the specialty Anaesthesia): Approval of Title

We have pleasure in advising that your proposal entitled "*Evaluation of adherence to the glucose control protocol in a cardiothoracic ICU*" has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix B

Permission from Ethics Committee

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Dyuti Maharaj

CLEARANCE CERTIFICATE	**M120109**
PROJECT	Evaluation of Adherence to the Glucose Control Protocol in a Cardiothoracic ICU
INVESTIGATORS	Dr Dyuti Maharaj.
DEPARTMENT	Department of Anaesthesiology
DATE CONSIDERED	27/01/2012
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 27/01/2012 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Ms Helen Perrie

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

Appendix C

Approval Letter from CEO at CMJAH

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Office of the CEO
Enquiries:
Ms. L. Mngomezulu
(011): 488-3793
(011) 488-3753
10th October 2012

Dr. Dyuti Maharaj
Registrar – Aneasthesiology Department
Charlotte Maxeke Johannesburg Academic Hospital

Dear Dr. Maharaj

RE: "evaluation of adherence to the glucose control protocol in a cardiothoracic ICU "

Permission is granted for you to conduct the above research 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.

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.

Yours sincerely

Dr. T.E. Selebano
Chief Executive Officer

Appendix D

Approval Letter from HOD of ICU at CMJAH

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Johannesburg Hospital
+27832668378
+27114883654
Fax +27114884675
7/11/11

Ms Rosen Mhlongo
Post Graduate Research Office

Re : Permission to conduct research in the Cardiothoracic ICU at CMJAH

Dear Ms Mhlongo

Dr Dyuti Maharaj is granted permission to conduct her MMed research which will evaluate the compliance to the glucose control protocol in the cardiothoracic ICU (ward 467).

Yours Sincerely

.....

Professor GA Richards
MBBCh PhD FCP (SA) FRCP FCCP
Director Intensive Care Charlotte Maxeke Johannesburg Academic Hospital
Chief Physician and Director of Critical Care
Associate Professor Dept of Pulmonology and University of the Witwatersrand

APPENDIX E

DATA COLLECTION SHEET (A)

Day of ICU _____ Patient study number _____ Date_____

06:00 Nurse No: -BG -Tx -Violation Y/N	**07:00** Nurse No: -BG -Tx -Violation Y/N	**08:00** Nurse No: -BG -Tx -Violation Y/N
09:00 Nurse No: -BG -Tx -Violation Y/N	**10:00** Nurse No: -BG -Tx -Violation Y/N	**11:00** Nurse No: -BG -Tx -Violation Y/N
12:00 Nurse No: -BG -Tx -Violation Y/N	**13:00** Nurse No: -BG -Tx -Violation Y/N	**14:00** Nurse No: -BG -Tx -Violation Y/N
15:00 Nurse No: -BG -Tx -Violation Y/N	**16:00** Nurse No: -BG -Tx -Violation Y/N	17:00 Nurse No: -BG -Tx -Violation Y/N
18:00 Nurse -BG No: -Tx -Violation Y/N	**19:00** Nurse No: -BG -Tx -Violation Y/N	**20:00** Nurse No: -BG -Tx -Violation Y/N
21:00 Nurse -BG No: -Tx -Violation Y/N	**22:00** Nurse No: -BG -Tx -Violation Y/N	**23:00** Nurse No: -BG -Tx -Violation Y/N
00:00 Nurse No: -BG -Tx -Violation Y/N	**01:00** Nurse No: -BG -Tx -Violation Y/N	**02:00** Nurse No: -BG -Tx -Violation Y/N
03:00 Nurse No: -BG -Tx -Violation Y/N	**04:00** Nurse No: -BG -Tx -Violation Y/N	**05:00** Nurse No: -BG -Tx -Violation Y/N

APPENDIX F

DATA COLLECTION SHEET (B)

Nurses Demographic Data

1. Nurse research number

2. Nurse qualification

ICU trained professional nurse	
Professional nurse	
Staff nurse	
Auxiliary nurse	

Data not available	

3. Years of ICU experience

Data not available	

4. Permanent/Agency staff

Data not available	

5. Permanent Day/Night staff

Data not available	

APPENDIX G

INSULIN SLIDING SCALE PROTOCOL

BG (mmol/l)	Rapid acting insulin **(Subcutaneous)**
<4	NIL <u>Treat as hypoglycaemia</u> 1. Call medical doctor. 2. Administer 25 ml of DW50 3. Recheck BG every 15 minutes until >5 mmol/l 4. Thereafter recheck BG hourly
4.1-6	0 U
6.1-8	1U
8.1-12	2U
12.1-14	4U
14.1-16	6U
16.1-18	8U
18.1-20	10U
> 20	12U and call medical doctor

APPENDIX H

INSULIN INFUSION PROTOCOL

100 UNITS INSULIN (ACTRAPID) IN 100 mls NORMAL SALINE
THEREFORE: 1 ml = 1 unit of insulin

The aim is to keep the blood glucose level between **4 - 6 mmol/l**

If at any time prior to starting the insulin infusion the blood glucose is **6.1 mmol/l** or greater, repeat it one hour later. If the repeat blood glucose is still greater than **6.1 mmol/l** start the insulin infusion as per protocol.

Start the insulin infusion at 2 units per hour and repeat the dextrostix one hour later:

If blood glucose **< 3 mmol/l** → stop insulin infusion, give 50 mls of 50% dextrose water IV and repeat dextrostix after 15 min and again after 30 min.

If blood glucose = **3- 4 mmol/l** → stop infusion and repeat dextrostix after 30 min. Restart insulin infusion if repeat dextrostix is > 8 mmol/L.

If blood glucose = **4-6 mmol/l** → continue infusion and repeat dextrostix after 2 hours.

If blood glucose = **6-8 mmol/l** → increase insulin infusion by 1 unit per hour and repeat dextrostix after 1 hour.

If blood glucose = **> 8 mmol/l** → increase insulin infusion by 2 units per hour and repeat dextrostix after 1 hour.

If blood glucose is stable (i.e. 4-6 mmol/l) for longer than 12 hours on a constant insulin infusion the dextrostix can be done 4 hourly.

NB Stop insulin infusion if feeds or TPN are stopped or if patient develops intolerance for feeds. For patients who are discharged to the ward and in whom the insulin infusion has been stopped, flush the line/port that the insulin infusion was connected to with 5 ml N/Saline.