THE STATISTICAL VARIANCE OF BLOOD GLUCOSE LEVELS OF MEDICIAL INTENSIVE CARE UNIT PATIENTS WHILE ON AN INSULIN INFUSION PROTOCOL

by

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This thesis has been read by each member of the thesis committee and has been found to be satisfactory regarding content, English usage, format, citations, bibliographic style, and consistency, and is ready for submission to the Division of Graduate Education.

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ABSTRACT

Hyperglycemia has been shown to have many negative consequences in the critically ill patient. Many physicians and nurses have been searching for ways to provide quality care for the critically ill and decrease the hyperglycemia found in the diabetic and nondiabetic Intensive Care Unit (ICU) patient. Many physicians and nurses around the world are studying the use of the insulin infusion protocol to combat the hyperglycemia and therefore decrease the negative consequences associated with hyperglycemia.

This study was a retrospective chart review of medical ICU patients in three months in 2003 and the same three months in 2004 in order to determine the statistical variance of blood glucose readings while on an insulin infusion protocol (IIP). There is little literature about the nurses' experience with the IIP.

The study used medical patients from the Billings Clinic ICU in Billings, Montana who met inclusion criteria. Patients from the 2003 population utilized an IIP from 2002 and patients in the 2004 population utilized an IIP from 2003. Blood glucose readings were recorded and analyzed using SPSS 14.0.

The study found no statistical difference in blood glucose readings due to a small sample size. There were interesting trends in the blood glucose data from 2003 to 2004. The results of the trends could be related to a more proficient understanding of the protocol and the rationale behind the protocol from the bedside nurse, as they are the sole operator of the protocol.

Imogene King's Theory of Goal Attainment is one to be utilized for nurses operating the IIP. The goal of the IIP is to decrease hyperglycemia, therefore increasing the health of a person. Imogene Kings' theory integrates a personal, interpersonal, and social systems level to attain the ultimate goal, health. Nurses operating the IIP can utilize Imogene King's theory to attain health for the patient.

CHAPTER ONE

INTRODUCTION

Nurses and physicians caring for critically ill patients in Intensive Care Units (ICUs) are continually looking for ways to improve patient outcomes and decrease morbidity and mortality. In 2004 the mortality rate for ICU patients was approximately 20% (Lewis et al., 2004). Hyperglycemia is a common problem in the ICU patient population in both those with a known diagnosis of diabetes and those without (Umpierrez et al., 2002). The incidence of hyperglycemia may be as high as 50% in the nondiabetic ICU patient (Roberts & Hamedeni, 2004). Consequently, many ICUs have started to implement insulin infusion protocols (IIPs) to combat the hyperglycemia found in the ICU patient.

Hyperglycemia in the hospital setting is thought to lead to increased mortality and morbidity, increased length of stay, decreased wound healing, and increased infection rates (Van Den Berghe, 2001). Intensive study into IIPs has begun to emerge in hospitals around the world to decrease the incidence of hyperglycemia in ICU patients.

The precursor to hyperglycemia in patients, even those without a known diabetes diagnosis, is critical illness. The stress that critical illness applies to the patient has a large impact on many metabolic pathways, including cytokines, hormones, and nervous system counter-regulatory signals. Glucogenolysis, which results in an increase in blood glucose, is caused by increased levels of glucagons, cortisol, catecholamines, and growth hormones (Fraser, Lois, Robley, Peno-Green, 2006).

Problem Statement

Hyperglycemia in the hospital setting, which is thought to lead to increased infection rates, increased morbidity and mortality, decreased would healing, and increased length of stay is detrimental to the patient as well as society in general (Clement et al, 2004). The IIP has not been well researched in ICU settings for the medical patient.

Purpose of the Study

The purpose of this study is to examine the relationship between insulin infusion protocols and nurses' experience with blood glucose variance in ICU patients.

Setting

The study took place in the Billings Clinic Intensive Care Unit in Billings, Montana with a retrospective chart review of the blood sugars found in medical ICU patients during a three month time span in 2003 and a comparison of the same three months again in 2004.

Definition of Terms

Insulin Infusion Protocols are algorithms developed by various members of the healthcare team that may include, but not limited to, physicians, nurses, and dieticians. The protocol is designed to achieve an optimum blood glucose level by adjusting the

amount of intravenous insulin administered to a patient on a continuous basis based on the blood glucose reading.

Nurses are Registered Nurses working in the Billings Clinic ICU in 2003 and 2004. Registered Nurses are people who are graduate trained nurses that have been licensed by a state authority after passing a qualifying exam (Mish, 1985). Nurses provide a caring relationship, facilitate health and healing, and pay particular attention to human experiences and the response to health and illness within social, mental, and physical environments (ANA Nursing World, 2006).

Significance for Nursing

Nurses ultimately are the sole operators of the IIP in the ICU at the Billings Clinic. Operation of the IIP requires intense monitoring and an additional time commitment in caring for the critically ill. With the amount of time required to test the blood glucose level, adjust the intravenous insulin based on the algorithm, and provide quality patient care, nurses may find the IIP non-useful and a time constraint. By studying the protocol and blood glucose variance, nurses in the ICU and other patient care areas will be able to evaluate the usefulness of the IIP and how the experience level with the IIP affected the blood glucose variance from year to year. Nurses will be able to accurately identify the reward of adequately controlled blood glucose and the benefits of tight glycemic control.

Framework

The IIP has a goal to maintain strict glycemic control in order to decrease infection rates, decrease length of stay, and increase wound healing. Imogene King's theory of goal attainment is applicable to the application of the IIP in the ICU setting. Many nurses have little realization the work they are doing is based on theory. The theory of goal attainment sets a goal of bringing the patient closer to a healthy state by decreasing hyperglycemia and preventing hypoglycemia. King's theory aligns three interacting systems to bring about the goal. These systems include personal, interpersonal, and social (King, 1997). See Figure 1.

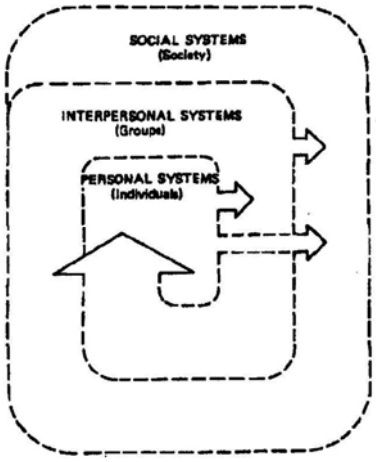

Figure 1. King's theory of goal attainment of interacting personal, interpersonal, and social systems (King, 1997)

King defined a system "as a set of elements connected by communication links that exhibit goal-directed behavior" (King, 1997, p. 180). King went on to describe the

essential elements in a system. These include goals, structure, decision-making, resources, and functions (King, 1997). Nurses and patients must interact in order to achieve health, which is the ultimate goal. Utilizing the IIP can be demonstrated in the conceptual framework from King. King's theory can be applied to many nursing and health situations. In the incidence of utilizing the IIP, nurses help patients preserve life at the personal systems level (King, 1990). The nurse helps the patient preserve life by decreasing the incidence of hyperglycemia and hypoglycemia and therefore decreasing the length of stay in the hospital and increasing wound healing. All of which are beneficial for the patient on a personal level.

The interpersonal level is directed by the nurse and the environment practiced in. There may or may not be much verbal communication between the patient and the nurse, however, the nurse must interact within the environment of the ICU to operate the IIP and therefore decrease hyperglycemia and hypoglycemia. Goals are still utilized to maintain health and function roles.

The social systems level is where the nurse may not realize she is interacting within a social system level. The nurse is operating the IIP and therefore decreasing length of stay in the hospital, preventing wound infections, and increasing wound healing time. All of the above mentioned leads to a decrease in health care dollars spent. The interaction becomes a social interaction when it affects more than just the patient and the nurse.

Nurses must use this model in order to achieve strict glycemic control with less hyperglycemia and hypoglycemia and ultimately achieve health as the final goal. "Nursing is defined as a process of action, reaction, interaction, and transaction whereby nurses assist individuals of any age group to meet their basic human needs in coping with their health status at some particular point in their life cycle" (King, 1968, p. 27). The nurses operating the IIP are assisting the patient and helping the patient to cope with hyperglycemia and/or hypoglycemia with the ultimate goal to be glycemic control.

In reviewing the concepts of Imogene King's theory of goal attainment listed above, nurses operating the IIP, follow these concepts. The process of action, reaction, interaction, and transaction can be applied to nurses operating the IIP. For example, the nurse initiates the IIP after following the order from the physician. The nurse acquires the patient's blood glucose value from a blood sample. After reviewing the result, the nurse acts by using the IIP to begin the continuous insulin infusion into the patient. The nurse reacts to the following blood glucose values by adjusting the insulin infusion in accordance with the directions of the IIP. The nurse interacts with many members of the healthcare team as well as the physician in order to maintain adequately controlled blood glucose values. If the IIP does not seem to be adequate for the patient or problems arise, the nurse interacts with the physician, other nurses, and pharmacy staff. Dependent upon the advice from the physician, nurses, pharmacy staff, or adjustment according to protocol, transaction occurs.

Other concepts included in King's theory include perception, judgment, and action (King, 1997). A nurse operating the IIP utilizes all of these concepts as well. The nurse perceives the blood glucose values and analyzes trends of the blood glucose values. If the nurse understands all of the health benefits of the IIP, they will be more likely to follow the protocol and be aggressive in treating the hyperglycemia once they have perceived the complications of hyperglycemia and hypoglycemia. The nurse then uses her jud gment to some degree to adjust the insulin infusion. When reviewing the protocol, there are some areas of adjustment that are left to the nurses discretion as to how much and what percent to change the insulin infusion. As discussed above, the nurse acts on the blood glucose values ascertained from the patient.

In bringing the person closer to a healthy state, the nurse must interact with the patient. The interaction may be both verbal, for example describing to the patient and family why normoglycemia is important or non-verbal. The nurse and patient interaction lead to a more healthy state for the patient.

Conclusion

This study is ultimately based on goal attainment; the decrease of hyperglycemia and hypoglycemia due to nurses' experience with the IIP. By incorporating Imogene King's theory of goal attainment framework into the utilization of the IIP, Billings Clinic ICU nurses experienced with the protocol will cause less hypoglycemic and hyperglycemic episodes therefore providing greater health to the patient, which is the

ultimate goal. Allowing the nurse to utilize the conceptual framework of the goal attainment theory in working with the protocol, the nurse will act, react, perceive, judge, and transact to reach a healthy state for the patient.

CHAPTER TWO

LITERATURE REVIEW

The Insulin Infusion Protocol (IIP) is becoming used more in the Intensive Care Unit (ICU) setting with surgical and medical patients. The IIP is used to control hyperglycemia and decrease the negative consequences associated with hypoglycemia. The following will discuss literature supporting the negative consequences of hyperglycemia and the positive outcomes when using and IIP.

Hyperglycemia

Hyperglycemia is defined as a blood glucose value above a defined number after an eight hour fast as well as two hours after eating, or postprandial (Diabetes dictionary, 2006). ACE recommends normoglycemia targets to be less than 110 mg/dL or less fasting, <180 mg/dL postprandial, or 80-110 mg/dL in the ICU (AACE, 2003). Hyperglycemia was defined with many different numbers in the various studies. Krinsley designed his IIP to be used to keep blood glucose values less than 140 mg/dL (Krinsley, 2004). Van den Berghe and colleagues designed their intense IIP to keep blood sugar values between 80 mg/dL and 110 mg/dL (Van den Berghe, 2001). The IIP designed by the Billings Clinic used the goal blood sugar between 80 mg/dL and 110 mg/dL.

Hyperglycemia has been studied in in-vitro systems and animal models. It has been found to have deleterious effects on the immune system, mediators of inflammation, vascular responses, and brain cell responses as well as affect morbidity and mortality in the ICU patient (Clement, et al, 2004). Hyperglycemia is not only found in the patient with a known diagnosis of diabetes mellitus. Fifty percent of nondiabetic ICU patients are found to be hyperglycemic (Roberts, S. & Hamedani, B., 2004).

Hyperglycemia has extreme effects on the body systems and causes metabolic alterations. Hyperglycemia is caused initially by injury or stress to the body which cause one or all of the following and lead to the hyperglycemia: an increase in insulin resistance in the peripheral tissues, increased hepatic gluconeogenesis, and the release of both counter regulatory hormones and inflammatory cytokines (Roberts, S. R. & Hamedani, B. 2004).

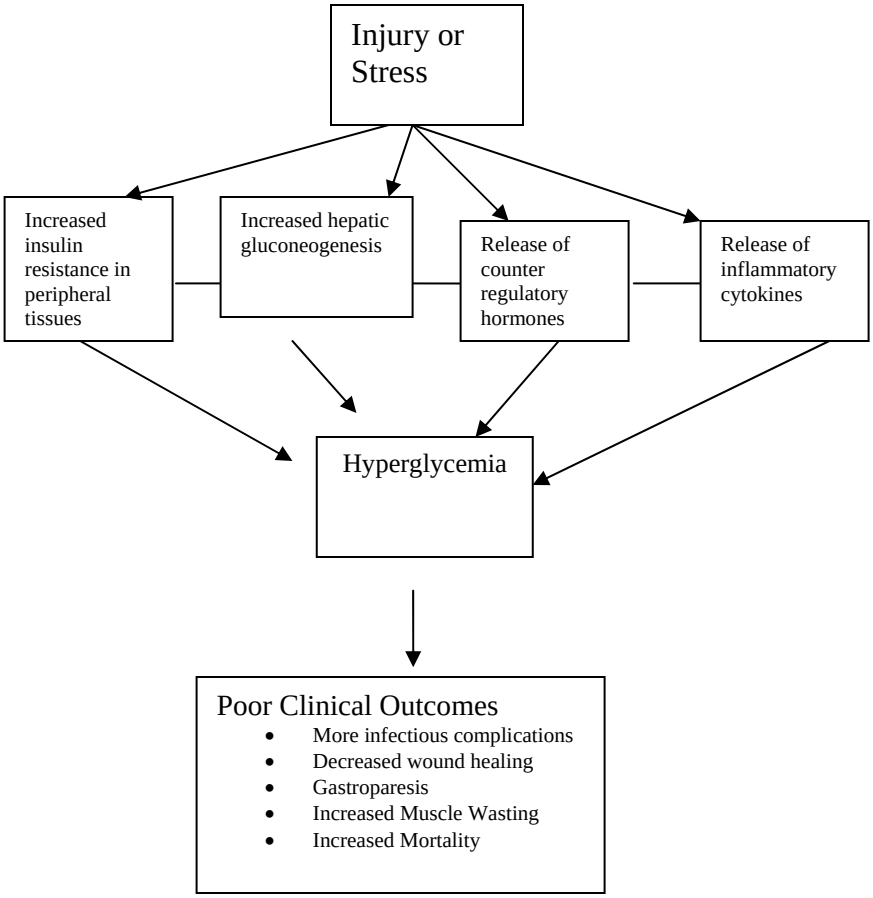

Figure 2. The effects of hyperglycemia. (Roberts & Hamedani, 2004).

Insulin Infusion Protocols

Literature surrounding the use of insulin infusion protocols is lacking in the study of medical ICU patients. The information available concerning surgical ICU patients, especially cardiovascular patients, and IIPs is more readily available. However, after seeing the benefit of the IIP to surgical patients, more literature is available due to increased studies of the effect of IIP on medical ICU patients.

In 1990 Klas Malmberg devised the DIGAMI study (diabetes mellitus, insulin glucose infusion in acute myocardial infarction) which reviewed the effect on mortality of diabetic patients after an acute myocardial infarction with the intense treatment of insulin (Malmberg, 1997). Mortality was reduced by 11% and long term survival of diabetic patients following an acute myocardial infarction was improved by a third in the use of the insulin-glucose infusion (Malmberg, K, 1997).

In another study, an insulin infusion protocol was developed by Greet Van den Berghe, M.D., Ph.D. and her team at the University Hospital Gasthuisberg, University of Leuven in Belgium. The protocol was studied on 1548 surgical adult intensive care unit patients from February 2, 2000 to January 18, 2001.

Van den Berghe and her team studied surgical adult ICU patients who were mechanically ventilated at the time. The Leuven study, which was a randomized controlled study, assigned patients to either receive intense insulin therapy or a more conventional mode of blood glucose monitoring and insulin use. The intense insulin therapy was used to maintain blood glucose levels between 80 and 110 mg/dL. The conventional treatment group did not receive the continuous insulin infusion until the blood glucose level exceeded 215 mg/dL. The blood glucose levels in the conventional group were maintained between 180 and 200 mg/dL.

The Leuven study found a decrease in morbidity and mortality in critically ill patients when allowing blood glucose levels no higher than 110 mg/dL in the surgical adult ICU patient, regardless if there was a previous diagnosis of diabetes (Van den

Berghe, 2001). The study also found those patients receiving "intensive insulin therapy also reduced overall in-hospital mortality by 34 percent, blood stream infections by 46 percent, acute renal failure requiring dialysis or hemofiltration by 41 percent, the median number of red-cell transfusions by 50 percent, and critical-illness polyneuropathy by 44 percent, and patients receiving intensive therapy were less likely to require prolonged mechanical ventilation and intensive care" (Van Den Berghe, 2003, p. 57).

Hospital mortality has been strongly correlated with the amount of glycemic control. Following the Leuven study, Dr. James Stephen Krinsley MD, reviewed the consecutive admissions of 1826 patients admitted to a medical-surgical ICU. He found mortality to be strongly correlated to glycemic control during the ICU stay. There was 9.6% hospital mortality in those patients with mean glucose between 80 and 99 mg/dL, 12.5% mortality in those with mean blood glucose levels between 100 and 119 mg/dL, and 42.5% hospital mortality in patients with mean blood glucoses exceeding 300 mg/dL (Krinsley, 2004). Not only does tight glycemic control lead to decreased mortality, but it also leads to a reduction in hospital and ICU length of stay, increased wound healing, and decreased infections (Roberts & Hamedani, 2004).

Van den Berghe completed a second study related to insulin in the critically ill, however this study was related to the effect the IIP has on the medical ICU patient. Van den Berghe and associates did a prospective, randomized, controlled study of adult medical ICU patients who needed intensive care for three days (Van den Berghe et al., 2006). The intense insulin group received continuous insulin infusion to maintain a

blood glucose value 80-110 mg/dL. The conventional treatment group started continuous insulin infusion when the blood glucose level exceeded 215 mg/dL.

The study found in hospital mortality decreased from 53% to 43% in those individuals who were in the ICU for three or more days on intense insulin therapy. Those staying less than three days and on intense insulin therapy had a higher mortality rate than those in the conventional insulin treatment group (Van den Berghe et al., 2006). Less kidney difficulties, more rapid wean from mechanical ventilation, decreased length of stay in the ICU and hospital was seen in the intense insulin treatment group, therefore reducing morbidity in the intense insulin treatment group (Van den Berghe et al., 2006).

The use of the insulin infusion protocol is one of medical necessity. Van den Berghe found approximately 30% of ICU patients require >5 days of intensive care and the risk of mortality is 20% (2003).

Goldberg and his team designed an IIP to be used in a medical intensive care unit (MICU) in the Yale New Haven Hospital (Goldberg et al, 2004). Data was collected from 52 MICU patients who were started on the IIP. The additional segment to this study was the response of the nursing staff to the implementation of an IIP in an already busy MICU. The IIP was to be utilized on those medical patients whose blood glucose exceeded 200 mg/dL. In addition to the blood glucose values, the Goldberg study also focused on four clinical interventions: corticosteroids, vasopressors, enteral nutrition, and parenteral nutrition (Goldberg et al., 2004). These four factors are found to be risk factors for poor glycemic control.

Goldberg found that the insulin requirements were "not affected significantly by age, sex, severity of illness, or clinical use of corticosteroids, vasopressors, or enteral/parenteral nutrition" (Goldberg et al., 2004, p. 464). Goldberg and associates did find the ability to adequately control blood sugars with the use of the IIP.

At Loma Linda University Medical Center, a pilot study was conducted in a 20 bed MICU. It was found that of the eight patients enrolled in the study, the group receiving intensive insulin therapy had a mean blood glucose level of 105.3 mg/dL whereas the patients in the conventional group had a mean blood glucose of 177.4 mg/dL (Bland et al., 2005).

Nurses' Experience

Literature is lacking surrounding nurses' experience with IIP. Many studies note the hesitancy nurses had with the various protocols because of the time commitment the protocol instilled in an already busy ICU, fear of hypoglycemia, and inconsistency in the protocols. Little mention is made about the nurses' experience with the protocol. Nurses at Yale New Haven Hospital found the IIP to cause an increased workload; however they were excited about using the protocol after understanding the benefits and rationale behind the protocol (Goldberg et al., 2004).

The nurse is the administrator of the insulin therapy. The nurse is a key component of providing the patient with quality care and improving the patient's chance of a recovery without complications caused by the hyperglycemia (Roberts & Hamedani,

2004). Nurses who utilized a protocol at Loma Linda University Hospital reported difficulty in managing daily patient care activities as well as operating the protocol and meeting study requirements (Bland et al., 2005).

Other hesitancies nurses had to the utilization of an IIP included the fear of hypoglycemia as well as discomfort to the patient from frequent blood glucose sticks. Nurses in the Loma Linda University Medical Center pilot study felt the use of arterial catheters was necessary in patients on the IIP to decrease the discomfort from frequent blood glucose sticks (Bland et al., 2005). Hypoglycemia was found in the studies reviewed to be of minor significance and many protocols, such as the Goldberg study, implemented the treatment of hypoglycemia as part of the protocol (Goldberg et al., 2004).

Hypoglycemia, which was defined by Van den Berghe and her research team, as a blood glucose value less than 40 mg/dL, was seen in 39 of 765 patients treated in the intense insulin therapy group and 6 of the 783 patients in the conventional insulin treatment group (Van den Berghe et al., 2001). The study done by Van den Berghe and her team in a medical ICU also reported no hemodynamic deterioration, convulsions, or other harmful events in association with hypoglycemia (Van den Berghe et al., 2006).

Blood Glucose Variance

There is no well documented literature defining the effect of variant blood sugars to a patient's healing, length of stay, or well-being. Blood glucose variance can be seen

in the patient whose average blood glucose was 110 mg/dL, however throughout the day the blood sugars were 90 mg/dL to 130 mg/dL. A patient can have an average blood glucose of 110 mg/dL but spend 25% of the time hyperglycemic and 25% of the time hypoglycemic. The overall effects of hyperglycemia are well documented, however there is no documentation concerning the ill or well effects of variant blood glucose.

The dangerous effects of hyperglycemia have been proven. There is strong literature surrounding the use of the IIP and the positive effects it has had on the attainment of euglycemia, and more importantly the decrease in hyperglycemia. Literature notes the fear nurses have with the protocol and hypoglycemia, as well as the additional time commitment the protocol requires. However, in providing quality care to the patient, it has been shown the advantages to the continuous insulin infusion and the attainment of health by decreasing infection rates, decreasing length of stay in the hospital and ICU, and decreasing mortality and morbidity.

Summary

Studies concerning the use of the IIP on medical and surgical ICU patients are available. The studies provide information about the benefit of the IIP to decrease hyperglycemia and the negative outcomes associated with it. Literature, however, is lacking about blood glucose variance, good or bad, and the nurses experience with the IIP.

CHAPTER THREE

METHODOLOGY

This is a descriptive study that used retrospective chart review to determine the amount of statistical variance in medical Intensive Care Unit (ICU) patients on an Insulin Infusion Protocol (IIP). The study will also quantitatively review the nurses' experience with the protocol and the relationship between experience and statistical variance of the blood glucose values.

Sample

A convenience sample was used for this study. Patients were all patients in the Billings Clinic ICU between February 1, 2003 and April 31, 2003 and the other comparison group was patients in the ICU between February 1, 2004 and April 31, 2004.

Patients were chosen for the study based on a medical diagnosis listed in the ICU log books located in the Billings Clinic ICU. Log books are the list of all patients admitted to the Billings Clinic ICU with the date of admission and discharge to the ICU and admitting diagnosis. The log books are kept up to date by the unit clerks in the ICU.

Inclusion Criteria

The following medical diagnoses were considered for the study: shortness of breath, chronic obstructive pulmonary disease (COPD), COPD exacerbation, respiratory failure, respiratory distress, sepsis, and rule out pulmonary embolism (PE). The IIP had

to be utilized on the patient for at least 48 hours and no more than 72 hours in the ICU. Required age was 18 to 90.

Exclusion Criteria

Patients were excluded from the study if the admitting diagnosis to the ICU included surgical diagnosis. They were also excluded if the time on the IIP was less than 48 hours, age less than 18 or greater than 90, and if their course of hospital time included multiple admissions to the ICU during the three month time span in each year. Exclusion also included a patient who expired in ICU.

Procedure

Institutional Review Board (IRB) Approval

Permission was granted by the manager of the ICU at the Billings Clinic to identify patients for the study from the log books. The study was deemed exempt by the Montana State University IRB and approval was granted to begin the study. No informed consent was needed for the study participants. The study was a descriptive study using retrospective chart review. All identifying patient information used to identify the sample was destroyed upon completion of the study. Permission was granted for the study from the Billings Clinic research manager after copies of the IRB approval from MSU was submitted.

Data Analysis

The study was to determine the statistical differences between blood glucoses of medical ICU patients in a three month time span in 2003 and the same three months in 2004. Blood glucose values were collected from the medical record of patients who met the inclusion criteria. Other data collected included co-morbidities, sex, age, and admitting medical diagnosis. A t-test was used to look for differences between blood glucose levels between groups by year. SPSS 14.0 was used for all statistical calculations.

Summary

Permission for the study was granted by the MSU IRB committee as well as the Billings Clinic Research Division. Study participants were identified by utilizing the inclusion and exclusion criteria. The final sample was determined and data was analyzed to determine the statistical difference in blood glucose values from patients on the IIP in 2003 and 2004. SPSS 14.0 was used for all statistical calculations.

CHAPTER FOUR

RESULTS

Introduction

The study was done as a retrospective chart review of medical ICU patients on an IIP in February, March, and April of 2003 and 2004. Blood sugar values were compared from 2003 and 2004 to determine the statistical variation, if any, between the two years. A sample size of 14 patients was used, 8 from 2003 and 6 from 2004. Co-morbidities, sex, admitting diagnosis, mechanical ventilation time, and the individual insulin protocol were also extrapolated from the medical chart.

Demographics

A total of 37 patients in 2003 and 33 patients in 2004 were eligible for the study. Of these 37 and 33 patients in 2003 and 2004 respectively, 11 patients in each year utilized the IIP for at least 48 hours during their stay in the Billings Clinic ICU. Three medical charts of patients in each year were unable to be located by medical records staff. Two patients in 2004 and three patients in 2003 were excluded from review due to multiple admissions to the ICU as well as being originally admitted to the ICU for cardiovascular surgical intervention. Further exclusion from the study included three patients from the 2004 group and six patients from the 2003 study group for not being on the IIP for 48 hours while being patients in the Billings Clinic ICU.

Final patient sample was 8 in 2003 and 6 in 2004. Blood glucose readings for the 48-72 hours were extrapolated from the chart. Other information gathered from the chart included: age, sex, admitting diagnosis, time ventilated, previous diagnosis of diabetes, and other co morbid conditions.

A total of 14 charts were reviewed for the study; eight in 2003 and six in 2004. The ages ranged from 42 – 79 with a mean age of 59 and 43% (n=6) were male and 57% (n=8) were female. (see Table 1)

Prior to being placed on the IIP, 64 % (n=9) were diagnosed diabetics and 35.7% (n=5) were without a diagnosis of diabetes. Fifty percent of the population had a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) and 50% did not. Sixty four percent (n=9) of the patients were without a diagnosis of hypertension, while 36% (n=5) were with a diagnosis of hypertension. Other co morbidities included hypothyroidism 86% (n=12) without and 14% (n=2)with; 93% (n=13) subjects diagnosed without CHF and 7% (n=1) without; 79% (n=11) patients without Coronary Artery Disease (CAD) and 21% (n=3) with; all subjects were free from an myocardial infarction; 79% (n=11) subjects were without hyperlipidemia whereas 21% (n=3) were with hyperlipidemia; 29% (n=4) had other cardiac co-morbidities such as cardiomyopathy; 14% (n=2) had a cancer listed as a co morbid condition; and 43% (n=6) had no other co morbidities whereas 57% (n=8) of the subjects studied had other co morbidities such as smoking, operations, and kidney disorders. (see Table 2) Mechanically ventilated patients for greater than one day included 93% (n=13) of the subjects, one subject was

not ventilated for greater than one day. (see Table 3) There were two separate protocols utilized; 43% (n=6) of the subjects were on the 2002 IIP, which correlated to the patients from 2003, while 57% (n=8)) of the subjects were on the 2003 IIP, which correlated to the patients from 2004. (see Table 4) The 2002 IIP correlated with medical ICU patients admitted in February, March, and April of 2003 while the 2003 IIP correlated with medical ICU patients admitted in February, March, and April of 2004.

Table 1. Sex of study participants.

SEX	PERCENT	NUMBER
Male	43	N=6
Female	57	N=8

Table 2. Co-morbidities of study participants.

Co-Morbidities	n=number of patients with the comorbidity	n=number of patients without the comorbidity
Diagnosed Diabetes	5	9
COPD	7	7
Hypertension	5	9
Hypothyroid	2	12
Congestive Heart Failure	1	13
Coronary Artery Disease	3	11
Myocardial Infarction	0	14
Hyperlipidemia	3	11
Other Cardiac	4	10
Cancer	2	12
Other (smoking, operations, kidney disorders)	8	6

Table 3. Mechanical ventilation time for study participants.

VENTILATED TIME	PERCENT	NUMBER
>1 day	93%	n=13
<1 day	7%	n=1

Table 4. Number of study participants on the Insulin Infusion Protocol.

INSULIN INFUSION PROTOCOL	PERCENT	NUMBER
2002	43%	n=6
2003	57%	n=8

Significance

Statistical significance was defined as $P<.05$. There was no statistical variance of any significance between medical patients on the IIP in 2003 compared to 2004. There were 49 data points in total to correlate between the blood glucose values in 2003 and 2004. After 49, one subject was discontinued on the IIP and the patients on the IIP continued to decrease after the 49th value. The sample size of 14 patients may not have provided enough data to demonstrate statistical significance.

Trends of glucose levels

In 2004 blood sugars were controlled more quickly than in 2003. For example, in 2003 the first mean blood glucose recorded from reviewing patient data was n=169 mg/dL and in 2004 at that same time as the first mean blood glucose recorded was n=211 mg/dL. The mean second blood glucose value in 2003 was 174 mg/dL and in 2004 the mean blood glucose value was 186 mg/dL. (see Figure 3).

Figure 3. Mean Blood Glucose vs. values 1-10 in 2003 and 2004

Notice in Figure 3 the mean first blood glucose reading was higher in 2004 than in 2003, however the decrease in blood glucose values was much more rapid than in 2004. In fact, in 2003, the blood glucose values increased before decreasing.

Figure 4 displays all 49 data points from each year, 2003 and 2004. Notice the less time required in 2004 to decrease the initial blood sugar. Also of note is the less variance in blood sugars in 2004 than in 2003. The blood glucose values in 2003 were much more elevated for a longer length of time than those in 2004. Once the blood glucose values decreased in 2004, however, they decreased dramatically and then rose rather sharp as well.

The study resulted in no statistical variation in the blood glucoses from 2003 to 2004, however, the average mean blood glucose did decrease from 2003 to 2004. The average blood glucose was calculated as an average of the mean blood glucose readings in 2003 and 2004. The average mean blood glucose, calculated each year from a total of 49 blood glucose values, was 145 mg/dL in 2003 and 115 mg/dL in 2004.

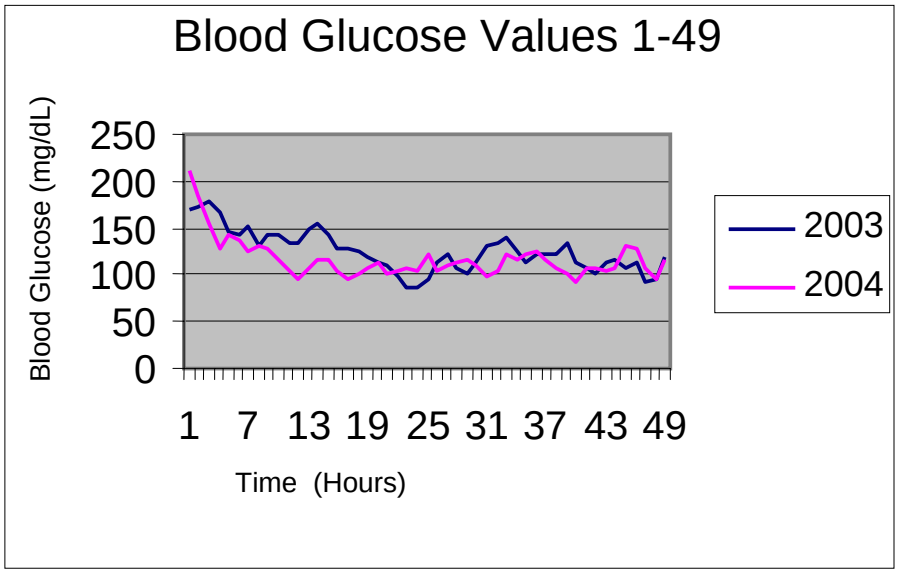

Figure 4. Mean Blood Glucose Values 1-49 in 2003 and 2004.

Hypoglycemia

The incidence of hypoglycemia or a blood glucose less than 60 was found to occur nine times in all 98 blood glucoses collected in 2003 and 2004 together. Therefore, there was a total of 1% of the blood glucose readings reviewed for both 2003 and 2004 less than 60. The range of hypoglycemia was 32-60 mg/dL. When broken down to individual years, there were 8 blood glucose readings less than 60 mg/dL in the 2003 patient population. In the 2004 patient population, there was one episode of the blood glucose reading less than 60 mg/dL.

Differences in Insulin Infusion Protocols 2002 and 2003

Two separate protocols were used on patients. The patients from the year 2003 were on a protocol designed in 2002. Patients from 2004 were on a protocol designed in 2003. There were some differences to the protocols. This study did not include the differences in the protocols, however, it is important to mention as the different protocol may have had an effect on the decrease in average mean blood glucose value as well as better control of hyperglycemia more rapidly in 2004.

The 2002 protocol did not initially bolus patients with insulin as well as start the continuous insulin infusion until the blood glucose was 301 mg/dL or greater. In the 2003 protocol, bolus insulin was given as well as the continuous insulin infusion at 251 mg/dL or greater. Therefore, more insulin was given on an earlier basis to the 2004 patients. The bolus insulin was weight based and was the same on both protocols being 0.15 units/kg of regular insulin.

The protocol in 2003 was also much more aggressive in the rate to start the continuous insulin infusion. In 2002 if a patient's blood glucose was 301 mg/dL or greater, the patient was bloused with 0.15 units/kg as well as the continuous insulin infusion started at 4 units/hr. With the 2003 protocol, if a patient's blood glucose was 301-350 mg/dL the patient was bolused with 0.15 units/kg as well as started at 6 units/hr with the continuous infusion of insulin. If the patient's blood glucose was 351-400 mg/dL on the 2002 protocol the patient was started on 4 units/hr of continuous insulin and bolused with 0.20 units/kg. In 2004, utilizing the 2003 protocol, the same patient

would have been started on a continuous insulin infusion at 6 units/hr and also been bolused 0.20 units/kg. With the above examples, one can see the more aggressive continuous insulin infusion regimen.

The protocol in 2003 gave the nurse operating the IIP more autonomy in adjusting the protocol to the patient's blood glucose value. For example, when blood glucose values were decreasing on two consecutive levels, nurses had the choice to decrease the continuous insulin infusion rate based on a percentage range: 25-75% decrease, 0-10% decrease, 0-50% decrease, and others. With the 2002 protocol, there was no adjustment of the continuous insulin infusion if consecutive blood glucose values were decreasing. The infusion rate stayed constant. This gave nurses at the bedside the ability to treat the patient based on the patient's past response to the continuous insulin infusion. With the 2002 protocol, nurses did not have the ability to adjust with such autonomy.

The protocol in 2002 did not give nurses the autonomy that was given to them with the protocol in 2003. The autonomy given to the nurses allowed the primary care giver and sole operator of the infusion the ability to treat the patient based on their past responses to the infusion as well as in association with other medications and treatments. There are more differences in the IIPs in 2002 and 2003, however the above listed highlights some of the major differences.

Summary

There were no statistical differences found in blood glucose values between patients on the IIP in 2003 compared to 2004. However, there were many trends found about the blood glucose values from 2003 and 2004, comparatively. There was very little hypoglycemia in patients on the IIP as well.

CHAPTER FIVE

DISCUSSION

The purpose of this study was to determine the statistical variance of blood glucose levels on medical Intensive Care Unit (ICU) patients on an Insulin Infusion Protocol (IIP) in 2003 and again in 2004. However, no statistical variance in blood sugar values of medical patients in 2003 and 2004 on the IIP was found. In reviewing the data, the sample size was too small to provide statistical significance. The data provided trends that relate to Imogene King's idea of goal attainment, such as using a goal blood glucose of 110 mg/dL for the blood glucose reading. The goal also was to find that nurses' experience with the protocol enabled them to better provide quality care to the patient, prevent hyperglycemia, which in effect will decrease length of stay, increase wound healing time, decrease morbidity, and decrease hypoglycemia. By reviewing the blood glucose readings from both years and comparing them consecutively, it does show that there is better control of the hyperglycemia in a more expedient manner in 2004 than 2003. This could relate to one that the nurse operating the IIP had more experience with the protocol than in 2003. The average blood glucose, calculated as an average of the mean blood glucose readings in each year, was 145 in 2003 and 115 in 2004.

The nurse is the sole operator of the IIP and with the mean average blood glucose being lower in 2004 than in 2003 the nurses had more experience with the protocol and therefore were more aggressive in treating the hyperglycemia and utilizing the IIP to its

maximum benefit. Nurses also were more educated about the protocol in using them more and more.

The study by Van den Berghe resulted in a decrease in mortality in ICU surgical patients when the blood glucose values are maintained between 80-110 mg/dL for an ICU stay greater than five days (2001). The second Van den Berghe study in medical ICU patients also found a decrease in morbidity in the medical ICU patient, however mortality was not affected until the length of stay was greater than 3 days (2006). The study presented here did not evaluate blood glucose readings after 72 hours and after 49 blood glucose readings on the patient, many patients were discontinued from the IIP.

IIPs were first initiated into the ICU at the Billings Clinic to be used on surgical cardiovascular patients in 2001. The use of the IIP on a medical patient was something not yet routinely done in 2003 and 2004. Not only does that suggest some discrepancy to the study, but a limitation was well. This led to a small, non-statistical sample size.

In referring to the goal attainment theory by Imogene King, nurses that utilized the protocol did control the hyperglycemia in most instances, as noted by the trends in the blood glucose values, especially those in 2004 when the values decreased once the patient was on the IIP. See Figure 3. King's theory used the concepts of action, perception, judgment, reaction, and transaction in order to attain a goal (King, 1997). The theory of goal attainment also intertwined the personal, interpersonal, and social systems levels to achieve a goal (King, 1990). It can be seen in the use of the IIP, nurses acted on the blood glucose values, perceived the hyperglycemia or hypoglycemia, used their judgment

as to the treatment and then reacted to the result. The transaction occurred in visiting with other healthcare team members or the family of the patient. Nurses would be more likely to perceive the necessity for the IIP, however if they understood more about the effects of hyperglycemia. The rationale to the protocol would be more widely understood and more accepted.

The protocols in the two patient populations are different. The patient population in 2003 had a protocol corresponding to 2002. The patient population in 2004 had a protocol corresponding to 2003. There were nine total blood glucose values less than 60 mg/dL of the total blood glucose values, 686 blood glucose readings, in 2003 and 2004. In 2004 there was only one blood glucose value less than 60 mg/dL. In the 2003 patient population, there was 8 blood glucose values less than 60 mg/dL. The range of blood glucose less than 60 mg/dL in 2003 was 32 mg/dL to 60 mg/dL. The value in 2004 was 55 mg/dL.

The results suggest better control of hypoglycemia with the 2003 protocol, which corresponds to the 2004 patient population. The 2003 protocol allowed nurses more autonomy to adjust the insulin infusion by percentages once two consecutive blood glucose readings were decreasing. The 2002 protocol did not allow for any adjustment once the blood glucose readings were decreasing.

Limitations

The major limitation of this study was the small sample size. A larger sample size was needed to determine the possibility, if any, of statistical significance between the two groups.

Two separate IIPs were utilized for this study. The protocols were reviewed for major differences between the IIPs used in 2003 and 2004. It is a possibility that the difference in trends and blood glucose value results from 2003 and 2004 was affected by the variation in the protocols.

Blood glucose values were ascertained for this study during a 48 hour time period and up to 72 hours. Not always was there a blood sugar for every hour or every two hours as deemed by the protocol. The lack of utilizing the directions of the protocol found some blood glucose values to be hours apart instead of on a regular hour by hour basis.

There are times when a patient must leave the ICU to travel to a different department for a variety of tests or procedures. During this time the blood glucose values were not checked and recorded and at times the continuous insulin infusion is discontinued and the patient is not on the IIP. The study, however, did not account for these varied blood sugars or lack thereof.

Implications for Clinical Practice

Literature supports the benefit of the IIP to control hyperglycemia. This study lacked statistical evidence to support improvement in blood glucose readings in 2004, however the study did show the decrease in blood glucose values more rapidly with the use of the 2004 protocol. Studies prove the complications from hyperglycemia lead to increased infection, decreased wound healing, and increased length of stay in the hospital setting (Van Den Berghe, 2001). Hyperglycemia can be decreased with the use of the IIP. The IIP has been shown with other studies and this small study, to be of benefit to clinical practice. Further study into the IIP and the individual differences from year to year would be of benefit as well.

Implications for Education

There is still more work needed to be done in educating the nurse at the bedside in the benefits to the IIP and the rationale behind decreasing episodes of hyperglycemia. Using the IIP for goal attainment of blood glucose values between 80-110 mg/dL does decrease morbidity and mortality (Van den Berghe, 2001). Educating the nurse in understanding of the individual protocol would ensure a decrease in morbidity and mortality to patients in the Billings Clinic ICU.

Recommendations for Research

Literature is lacking concerning the use of IIP on medical ICU patients. Further study into the use of the IIP on medical ICU patients is necessary to prove the IIP is beneficial to ascertain strict glycemic control. Further study into the use of the IIP to decrease morbidity, decrease length of stay, and increase wound healing in MICU patients is also necessary.

This study did not review the differences in the two separate protocols from 2003-2004. The IIP in 2003 was different than the protocol used in 2004. Study into the IIP and their differences and effect on blood glucose values would also prove itself beneficial.

There is a lack of literature surrounding nurses' experience with IIP. As sole operators of the IIP, more research into the effect on the knowledge level of nurses as well as the increase in time and energy in taking care of the critically ill patient would be beneficial. A year to year qualitative and quantitative study as to nurses knowledge and comfort level with the protocol and the rationale behind the use of the protocol would be advantageous.

Goldberg and his associates found the insulin requirements "not significantly affected by age, sex, severity of illness, or the clinical use of corticosteroids, vasopressors, or enteral/parenteral nutrition" (Goldberg, et al. 2004, p. 464). Increased studies into this area would be beneficial, especially in the medical ICU patient. Corticosteroids cause an increase in blood glucose and finding the association, if any,

between the control of blood glucose values and IIP when using corticosteroids would prove beneficial in controlling hyperglycemia.

Further study of blood glucose values after the IIP was discontinued would also be of significant value. When reviewing the medical charts to ascertain data for the study, it was noted by the primary researcher the large increase in blood glucose values once patients were discontinued from the IIP. It has been shown in the research the positive effects of the IIP in reducing hyperglycemia. The research has also shown the negative effects of hyperglycemia. The hyperglycemia should be controlled throughout the hospital stay to achieve maximum benefit and reduce negative consequences from the hyperglycemia.

Conclusion

The use of the IIP has proven itself to be of beneficial value, even in the few medical ICU studies in using the protocol that are available for review. While this study did not result in any statistical difference in the blood glucose values in 2003 and 2004, there is a trend in the blood sugar values that does suggest better blood glucose control with patients on the IIP in 2004. There is less variation in the blood sugars, more rapid time to a normoglycemic state, as well as a decreased mean average blood glucose in 2004. The IIP has been utilized with the start of the DIGAMI study, the studies by Van den Berghe, and others found in the literature. Hyperglycemia is found in more than just the diagnosed diabetic patient population.

Nurses are the operators of the IIP and ensuring their understanding of the rationale and benefit behind the IIP will allow the nurse to attain the goal of health. By using King's personal, interpersonal, and social systems all interacting with one another when operating the IIP, nurses can help the patient achieve euglycemia and therefore achieve the ultimate goal: health. The IIP is still under study in medical ICU patients as well as surgical ICU patients. But thus far, the benefits of the IIP and the decrease in negative outcomes, outweighs any risk the IIP may have.

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APPENDICES

APPENDIX A

INSULIN INFUSION PROTOCOL 2002

DATE	TIME . AM . PM	DOCTOR-PLEASE MARK INDIVIDUAL PATIENT ORDERS, INCLUDE DATE AND TIME. WRITE FIRMLY.

ICU INSULIN DRIP PROTOCOL PREPRINTED ORDERS **PAGE 1 of 2**

Allergies: _____

INITIATION

_X_ Mix 100 units Regular insulin in 100ml NS (concentration 1 unit/ml)
_X_ Flush tubing with 25cc of solution to coat tubing
_X_ Start infusion when blood glucose level exceeds 110mg/dl or _____ (do not treat with protocol for glucose levels below this).

_X_ Start at 1unit/hour for glucose 111 – 140
_X_ Start at 2units/hr for glucose 141 – 180
_X_ Start at 3units/hr for glucose 181 – 200
_X_ Start at 4units/hr for glucose 201 – 300
_X_ Start at 4units/hr for glucose 301 **and**
_X_ Bolus with 0.15units/kg of regular insulin IV for glucose 301 – 350
_X_ Bolus with 0.20units/kg of regular insulin IV for glucose 351 – 400
_X_ Bolus with 0.28units/kg of regular insulin IV for glucose > 401
_X_ Check blood glucose in 1 hour. Use arterial line or consider using central line for glucose checks.
_X_ Titrate drip.

_X_ If two consecutive (current hour and the preceding hour) blood glucose levels are > 110, but **decreasing**, do not adjust the infusion rate.
_X_ If two consecutive(current hour and the preceding hour) blood glucose levels are > 110, and **increasing**, follow the infusion rate change for the **next** higher titration level.

Titration Scale:

_X_ **BG 80 - 110, no adjustment necessary**
_X_ **BG 111 – 120, increase infusion rate by 0.5 units/hour**
_X_ **BG 121 – 140, increase infusion rate by 1 unit/hour**
_X_ **BG > 140, increase infusion rate by 2 units/hour**

_X_ If glucose remains >400 after 4 hours, re-bolus and continue titration

_X_ Check blood glucose hourly until infusion rate has not changed in a 2-3 hour period. When infusion rate is consistent for 2-3 hours, check blood glucose every two hours.

_X_ If blood glucose is 60-80, reduce infusion by one-half and check level in 30 minutes. (If insulin drip on >24 hours, follow insulin sensitivity.)

_X_ If blood glucose is < 60, stop infusion and check level in 30 minutes. If level continues < 70, give ½ amp D50 and check q30min until level is 80-110. Notify MD.

_X_ If blood glucose is < 40, stop the infusion and administer 1 amp D50. If level after 15 minutes remains less than 40, start a D10 infusion at 25-100cc/h. Check glucose level q15min until > 80. Notify MD.
_X_ Do not restart insulin drip for 2-3h after turning insulin drip off and infusing D10 for hypoglycemia.

DEACONESS BILLINGS CLINIC

Patient Sticker

_____

MD Signature

DATE	TIME . AM . PM	DOCTOR-PLEASE MARK INDIVIDUAL PATIENT ORDERS, INCLUDE DATE AND TIME. WRITE FIRMLY.

ICU INSULIN DRIP PROTOCOL PREPRINTED ORDERS **PAGE 2 of 2**

_X_ If blood glucose drops by more than 50% (in the first 24 hours), reduce the insulin dose to half and check blood glucose level in 30 minutes.

_X_ Maximum insulin dose is 50 units/hour. Notify MD when this level is reached.

Insulin Sensitivity:

_X_ If blood glucose has been maintained at 80-110 for 24 hours and falls below 80, decrease the insulin infusion by 10%. Check blood glucose level in 1h.

_X_ If blood glucose level continues to fall, decrease the insulin infusion by 20% and notify MD. Check blood glucose level in 1h.

Special Circumstances:

_X_ Check blood glucose q1h when **body temperature** > 100° F; **tube feeding** or **TPN** adjustments made; **glucocorticoid doses** are altered.

_X_ Pharmacy to notify nursing when patient is on glucose-altering medication.

_X_ Obtain sliding scale, maintenance insulin or insulin infusion orders prior to transfer of patient from ICU.

MD Signature

Patient Sticker

DEACONESS BILLINGS CLINIC

APPENDIX B

INSULIN INFUSION PROTOCOL 2003

X Initiation of insulin drip protocol will discontinue previous sliding scale.
X Mix 100 units Regular insulin in 100 ml NS (concentration 1 unit/ml)
X Flush tubing with 25 cc of solution to coat tubing.
X Start infusion when blood glucose level excess 110 mg/dl.
X Initiate infusion and bolus according to table:

Glucose Level	Bolus	Drip Rate
111- 140	0	1 unit/hour
141 - 180	0	2 units/hour
181 - 200	0	3 units/hour
201 - 250	0	4 units/hour
251 - 300	.15 units/kg	4 units/hour
301 - 350	.15 units/kg	6 units/hour
351 - 400	.20 units/kg	6 units/hour
401 or greater	.28 units/kg	8 units/hour

X Check blood glucose in 1 hour. Use arterial line or consider using central line for glucose checks.
X Titrate drip following table.

a. An adequate response to the insulin infusion is a reduction in blood glucose by 20 –40 mg/hour. If the blood glucose does not decrease by 20 mg/hour or the target blood glucose is not reached within 8 hours, notify MD for potential adjustment.
b. Titration of insulin infusion downward: the insulin infusion should be gradually tapered down as glycemic control is attained. When making the decision about how much to adjust the infusion rate, it is important to consider the rate of glucose change as well as the absolute level of glucose, in addition to the insulin infusion rate.

			2 consecutive levels			
			Increasing	*Decreasing*		
Glucose	**Bolus**	**Drip Change**	**Drip Change**	**Hold**	**Glucose**	**Rate**
< 60				60 minutes	25 –50 cc D50	↓25 – 75%
60 -79				30 minutes		↓ 25 – 50%
80 -110			↑ 0.5 units	30 – 60 minutes		↓ 0 – 50%
111 - 120		↑ 0.5 units	↑ 1 unit	0 – 30 minutes		↓0 –25 %
121 - 140		↑ 1 units	↑ 2 units	0 – 30 minutes		↓ 0- 10%
141 – 180		↑ 2 units	↑ 4 units	0 – 15 minutes		↓ 0 – 10%
181 - 250	0.15 u/kg	↑2 –3 units	↑ 3 - 4 units	0 – 15 minutes		↓0 – 10%
251 - 300	0.20 u/kg	↑ 2 –3 units	↑3 – 4 units			
301 - 350	0.28 u/kg	↑ 2 – 3 units	↑ 3 – 4 units			
351 - 400	0.28 u/kg	↑ 2 – 3 units	↑ 3 –4 units			

X Check blood glucose hourly until infusion rate has not changed in 2 – 3 hours. When infusion rate is consistent for 2 –3 hours, check blood glucose every 2 hours.
X Maximum insulin dose is 50 units/hour. Notify MD when this level is reached.

Nursing Considerations

X Check blood glucose every hour when body temperature is greater than 100 F (this may increase insulin requirements.

X Check blood glucose every hour when tube feedings or TPN adjustments are made. Discontinue drip when stopped and restart at same dose when restarted.

X Consider adding insulin to TPN.

X check blood glucose every hour when glucocorticoid doses are altered (may change insulin requirements)

X If patient is not receiving tube feeding or TPN, or the patient is on a regular diet, intitiate D-10 at 25 cc/hour. May infuse with insulin drip.

Documentation

- Record all blood glucose results on the ICU flowsheet; indicate whether it is a lab or glucometer value.
- Document time of initiation and time of discontinuation of infusion with corresponding blood sugar on flowsheet.
- Document insulin infusion infusion rate with corresponding glucose levels.
- Document adverse events.

APPENDIX C

INTENSIVE CARE UNIT MANAGER APPROVAL FOR STUDY

DEACONESS BILLINGS CLINIC

November 22, 2005

To Whom It May Concern,

I am writing this letter to confirm that Kimberly Ackerman has been granted approval to review the patient log books from the ICU at Billings Clinic. I understand that she will be using the information to identify patients for retrospective data collection for her thesis study on the relationship between insulin infusion protocols and nurses' knowledge to blood glucose variance in the ICU.

As a part of her study, Kim will be reviewing the patient's medical records in order to obtain the data elements needed for her study. I understand that she will not have any identifying information included in the data collected. All data elements will be obtained in the retrospective review.

We hope that Kim can provide our ICU with some insight into improving blood glucose management in the ICU setting at the end of her study.

Sincerely,

Christy Baxter

Christy Baxter, RN
ICU Manager

2800 Tenth Avenue North • P.O. Box 37000, Billings, Montana 59107-7000 • Deaconess Hospital (406) 657-4000 • Billings Clinic (406) 238-

APPENDIX D

INSTITUTIONAL REVIEW BOARD EXEMPT APPROVAL

INSTITUTIONAL REVIEW BOARD

For the Protection of Human Subjects

MONTANA STATE UNIVERSITY

960 Technology Blvd. Room 127
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Telephone: 406-994-6783
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Administrator:
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MEMORANDUM

TO: Kimberly Ackerman

FROM: Mark Quinn, Ph.D. Chair Mark Quinn Ch
Institutional Review Board for the Protection of Human Subjects

DATE: November 30, 2005

SUBJECT: *The Relationship Between Insulin Infusion Protocols and Nurses' Knowledge to Blood Glucose Variance in ICU Patients*

The above research, described in your submission of November 10, 2005, is exempt from the requirement of review by the Institutional Review Board in accordance with the Code of Federal Regulations, Part 46, section 101. The specific paragraph which applies to your research is:

___ (b)(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

___ (b)(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.

___ (b)(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

_X_ (b)(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.

___ (b)(5) Research and demonstration projects, which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

___ (b)(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA, or approved by the EPA, or the Food Safety and Inspection Service of the USDA.

Although review by the Institutional Review Board is not required for the above research, the Committee will be glad to review it. If you wish a review and committee approval, please submit 3 copies of the usual application form and it will be processed by expedited review.