The Effects of a Clinical Decision Support Software Program Stability Requirement on

Glycemic Outcomes

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Abstract

Although dysglycemia has been linked to poor clinical outcomes in hospitalized patients, 30-50% of inpatients continue to have out-of-range glucose values. The use of clinical decision support software to manage intravenous insulin infusions has been well established, but the clinical impact of the ongoing updates and modifications to the proprietary algorithms are not always clear. The purpose of this Doctor of Nursing project was to evaluate a software update implementing a clinical decision support software stability requirement and the effects on blood glucose control in hospitalized diabetic and hyperglycemic adult patients following discontinuation of an intravenous insulin regimen. A retrospective analysis of a before and after cohort evaluated the number of patient days with (a) a mean blood glucose value within the range of 70-180 mg/dL, (b) a blood glucose <40 mg/dL, (c) a blood glucose <70 mg/dL, (d) a blood glucose >180 mg/dL and (e) a blood glucose level >300 mg/dL in patients requiring intravenous insulin during the day of transition and up to three days following discontinuation of intravenous insulin in both a provider discretion cohort (pre-intervention) and a stability requirement cohort (post-intervention). The final data profile resulted in 103 individual patients for the provider discretion cohort and 104 for the stability requirement cohort, with a total n=207. The intervention did not significantly impact glycemic outcomes or clinical process outcomes, except for decreasing variation in provider utilization of transition orders based on pre-admission diabetes control. The results of this study demonstrate the importance of evaluating software updates prior to widespread implementation and beg the question of whether that responsibility should fall on the software creators or the implementation sites.

Keywords: diabetes mellitus, hyperglycemia, hypoglycemia, clinical decision support software, insulin dosing, blood glucose control, stability requirement

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Diabetes mellitus is a chronic disease currently affecting 9.3% of Americans, and the

Center for Disease Control and Prevention (2014) has projected that if current trends continue,

one in three Americans will suffer from diabetes by 2050. Within the inpatient setting,

approximately 25-30% of adult and critical care units are comprised of patients with a diagnosis

of diabetes (Draznin, Gilden, Golden, & Inzucchi, 2013). Over the last decade, the increase in

prevalence and impact of glycemia on long-term outcomes has placed attention on inpatient

glycemic management (ACE/ADA Task Force on Inpatient Diabetes, 2006). The American

Association of Clinical Endocrinology (AACE) and the American Diabetes Association (ADA)

have published extensive guidelines on the proper management of inpatient glycemia, which has

led to tremendous efforts by hospitals and administrations across the country to improve patient

care (Lowell R. Schmeltz, 2011).

In 2012, the estimated national cost of diabetes in the United States was $245 billion

(American Diabetes Association, 2013). Of the $245 billion, the largest contributor, composing

43%, was inpatient hospital care related to higher admission rates and longer lengths of stay per

admission for people with diabetes (American Diabetes Association, 2013). The annual per

capita health care expenditure for people with diabetes was 2.3 times higher than for those

without diabetes (American Diabetes Association, 2013).

The intersection of quality and economics can also be seen in the Joint Commission's

disease specific certification for inpatient diabetes management. The aims of this certification

include coordination of chronic care, early detection, preventive measures, and reduction of

overall healthcare costs (Braithwaite et al., 2008). This certification is based on compliance with

the national standards of care and promotes performance measurement and improvement projects within the realm of inpatient diabetes care (Braithwaite et al., 2008). Disease-specific certifications are increasing in importance to providers, patients, and healthcare institutions because of the commitment to quality and patient safety that is demonstrated with the attainment and maintenance of certification (Braithwaite et al., 2008).

The project site facility is a 504-bed, full-service community hospital located in a suburban, midwestern city and part of a 46-hospital multistate healthcare system. The inpatient diabetes program at this hospital serves adults of all ethnicities and cultural heritages. Additional vulnerable populations present in this hospital setting include pregnant women, elderly, homeless, illiterate, mentally ill, and economically and educationally disadvantaged individuals. The 2010 census data indicates population by race: White alone (86.34%), Black or African American alone (5.30%), Asian alone (3.05%), American Indian and Alaska native alone (0.39%) and Native Hawaiian and other Pacific native alone (0.08%; U.S. Census Bureau, 2012). Population by Hispanic or Latino origin - of any race - indicates 7.48% (U.S. Census Bureau, 2012).

Problem

Although research and national evidence-based practice guidelines support the negative impact of dysglycemia on patient morbidity and mortality, significant barriers are encountered in obtaining proper glycemic control within the inpatient setting. It is reported that 30-50% of adult inpatients have hyperglycemia during their hospital admission (Draznin, Gilden, Golden, &Inzucchi, 2013). The standard of care for glycemic management of critically ill individuals includes the use of intravenous insulin infusions which can accommodate the complex medical status and numerous variables impacting this patient population (American Diabetes Association,

2016). The use of clinical decision support software (CDSS) programs have been found to be safe and effective in the dosing of intravenous insulin and are widely implemented in hospitals throughout the country and the world (American Diabetes Association, 2016; Mann, Jones, Wolf, & Wade, 2011; Van Herpe et al., 2013). The purpose of this Doctor of Nursing project was to evaluate a software update implementing a CDSS stability requirement and the effects on blood glucose control in hospitalized diabetic and hyperglycemic adult patients following discontinuation of an intravenous insulin regimen.

Facilitators of this project included the multi-state 46-hospital health care system and the hospital administrators of the project site facility. A task force created by the health care system and composed of representatives from numerous hospitals throughout the system was actively evaluating the CDSS utilized by the healthcare system when this project was proposed by the student investigator in order to better understand the clinical impact of the software updates. The most significant barrier was that the CDSS only allows for analysis of glycemic data while a patient is on intravenous insulin. A substantial amount of time and manual data collection was needed to evaluate the glycemic data of these individuals following their transition from intravenous insulin to subcutaneous insulin.

The sustainability of this program is probable due to the results of this study and continued implementation by the program creators and the site facility. From a cost-savings perspective, dysglycemia during hospital admission has been shown to be correlated with higher charges, longer lengths of stay and higher morbidity and mortality rates (Curkendall, et al., 2009; Gandhi, Nuttall, Abel, Mullany, & al, 2005; Moghissi et al., 2009; Van den Berghe et al., 2001, 2006). The national hospital adjusted expense per patient is estimated at $2,212 per patient day, indicating that increased hospital length of stay can cost the patient and the health care system

additional expense (Curkendall, et al., 2009; Health Forum, LLC, 2015; L. R Schmeltz, 2011;

See Appendix A for Logic Model).

Review of the Evidence

The aim of this study was to investigate the following question: In hospitalized diabetic

and hyperglycemic adult patients requiring intravenous insulin, did the implementation of a

stability requirement to an intravenous insulin dosing clinical decision support software

compared to patients transitioned off of intravenous insulin under provider discretion affect the

number of patient days with (a) a mean blood glucose value within the range of 70-180 mg/dL,

(b) a blood glucose <40 mg/dL, (c) a blood glucose <70 mg/dL (d) a blood glucose level >180

mg/dL, and (e) a blood glucose level >300 mg/dL during the day of transition and up to three

days following discontinuation of intravenous insulin during a three-month timeframe prior to

and following implementation of a software update at the site facility?

Secondary questions included the following: (a) Did provider utilization of the CDSS

transition orders differ by cohort? (b) Did the hospital length of stay differ by cohort? (c) Was

there a relationship between hemoglobin A1c for individuals with or without transition orders by

cohort? And (d) Was there an interaction between use of transition orders and cohort when

measuring patient days requiring intravenous insulin?

To determine the existing evidence related to inpatient glycemic management and

computerized insulin dosing software, a review of the literature was conducted using the

following databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL),

EBSCOhost Databases, MEDLINE (Ovid), Medline Plus, Cochrane, and Proquest Nursing and

Allied Health Source. Search terms used were diabetes mellitus, blood glucose, hyperglycemia,

hypoglycemia, clinical decision support software, intravenous insulin dosing, subcutaneous

insulin dosing, transition and stability requirement. A total of 30 studies were selected including four evidence-based practice guidelines, one systematic review, 15 quantitative studies, one qualitative study, and nine editorials/reports. Organized by a rating system for the hierarchy of evidence (see Appendix B), five Level I studies, six Level II studies, three Level III studies, six Level IV studies, one Level VI study, and nine Level VII studies were identified (Melnyk & Fineout-Overholt, 2015).

Dysglycemia and the Effects on Clinical Outcomes

Inpatient glycemic management has been brought to the forefront of inpatient care over the last 15 years due to the recognition that glucose control, even for a short time during an inpatient admission, can have a substantial impact on patient outcomes. The publication of interventional studies showing improved outcomes for patients with better glucose control experiencing myocardial infarction, cardiac surgical procedures, infection and critical illnesses has forced healthcare to make substantial strides towards improving glycemic outcomes (ACE/ADA Task Force on Inpatient Diabetes, 2006; Baker et al., 2006; Gandhi et al., 2005; Van den Berghe et al., 2001). Not only is hyperglycemia an independent risk factor for inpatient mortality, but also the degree of hyperglycemia is associated with increased risk of adverse outcomes. The higher the blood glucose level, the higher the relative risk (Baker et al., 2006; Prieto-Sanchez, 2011). Improved glucose control in both medical and surgical patients has been shown to result in lower rates of hospital complications such as sternal wound infections, sepsis, stroke, coma, acute renal failure, new-onset atrial fibrillation, cardiac arrest, prolonged ventilation, pneumonia, and death (American Diabetes Association, 2016; Gandhi et al., 2005; Moghissi et al., 2009; Umpierrez et al., 2012).

While the effects of hyperglycemia on clinical outcomes may be more recent, the identification of severe hypoglycemia (blood glucose <40 mg/dL) as an independent risk factor for mortality is not new (Curkendall et al., 2009; Moghissi et al., 2009). Hypoglycemia can contribute to cardiac arrhythmias, seizures, brain damage and death (Prieto-Sanchez, 2011). The counter regulatory response to hypoglycemia places a substantial amount of stress on the body and is associated with increased adverse outcomes (American Diabetes Association, 2016; Moghissi et al., 2009).

Inpatient Glycemic Goals and Treatments

The evidence-based practice guidelines for inpatient glycemic management focus on the importance of maintaining normoglycemia while avoiding both hyperglycemia and hypoglycemia. There has also been contradictory research published on the benefits of *strict* glycemic control (Griesdale et al., 2009; NICE-SUGAR Study Investigators, 2009; Van den Berghe et al., 2001, 2006). Initially, the recommendation for critical ill patients was to keep the blood glucose as close to 110 mg/dL as possible and for non-critically ill patients the recommendation was 90-130 mg/dL (American Diabetes Association, 2005). After the publication of a large, international randomized trial indicating that patients in the intensive treatment group (target blood glucose of 81-108 mg/dL) had increased mortality when compared to those with a target blood glucose of 180 mg/dl or less, the national guidelines subsequently loosened the target blood sugar goals and focused on avoiding hypoglycemia while maintaining adequate glycemic control (Moghissi et al., 2009; NICE-SUGAR Study Investigators, 2009; Umpierrez et al., 2012). Currently, a glucose target between 140-180 mg/dL is recommended for most critically and non-critically ill patients, while recognizing that some patients who are

clinically stable may be appropriate for glucose targets <140 mg/dL (American Diabetes

Association, 2016).

Current clinical practice guidelines recommend the use of intravenous insulin for

glycemic management of the critically ill patient population (American Diabetes Association,

2016; Moghissi et al., 2009; Qureshi, Deakins, & Reynolds, 2012; Umpierrez et al., 2012). The

advantage of utilizing intravenous insulin is related to the ability to titrate the infusion frequently

and safely in the presence of significant variables impacting glucose levels of severely ill

individuals. Within the acute care - non-critical care - setting, the treatment of diabetes and

hyperglycemia should be managed with a subcutaneous multi-modal insulin regimen (see

Appendix C) as oral hypoglycemia medications are not recommended for the majority of

hospitalized patients (American Diabetes Association, 2016; Moghissi et al., 2009; Umpierrez et

al., 2012). As an individual's acuity and illness improve, it is necessary to transition from an

intravenous insulin infusion to a subcutaneous insulin regimen.

Barriers to Obtaining Optimal Glycemic Control Following Transition

The delicate balance of avoiding dysglycemia can be extremely difficult to achieve in a

setting with a number of variables including unanticipated changes in nutrition, medication

changes, the use of medications associated with increased insulin resistance, complicating

comorbidities, and organizational barriers (Moghissi et al., 2009). The transition of patients from

an intravenous insulin infusion to a multimodal subcutaneous insulin regimen has been

associated with inadequate glycemic control and is often complicated by the patients' acuity and

nutritional intake (Avanzini et al., 2011; Kreider & Lien, 2015). Other identified factors

inhibiting optimal control include clinical inertia and knowledge deficits among providers

regarding the management of inpatient glycemia (Braithwaite et al., 2008; Draznin et al., 2013;

Prieto-Sanchez, 2011; Ross et al., 2012). Specifically, problems that have been identified

following transition from intravenous to subcutaneous insulin regimens often include

discontinuing the infusion when it is not yet safe or rather at a safe time but logistical errors

occur such as provider uncertainty surrounding the dosage calculations and distributions required

to adequately address insulin requirements when transitioning (Kreider & Lien, 2015; Qureshi et

al., 2012). A subsequent barrier inhibiting optimal transitions is the lack of adequate time for the

subcutaneous regimen to overlap with the intravenous regimen; the Endocrine Society currently

recommends at least one to two hours of overlap (Qureshi et al., 2012; Umpierrez et al., 2012).

Following transition, proper implementation of a multi-modal subcutaneous insulin

regimen requires frequent review and revision of the regimen based on glycemic outcomes, and

can be a time-intensive process (Prieto-Sanchez, 2011). Recognized solutions currently seen in

practice across the country include the use of inpatient diabetes specialists, administrative

support of interdisciplinary quality improvement committees, order sets promoting the use of

scheduled insulin, insulin algorithms, and provider/staff education (Draznin et al., 2013; Ross et

al., 2012; Lowell R. Schmeltz, 2011; Umpierrez et al., 2012). Although significant national

initiatives exist to incorporate these standards of care into daily practice, 30-50% of adult

inpatients do not demonstrate good glycemic control during their inpatient hospital stay (Draznin

et al., 2013).

Clinical Insulin Dosing Software Programs

Intravenous insulin infusions directed by CDSS programs have become well established

in critical-care settings across the country and are supported in the national guidelines for

inpatient diabetes management (American Diabetes Association, 2016; Kalfon et al., 2014;

Mader et al., 2014; Mann et al., 2011; Neubauer et al., 2015; Van Herpe et al., 2013). Computer

driven programs have been shown to have better glycemic control and fewer out of range glucose results than paper-based protocols in a prospective cohort analysis (Saur, Kongable, Holewinski, O'Brien, & Nasraway, 2013). The CDSS utilized by the site-facility was cited in two articles that indicated the program was effective in managing hyperglycemia with less variability and no increase in hyperglycemia (Cochran et al., 2006; Igneri et al., 2016). Both were retrospective reviews in the critical care setting evaluating only glucose management on intravenous insulin regimens. While no studies were found evaluating a CDSS stability requirement, predictors of poor transition outcomes included wide blood glucose fluctuations and high variability of blood glucose levels and insulin infusion rates (Kreider & Lien, 2015). A substantial amount of the literature pertaining to transition from intravenous to subcutaneous insulin depicts the different algorithms and options for dosing insulin when transitioning patients to subcutaneous insulin. These were not considered relevant to this project as both cohorts for this project were transitioned based on the CDSS's proprietary algorithm.

Theory

Imogene King's Theory of Goal Attainment originated from a conceptual system incorporating three interacting systems: personal, interpersonal, and social (Butts & Rich, 2015; Messmer, 2006). Due to the ever-changing field of healthcare practice in response to technological and research advances, healthcare teams need interpersonal skills and knowledge to adapt to the constantly changing environment (King, 2007). King has identified four concepts that compose the transaction process: perception, communication, interaction, and transaction (King, 2007). This framework provides a theoretical basis on which the nursing process is built, and the effectiveness of nursing care is based on outcome goals (Butts & Rich, 2015; King, 2007). The Theory to Application Diagram (see Appendix D) shows King's Model of

Transactions applied to the implementation of a CDSS stability requirement. From a broader

perspective, King's transaction process facilitates establishing goals for evaluating quality care

and evidence based practice in the healthcare environment that is constantly being forced to

change in response to technological advances (King, 2007).

Methods

The site facility does not have an Institutional Review Board, thus human subjects

determination was established by the University of Missouri-Kansas City IRB (see Appendix E

for IRB Approval Letter). The student investigator has no employment or financial affiliation

with the developer of the CDSS; the student investigator is employed by the site facility.

Setting and Participants

The setting for this project was a 504-bed community hospital located in the Midwest and

part of a 46-hospital multistate healthcare system. The CDSS underwent an update in April of

2015, at which time an addition of a stability requirement was made which must be met by each

patient before the provider can access the programs' dosing algorithm for transition to

subcutaneous insulin. Thus, a single-center, retrospective analysis was conducted of a before and

after cohort including adult, hospitalized patients requiring a continuous insulin infusion between

the dates of Jan 1, 2015 – March 31, 2015 (provider discretion cohort) and May 1, 2015 – July

31, 2015 (stability requirement cohort).

A report generated by the hospital's corporate clinical effectiveness team was used to

identify adult, hospitalized individuals requiring intravenous insulin during the pre-determined

time frames before and after the program update. Patients were excluded if they did not receive a

minimum of 12 hours of intravenous insulin dosing and if they did not have a minimum of one

patient day on subcutaneous insulin following transition off intravenous insulin. Data was

collected and stored under a generic identification number which could not be associated with

participants protected health information. There was no ability to link the data back to the subject

after the data was entered. The data was stored on the health system's secure sever that complies

with the Health Insurance Portability Accountability Act.

For each patient day that data was available, the following information was collected:

type of insulin regimen, average blood sugar level, if the average blood sugar was within range

of 70-180 mg/dL, if a blood sugar of <40 mg/dL occurred during that patient day, if a blood

sugar of <70 mg/dL occurred during that patient day, if a blood sugar of >180 mg/dL occurred

during that patient day, and if a blood sugar of >300 mg/dL occurred that patient day. Patient

demographic and diagnostic data including age, sex, type of diabetes, serum creatinine at

admission, hemoglobin A1c, body mass index, hospital length of stay in days, hospital days with

intravenous (IV) insulin, and presence of diabetic ketoacidosis or hyperosmolar hyperglycemia

syndrome on admission were collected. For each individual, it was noted whether or not the

CDSS transition order for subcutaneous insulin dosing was utilized by the provider (see

Appendix F for Data Collection Template).

Evidence Based Practice Intervention

Intravenous insulin dosing computerized decision support software programs operate on

proprietary algorithms that require data to be uploaded via interphase or manually entered by the

clinician. The site facility utilized the same CDSS since 2009 in the emergency department,

intensive care unit, and cardiac care unit. The update that occurred on April 7, 2015 changed the

software from a local workstation to a cloud-based program, allowing clinicians easier access to

the program directly from the electronic medical record. In addition to the change in how the

program was accessed and the visual display of the program, there were updates to the predictive

algorithm including estimated residual extracellular insulin (EREI), diabetic ketoacidosis (DKA) status, and hyperosmolar hyperglycemia syndrome (HHS) status. The EREI uses information based on the change in blood sugar and kidney function to estimate insulin that may still be on board to prevent hypoglycemia. The program also makes a recommendation for recovery carbohydrate if indicated. The addition of the DKA and HHS status allowed for goal ranges based on the status chosen. Unless otherwise specified, the goal range was 100-140 mg/dL. If the patient was put into the DKA status, the goal range was 150-200 mg/dL. For HHS, the goal range was 200-250 mg/dL. Once specific criteria had been met (resolution of DKA/HHS), the patient was transitioned into the standard mode of therapy and a goal range of 100-140 mg/dL. These changes impacted the predictive dosing model, while the patient was on intravenous insulin, and were not evaluated as part of this project.

The April 2015 update also included the addition of a stability requirement for providers to access the subcutaneous transition orders. Prior to this update, the provider was able to access the transition orders at any point in time when they considered the patient's medical status and blood glucose was appropriate for transition. This decision, based on provider discretion, required the provider to analyze many variables including, but not limited to, the hemodynamic and metabolic state of the patient, intravenous insulin requirements to maintain optimal blood sugar control, whether the patient was able to tolerate oral intake or not, and other comorbidities and treatments that could have impacted glucose control. Once the provider decided to transition the patient to subcutaneous insulin, they could access the transition orders generated by the CDSS. The proprietary algorithm would then determine the subcutaneous insulin regimen based on the patients' nutritional intake and intravenous insulin requirement. These orders were entered into the electronic medical record by the pharmacist, and the patient

would be transitioned from intravenous to subcutaneous insulin. The facility policy requires

patients receive a dose of basal insulin three hours prior to discontinuation of the insulin infusion

to avoid rebound hyperglycemia.

The stability requirement that was added no longer allowed the provider to access the

transition orders at any point in time, but rather only after the CDSS deemed the patient stable

based on several factors built into the algorithm. These factors required that the patient have a

mean blood glucose <140 mg/dL and a blood glucose variability <25. The program would mark

the patient as "Stable" and then the transition orders could be selected and generated. Prior the

patient being "Stable", the transition orders would be dithered out (See Appendix G for

Intervention Explanation). The purpose of the stability requirement was to only allow providers

to access the CDSS's generated orders during appropriate times when enough data was available

and the blood glucose was stable enough for accurate subcutaneous dosing to be calculated.

Following implementation of the update, there was concern voiced by clinicians that it could

cause a delay in transition because of difficulty attaining stability that could result in possible

increase in time required on intravenous insulin and ultimately hospital length of stay. The

primary barrier reported by clinicians to achieving criteria for stability was post-prandial blood

glucose excursions in patients who ate while on intravenous insulin. Oral intake is generally

considered a sign of improving medical status, but can make glycemic control challenging on

intravenous insulin regimens.

Change Theory and Evidence Based Practice Model

Due to uncertainty surrounding the program update and questions regarding the necessity

and benefit of the CDSS stability requirement, Kotter and Cohen's Model of Change was chosen

as the change theory for this project. This model relies on appealing to one's emotion for

achieving behavior change and emphasizes that individuals are more likely to change when their feelings are influenced by truths than when merely given facts meant to affect their way of thinking (Melnyk & Fineout-Overholt, 2015). This model embraces an 8-step process that was recently updated in 2014 from the original model in 1996 to include the following: 1) create sense of urgency 2) build a guiding coalition 3) form a strategic vision and initiatives 4) enlist a volunteer army 5) enable action by removing barriers 6) generate short-term wins 7) sustain acceleration, and 8) institute change (Kotter International, 2016).

Marita Titler's Iowa Model of Evidence Based Practice was the evidence-based practice model applied to this project (Titler, 2007). The Iowa model relies on both problem focused and knowledge based triggers to lead healthcare providers towards improved quality of care (Melnyk & Fineout-Overholt, 2015). After considering clinical application and organizational priorities, a team is formed, the relevant research and literature is critiqued, the practice change is piloted, and if appropriate, the practice change is integrated into general practice (Melnyk & Fineout-Overholt, 2015). Throughout the process, there are feedback loops in place to direct decision-making. This feedback loop is imperative for continued sustainability of the intervention and long-term maintenance of change.

Study Design and Validity

After receiving a Not Human Subjects Determination, a single-center, retrospective analysis was conducted of a before and after cohort including adult, hospitalized patients requiring a continuous insulin infusion between the dates of Jan 1, 2015 – March 31, 2015 (provider discretion cohort) and May 1, 2015 – July 31, 2015 (stability requirement cohort).

The participants included individuals admitted to the intensive care unit and the cardiovascular care unit at the site facility. Patients requiring intravenous insulin must be

admitted to one of these two units due to nursing training on the CDSS based on the site facility's policy.

Internal validity of this project could be threatened by the retrospective, observational nature of the study with a lack of randomization. Due to the before and after cohort design, there would be the possibility of extraneous variables impacting glucose control. Some examples include heightened awareness related to provider and staff education surrounding the intervention, additional ongoing process improvement projects at the site facility, variations in providers and nursing staff, and a patient population that is always changing. Also, the quality and consistency of provider and staff education related to glucose management and their familiarity with technology could impact the validity of the study.

The intervention may only be applicable to other intensive care and cardiac care units. External validity is strengthened by evaluating both a critical care and acute care nursing unit that incorporates a wide variety of patient acuity levels and diagnoses (See Appendix H for Project Timeline Flow Graphic and Appendix I for Intervention Flow Diagram).

Outcomes and Measurement Instruments

Primary outcomes for this project include measurement of glycemic outcomes for the provider discretion cohort and the stability requirement cohort. Glycemic outcomes evaluated by cohort include the following: the number of patient days with (a) a mean blood glucose value within the range of 70-180 mg/dL, (b) a blood glucose <40 mg/dL, (c) a blood glucose <70 mg/dL, (d) a blood glucose >180 mg/dL, and (e) a blood glucose level >300 mg/dL in patients requiring intravenous insulin during the day of transition and up to three days following discontinuation of intravenous insulin. Secondary outcomes include provider utilization of the CDSS transition orders by cohort, hospital length of stay by cohort, the relationship between

hemoglobin A1c and utilization of transition orders by cohort, and patient days requiring IV

insulin by cohort.

A recent study supported the use of mean blood glucose as a simple, accurate form of

glycemic measurement during the inpatient stay, as well as powerful predictor of in-hospital

mortality (Kosiborod et al., 2008). Mean blood glucose is the average of a patient's glucose level

over time. Based on clinical practice guidelines, the recommended range for a random blood

glucose is 70-180 mg/dL (Umpierrez et al., 2012). In the pursuit of decreasing hyperglycemia, it

is imperative that hypoglycemia is not inadvertently increased due to the morbidity and mortality

associated with hypoglycemia (Prieto-Sanchez, 2011; Umpierrez et al., 2012). Therefore, this

project measured two different hypoglycemia outcomes: blood glucose <40 mg/dL and blood

glucose < 70 mg/dL. A commonly utilized metric in the inpatient setting is the patient-day unit;

there is support for the use of this metric in the assessment of hypoglycemic events (Goldberg et

al., 2006). A severe hypoglycemic event is defined as a blood glucose <40 mg/dL and a

hypoglycemic event is defined as a blood glucose <70 mg/dL (American Diabetes Association,

2016). Both values are being measured independently due to the increased morbidity associated

with severe hypoglycemia (Moghissi et al., 2009). The percent of patient days with a blood

glucose >180 mg/dl and >300 mg/dL were also evaluated as two of the primary outcomes. These

outcomes evaluated for hyperglycemia and severe hyperglycemia that may not be fully

recognized by a mean blood glucose alone.

While arterial and venous blood glucose samples have been established to have high

reliability and validity, there has been concern related to the accuracy of point-of-care blood

glucose meters (Nichols, 2011). Errors in blood glucose meter results can stem from patient or

methodology inferences, such as: low hematocrit, decrease peripheral perfusion and/or certain

medications including ascorbic acid, maltose, and galactose (Lou & Robinson, 2010; Nichols,

2011). Due to the high number of personnel using glucose meters throughout the inpatient

hospital setting, there are also a variety of errors that can result from operator error. A few

possibilities include expired reagents, incorrect disinfection, failure to analyze controls, and

incorrect patient identification (Nichols, 2011).

The pilot site facility utilized the Nova Biomedical StatStrip glucose meters. As of 2014,

this meter was utilized by 53% of all hospitals in the United States and has been designed to

eliminate the effects of abnormal hematocrit, ascorbic acid, uric acid, acetaminophen, bilirubin,

maltose, galactose, and oxygen (Nova Biomedical, 2014). There have been 138 studies

evaluating analytical performance of the Nova StatsStrip glucose meter between 2007 and 2014,

and the sensor technology has been shown to improve accuracy when compared to numerous

other glucose meters (Lou & Robinson, 2010; Nova Biomedical, 2014). To minimize user error,

the site facility policy required that new staff receive orientation and validate proper use of the

meter upon hire followed by annual competency for all associates. The site facility policy

required staff to use venous or arterial samples when a patient was deemed inappropriate for

capillary sampling. Some examples of patients who are inappropriate for capillary sampling

include critically ill patients who were hemodynamically unstable and/or had decreased

peripheral perfusion (Inoue, Egi, Kotani, & Morita, 2013).

Quality of Data and Analysis Plan

Cohort groups were compared for initial demographic equality. The Independent t-test

was used to compare continuous variables (hospital length of stay in days, age, serum creatinine

at admission, hemoglobin A1c, body mass index, and hospital days with IV insulin). Categorical

variables (sex, diabetes status and history of DKA or HHS) were compared using the chi square test of association.

All continuous data is presented as mean +/- standard deviation. All categorical data is presented as numeric counts of percentages. Primary outcomes data were analyzed using the chi square test of association. The secondary outcome regarding the use of transition orders by provider was analyzed using the chi square test of association. The influence of cohort group on hospital length of stay was assessed using an independent t-test. A 2x2 factorial independent analysis of variance was employed to assess the relationship between hemoglobin A1c for individuals with or without transition orders by cohort group. Finally, a 2-way ANOVA was used to assess whether there was significant interaction between the use of transition orders and cohort when measuring patient days spent in the hospital with IV insulin. Data analysis was completed using SPSS v24.

Results

Setting and Participants

The setting for this project was a 504-bed community hospital located in a suburban, midwestern city and part of a 46-hospital multistate healthcare system. This single-center retrospective analysis was conducted on a before and after cohort including adult hospitalized patients requiring a continuous insulin infusion between the dates of Jan 1, 2015 – March 31, 2015 (provider discretion cohort) and May 1, 2015 – July 31, 2015 (stability requirement cohort). Patients were excluded if they were on intravenous insulin for less than 12 hours or if there was not at least one patient day of glucose data while on a subcutaneous insulin regimen post-transition.

Intervention Course

Following receipt of IRB Approval for Not Human Subjects Determination on January

31, 2017 (See Appendix E for IRB Approval Letter), the student investigator obtained reports

from the organization's clinical effectiveness office that identified patients requiring intravenous

insulin between January 1, 2015 – March 31, 2015 and May 1, 2015 – July 31, 2015 at the site

facility. These reports also contained the primary glycemic outcomes by patient day. The data

was transcribed from the report to the excel data collection sheet. In addition, the demographic

and diagnostic data was collected from the electronic medical record at the same time and

entered into the excel data collection sheet. All information on the excel data collection sheet

was de-identified with no ability to link information back to the patient and all data collection

was performed on the site-facility's secure network. The data was then transcribed and uploaded

to SPSS software for statistical analysis.

Outcome Data

The final data profile resulted in 103 individual patients for the provider discretion cohort

and 104 for the stability requirement cohort, with a total n=207. Individuals in which the

provider utilized the transition orders totaled n=128, 71 in the provider discretion cohort and 56

in the stability requirement cohort. The data indicates that the cohorts were well matched with no

significant differences in demographics or diagnostics.

The provider discretion cohort participants were 54% male and 46% female. Seventeen

percent had no history of diabetes, 17% had a history of Type 1 Diabetes, and 67% had a history

of Type 2 diabetes. Sixty-two percent of participants did not have DKA or HHS documented

during the admission; 36% had DKA and 2% had HHS documented. The stability requirement

cohort participants were 50% male and 50% female. Sixteen percent had no history of diabetes,

25% had a history of Type 1 Diabetes, and 59% had a history of Type 2 Diabetes. Sixty-two

percent of participants in the stability requirement cohort did not have DKA or HHS documented during the admission; 35% had DKA and 3% had HHS documented.

For the data collected on the day of transition from intravenous to subcutaneous insulin for individuals in which the transition orders were utilized each cohort was analyzed using the chi square test of association for differences in the number of days that the average blood sugar was within range of 70-180 mg/dL, the number of days that the patient experienced a blood sugar <40 mg/dL, <70 mg/dL, >180 mg/dL, and >300 mg/dL. There was no significant difference between the provider discretion cohort and the stability requirement cohort in individuals in which the transition orders were utilized on the day of transition for average blood glucose within range of 70-180 mg/dL (X^2_1 = 1.451; p = .228), the number of days that the patient experienced a blood glucose <40 mg/dL (X^2_1 = 2.032; p = .154), <70 mg/dL (X^2_1 = 1.021; p = .312), >180 mg/dL (X^2_1 = 1.205; p = .272), and >300 mg/dL (X^2_1 = 1.951; p = .163).

Using the chi square test of association for individuals in which transition orders were utilized, the average blood sugar within range of 70-180 mg/dL, the number of days that the patient experienced a blood sugar <40 mg/dL, <70 mg/dL, >180 mg/dL, and >300 mg/dL were evaluated for day one, day two, and day three of subcutaneous insulin regimen following discontinuation of intravenous insulin. There was no significant difference between the provider discretion cohort and the stability requirement cohort in individuals in which transition orders were utilized on the first day of subcutaneous insulin for average blood glucose within range of 70-180 mg/dL (X^2_1 = 2.360; p =.124), the number of days that the patient experienced a blood glucose <40 mg/dL (X^2_1 = 1.772; p =.183), <70 mg/dL (X^2_1 = 1.090; p = .296), >180 mg/dL (X^2_1 = .319; p =.572), and >300 mg/dL (X^2_1 = .009; p = .924). There was no significant difference between the provider discretion cohort and the stability requirement cohort in individuals in

which transition orders were utilized on the second day of subcutaneous insulin for average blood glucose within range of 70-180 mg/dL ($X^2_1 = .062$; p = .803), the number of days that the patient experienced a blood glucose <40 mg/dL ($X^2_1 = 2.979$; p = .084), <70 mg/dL ($X^2_1 = 2.085$; p = .149), >180 mg/dL ($X^2_1 = .007$; p = .932), and >300 mg/dL ($X^2_1 = .132$; p = .716). There was no significant difference between the provider discretion cohort and the stability requirement cohort in individuals in which transition orders were utilized on the third day of subcutaneous insulin for average blood glucose within range of 70-180 mg/dL ($X^2_1 = .029$; p = .865), the number of days that the patient experienced a blood glucose <40 mg/dL ($X^2_1 = 2.119$; p = .145), <70 mg/dL ($X^2_1 = 2.119$; p = .145), >180 mg/dL ($X^2_1 = .047$; p = .829), and >300 mg/dL ($X^2_1 = .053$; p = .818).

The secondary question of whether provider utilization of the CDSS transition orders differed by cohort was analyzed using the chi square test of association. There was not a significant difference between cohorts in the number of individuals that the providers choose to use the CDSS transition orders ($X^2_1 = 4.375$; P=.036). The influence of cohort group on hospital length of stay (LOS) was assessed using an independent t-test. LOS in days was 7.27 +/- 5.412 days for the patients in the provider discretion group and 6.67 +/- 4.501 days for the patients in the stability requirement group. The mean difference in LOS between cohort groups was .601 days. This was found to be not statistically significantly different ($t_{(126)} = .679$; P = .503). It can be said that cohort group assignment did not significantly influence LOS.

A 2x2 factorial independent analysis of variance was employed to assess the relationship between hemoglobin A1c for individuals with or without transition orders by cohort group. In the provider discretion cohort, there was a significant difference in the mean A1c for individuals in which the provider chose to utilize the CDSS transition orders and those that they did not. The

mean A1c was 1.586% higher (P = .002) for individuals that had transition orders used in the provider discretion cohort. In comparison, there was no statistical difference between the mean A1c for individuals in the stability requirement cohort that had transition orders utilized versus those that did not (mean difference = .061; P = .898).

A 2-way ANOVA was used to assess whether there was significant interaction between the use of transition orders and cohort when measuring patient days spent in the hospital with IV insulin. The interaction between cohort and the writing of transition orders was found to be not statistically significant. With this, one should look at both contributing variables individually. It was found that the cohort group did not influence the number of days the patient spent in the hospital in IV insulin ($F_{(1.203)}$ = 1.83; p = .178). Also, whether or not transition orders were written did not influence the number of days in the hospital on IV insulin ($F_{(1,203)}$ = .025; p = .876; See Appendix J for Statistical Analysis).

Discussion

Successes

The most important success of this study was the evaluation of a CDSS stability requirement that has not previously been researched. While glycemic outcomes did not change significantly between the provider discretion and the stability requirement cohort, there was not a significant increase in the length of time patients were required to be on intravenous insulin, an increase in the hospital length of stay, or a reduction in the provider's utilization of the transition orders. Thus, the software update did not appear to have a clinically significant impact on glycemic outcomes or clinical process outcomes.

Study Strengths

Strengths of this study included the site facility, a culture supportive of research, and the provision of resources by leadership. This 504-bed community hospital supports a broad range of patients from the Kansas City metro area and the use of intravenous insulin in both the intensive care unit and the cardiac care unit facilitated a large range of patient acuity levels. Also, this facility has several variables encouraging a culture that supports inpatient glycemic management such as monthly evaluation by the health system's leadership regarding nine different glycemic outcomes for the entire hospital, a disease specific accreditation by the Joint Commission in Inpatient Diabetes Care, and a team of Endocrinologists on staff. This study was supported not only by local leadership but by the hospital system's clinical leadership as well. The stability requirement implemented in April 2015 continues to be part of the CDSS propriety algorithm and utilized daily by providers and clinicians.

Results Compared to Evidence in the Literature

There were no previously published studies in the literature specifically evaluating a CDSS stability requirement for the transition from intravenous to subcutaneous insulin. While there is large amount of literature to support the use of CDSS in the dosing of intravenous insulin, including two that directly site the program evaluated in this study, there is significantly less literature related to the transition process following CDSS dosing recommendations (Cochran et al., 2006; Igneri et al., 2016). Recently, the implementation of CDSS dosing subcutaneous insulin has been evaluated, but these programs actually modify subcutaneous doses during the inpatient admission and differ substantially from the one-time orders generated by the CDSS evaluated in this study (Neubauer et al., 2015).

Limitations

The retrospective design of this study was the most substantial limitation. The student investigator attempted to reduce the impact of confounding variables on the internal validity of the study by evaluating factors in each cohort group that could have otherwise impacted insulin regimen transition and glycemic control: age, sex, type of diabetes, serum creatinine at admission, hemoglobin A1c, body mass index, hospital length of stay in days, hospital days with intravenous (IV) insulin, and presence of diabetic ketoacidosis (DKA) or hyperosmolar hyperglycemia syndrome (HHS). The lack of a statistically significant difference in any of the variables for the pre/post intervention cohorts strengthens the internal validity of the study. Variables not accounted for that could threaten the internal validity of the study include the use of medication/nutritional regimens such as vasopressors, steroids, and total parental nutrition or tube feedings. Additionally, this study did not capture the acuity level of the patient or diagnostic features outside of type of diabetes and DKA/HHS. The CDSS did undergo more updates in April 2015 than just the addition of the stability requirement, indicating there could be some imprecision in the intervention process that could threaten internal validity. The additional updates primarily impacted the dosing of the intravenous insulin regimen, not the transition process or subcutaneous dosing recommendations.

External validity was strengthened by including both an intensive care unit (ICU) and a cardiac care unit, allowing for additional generalizability outside of the ICU. The inclusion of adults with type 1 diabetes and those without a history of diabetes also improve the generalizability outside of just those with type 2 diabetes.

Interpretation

The expected outcome of the study indicated that by requiring patients on intravenous insulin to meet a stability requirement, prior to transition to subcutaneous insulin, there would be

an improvement in glycemic control following transition. The addition of a CDSS stability requirement did not result in any significant difference of the primary glycemic outcomes in patients transitioning from intravenous to subcutaneous insulin regimens. In addition, there was not a significant difference in the utilization of the CDSS transition orders between the two cohorts which indicated that the addition of the stability requirement did not significantly inhibit the provider's use of the transition orders.

Of interest was the significant difference in mean A1c for individuals in which the provider chose to utilize the CDSS transition orders in the provider discretion cohort. This difference was not apparent in the stability requirement cohort which indicated to the student investigator that providers were more likely to utilize the transition orders in the provider discretion cohort for individuals with poorer pre-hospital diabetes control (higher A1c), and less likely to use the transition orders in individuals with better pre-hospital diabetes control. The addition of the stability requirement may have contributed to removing this variance in use of the transition orders. The concern expressed by clinicians that the addition of the stability requirement might increase hospital length of stay or time required on intravenous insulin had no significant difference in hospital length of stay or days on intravenous insulin between the two cohorts.

As the use of CDSS has increased in the hospital setting, software updates have become more commonplace. Sometimes, these updates occur entirely in the background such as updates to a proprietary algorithm that have not been readily apparent to frontline clinicians. Other updates have been much more apparent and have had an impact on the day-to-day practice of the clinicians. The clinical effectiveness of these updates is often unknown at the time of the update. The implementation of the stability requirement was based on recommendations that transition

off of intravenous insulin should occur when blood glucose variability was low and average

blood glucose level was within goal range (Kreider & Lien, 2015). While this explanation, in

theory, would provide a benefit including improved glycemic control post-transition, this study

indicated that there was not a significant improvement. Moreover, the time of transition was no

longer under the provider's complete discretion, but rather had to rely on the patient meeting the

criteria for stability. Lack of effectiveness could have been partially related to the fact that the

site facility had an actively engaged Endocrinology service during the entire time of the data

collection. This program may have been more effective in a facility that did not have a robust

inpatient glycemic management service, or if patients were often being transitioned

inappropriately. A weakness noted by the implementation team was that the term 'stability

requirement' could infer stability of the patient's medical status, which was not the case. The

stability requirement only evaluated the stability of the patients' blood glucose level. Even with

the stability requirement, the decision to transition still required provider discretion regarding the

medical acuity of the patient and whether or not transition was indicated. The student

investigator's assessment of the stability requirement was that it may help to prevent

inappropriate transitions but does not necessarily lend to improved outcomes if safe practices

around intravenous insulin transition were already in place.

Lastly, the results of this study implore the question of whether the burden of

effectiveness should be on the program creators or the implementation sites. Community

hospitals may not have the infrastructure or resources available to evaluate these program

updates, and while analytic programs for CDSS may have been available, they only analyzed

data while the patient was on the CDSS. Thus, there was not data available to the site facility

from the program's analytics for patients after they transitioned off the CDSS. Rather, the data

had to be manually abstracted which is a time-consuming process that may not always be feasible when considering the number and rate at which program updates can occur. The 600 hours required for study design, data collection, data analysis, and dissemination were donated by the student investigator for the purpose of this DNP project, but considering the median annual salary of $97,450 for a 2000 hour work year in the state of Kansas for an advanced-practice nurse, this project would have cost $29,235 in worked hours alone (United States Department of Labor, 2016).

Conclusion

Considering that diabetes mellitus has increased at almost epidemic proportions, currently affecting almost one in ten Americans and predicted to affect one in three Americans by 2050 (Centers for Disease Control and Prevention, 2014), a natural assumption is that the inpatient population of those with a diagnosis of diabetes will increase. Regardless of the admitting diagnosis, any patient with diabetes in the hospital setting requires glycemic management. Intravenous insulin dosing is the standard of care for critically ill individuals, thus transition from intravenous to subcutaneous insulin, and the subsequent challenges it entails will continue to be a necessary component of inpatient glycemic management. While the addition of a CDSS stability requirement did not impact the glycemic outcomes or process outcomes evaluated in this study, it would be prudent to evaluate this process in a setting that may not have access to specialists' provider care or has a large variation in provider practice like an academic institution with annual changes to the residency staff. With the recent addition of CDSS for dosing of subcutaneous insulin regimens introduced to the inpatient settings, the ability to perform analytics will be improved and allow for real-time evaluation of glycemic outcomes. If the site facility should adopt a CDSS for subcutaneous insulin dosing, a proposed future study

could be a prospective pre-post intervention quasi-experimental design study evaluating the new software.

   Dissemination of these findings have been presented by the student investigator at the site facility's Clinical Research and Evidence-Based Practice Council and the Glycemic Steering Committee with plans to present to the health's systems Office of Clinical Effectiveness. The student investigator also plans to submit a manuscript for publication to the *Journal of Diabetes Science and Technology*. This study supports the ongoing evaluation and research of inpatient diabetes management CDSS in an effort to improve glycemic outcomes and subsequently reduce morbidity and mortality caused by dysglycemia in the hospital setting.

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Appendix A

Logic Model

Inputs	Intervention(s) Outputs		Outcomes -- Impact		
	Activities	*Participation*	*Short*	*Medium*	*Long*
Evidence, sub-topics Connection between hyperglycemia and hypoglycemia and poor clinical outcomes Recommended standard of treatment for glycemic management in the acute care inpatient setting Barriers to obtaining optimal glycemic control during transition CDSS in the inpatient setting **Major Facilitators or Contributors** Health care system Hospital administrators Multi-hospital Task Force **Major Barriers or Challenges** Lack of CDSS ability to analyze data after transition Large amount of manual data collection and time required to analyze post-transition glycemic outcomes	**EBP intervention which is supported by the evidence in the Input column** Implementation of a clinical decision support software stability requirement in the transition from intravenous to subcutaneous insulin regimen **Major steps of the intervention** Initiate Educational Initiative at pilot facility Schedule educational sessions for clinical nursing staff Schedule educational sessions for providers Work with IT and Informatics department to ensure software is installed and functioning "Go-Live" Week with onsite technical and clinical training teams Data collection	**The participants (subjects)** Hospitalized diabetic and hyperglycemic adult patients **Site** Community Hospital in Suburbs of Kansas City **Time Frame** 3 months pre and post intervention **Consent Needed or other** **Person(s) collecting data** Student investigator **Others directly involved**	**(Completed as student)** **Outcome(s) to be measured with valid & reliable tool(s)** Mean average glucose Number of patient days with glucose <40 Number of patient days with glucose <70 Number of patient days with any glucose >180 mg/dL Number of patient days with any glucose >300 mg/dL **Statistical analysis to be used** Cohort groups compared for initial demographic equality. Independent t-test used to compare continuous variables. Categorical variables compared using the Chi Square Test of Association.	**(after student DNP)** **Outcomes to be measured** In the event the site facility adopts a CDSS for SQ dosing, would like evaluate glycemic outcomes before and after intervention	**(after student DNP)** Outcomes that are potentials: Improved morbidity/mortality related to glycemic outcomes

Appendix B

Review of Evidence

First author, Year, Title	Purpose	Research Design, Evidence Level	Sample & Sampling, Setting	Measures & Reliability	Results & Analysis Used	Limitations & Usefulness
Dysglycemia and the Effects on Clinical Outcomes						
Center for Disease Control and Prevention (2014). National diabetes statistics report: Estimates of diabetes and its burden in the United States, 2014	This document is intended to provide up-to-date scientific data and statistics on diabetes and its burden in the United States.	Report published by the U.S. Department of Health and Human Services Level 7				Realistic use, Statistics that support the burden of diabetes in the US
Prieto-Sanchez (2011). Hyperglycemia in-hospital management.	To review the updated guidelines regarding IP glycemic management and the negative impacts of hyper/hypoglycemia on pt outcomes	Editorial Level 7	NA	Low Level	This editorial presents the pathology of hyper/hypoglycemia in the inpatient setting in a concise manner with supporting evidence.	Limited usefulness due to low level of evidence, provides good background information
Curkendall (2009). Economic and Clinical Impact of Inpatient Diabetic Hypoglycemia.	To assess the clinical and economic impact of hypoglycemia that develops during hospitalization	Retrospective cohort study Level 4	Data from 70 hospitals was used to compare those patients that developed hypoglycemia to those whose blood glucose values were all >70.	P <.01	Pts who developed hypoglycemia had higher charges (38.9%), longer lengths of stay (3.0 days), higher mortality, and higher odds of being discharged to a skilled nursing facility.	Large sample, lower level of data, realistic use

ACE/ADA Task Force on Inpatient Diabetes (2006). ACE and ADA Consensus Statement on Inpatient Diabetes and Glycemic Control.	Identify strategies to overcome barriers and facilitate improvement in inpatient diabetes care	Report from a Joint Task Force: Level 7				Sheds light on the progression of inpatient diabetes management a decade ago; background information
Baker (2006). Hyperglycemia is associated with poor outcomes in patients admitted to hospital with acute exacerbations of chronic obstructive pulmonary disease.	To determine the relationship between blood glucose concentrations, length of stay in hospital, and mortality in patients admitted with AECOPD.	Non-experimental, Retrospective, correlation; Level 4	433 admissions were identified, participants were divided into 4 groups by blood glucose quartiles	95% CI	Relative risk of adverse outcomes was the highest in the group with the highest blood glucose and lowest in the lowest blood glucose quartile.	Realistic use to show correlation
Gandhi (2005). Intraoperative Hyperglycemia and perioperative Outcomes in Cardiac Surgery Patients.	Estimate the association between intraoperative hyperglycemia and perioperative outcomes in pts who underwent cardiac surgery	Retrospective, observational: Level 4	409 pts	P<0.01 for all comparisons	Glucose levels were significantly higher in patients experiencing the primary end point	Older study significant to the progression of inpatient glycemic control over the past 10-15 years
Inpatient Glycemic Goals and Treatments						
American Diabetes Association (2016). Standards of Medical Care in Diabetes – 2016.	To provide clinicians with the components of diabetes care, general treatment goals, and needed tools	National Guidelines Level 1				

Umpierrez (2012). Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline.	To provide practice guidelines for the management of hyperglyce mia in hospitalized patients in the non-critical care setting.	Clinical Practice Guideline Level 1				
Moghissi (2009). American Association of Clinical Endocrinologists and American Diabetes Association Consensus Statement on Inpatient Glycemic Control.	To identify safe glycemic targets and to describe the system improvemen ts needed to attain them	Clinical Practice Guidelines Level 1				
NICE-SUGAR Study Investigators (2009). Intensive versus Conventional Glucose Control in Critically Ill Patients.	Determine the optimal blood glucose range in critically ill patients	Large, internation al randomize d trail: Level 2	6104 patients underwent randomiza tion to either the intensive control or the conventio nal control group	See next column.	Severe hypoglycemia significant greater in the intensive control group - 6.8% versus 0.5% (P<0.001).	Significant study in the progression of inpatient glycemic management recommendation s and guidelines
Griesdale (2008). Intensive insulin therapy and mortality among critically ill patients: a meta-analysis including NICE-SUGAR study data.	To update the totality of evidence regarding the influence of intensive insulin therapy compared with conventional insulin therapy	Meta-analysis; Level 1				
Kosiborod (2008)	Determine if persistent	Retrospecti ve,	16, 871 patients	P<0.000 1	Mean hospital glucose appears to	Realistic use in determining

	hyperglyce mia has a greater impact on adverse outcomes in AMI than a single, random BG.	correlation al: Level 4			be the most practical metric of hyperglycemia associate risk.	outcome metrics for this project
Van den Berghe (2006). Intensive insulin therapy in the Medical ICU.	To determine whether intensive insulin therapy improves the prognosis of patients in the medical ICU	Prospectiv, randomize d controlled study: Level 2	1200 patients	p = 0.33	Intensive insulin therapy reduced blood glucose levels by did not significantly reduce in-hospital mortality. Intensive insulin therapy did significantly reduce morbidity.	Significant study in the progression of inpatient glycemic management recommendation s and guidelines
Goldberg (2006). "Glucometrics" - assessing the quality of inpatient glucose management.	Discuss standardized metrics for inpatient glycemic control	Editorial: Level 7			The patient-day model appears to be the best reflection of the quality of inpatient glycemic control.	Realistic use the determination of outcome metrics for this project.
Garber (2004). American College of Endocrinology Position Statement on Inpatient Diabetes and metabolic Control	To review research, formulate standards, and suggest techniques by which these goals may be achieved	Position Statement; Clinical Practice Guidelines: Level 1				These are out-of date guidelines, but reviewed to establish the progression of inpatient management
Van den Berghe (2001)	Determine if normalizatio n of blood glucose with insulin therapy improves prognosis	Prospectiv erandomiz edcontrolle d study: Level 2	1548 pts	P<0.04	Intensive insulin therapy reduce mortality for patients in the intensive care unit compared to conventional treatment	Significant study in the progression of inpatient diabetes management over the last 15 - 20 years
Barriers to Obtaining Optimal Glycemic Control						
Draznin (2013). Pathways to Quality Inpatient Management of Hyperglycemia and	Goal of promoting clinical research in the area of management of hyperglycemi	Report from an expert committee Level 7	NA	Low Level	Examines the barriers to optimal diabetes management in the inpatient setting and identifies areas	Realistic use for identifying barriers

					that need further research.	
Ross (2012). Inpatient diabetes care: complexity, resilience and quality of care	To investigate how inpatient diabetes care is delivered and the implications for quality improvement.	Qualitative research design: Level 6	Non-proportional quota sampling: interviewed 32 diabetes specialists	Low Level	Sources of complexity in caring for inpatients with diabetes were identified and recommendations for coordination of care were made based on qualitative data collected.	Realistic use for identifying barriers and opportunities for improvement in care coordination
Schmeltz (2011). Management of Inpatient Hyperglycemia.	Chief Endocrinologist reviews current guidelines	Editorial by an expert Level 7	NA	Low Level	Provides practical insights and review of current guidelines by a practicing expert	Realistic use for identifying barriers
Braithwaite (2008). The case for supporting inpatient glycemic control programs now: The evidence and beyond	To address a variety of quality and safety measures surrounding the care of inpatients with diabetes.	Report from an expert committee Level 7	NA	Low Level	Committee reviews the available evidence and makes recommendations, some realistic use in identifying barriers	Realistic use for identifying barriers
Qureshi (2012). Obstacles to Optimal Management of Inpatient Hyperglycemia in Noncritically Ill Patients	To summarize obstacles in implementing standardized process to achieve glycemic goals	Expert opinion Level 7	NA	Low Level	Recommendations made by experts to give practical guidance to clinicians	Realistic Use for identifying obstacles
Kreider (2015). Transitioning Safely from Intravenous to Subcutaneous Insulin	To suggest a stepwise approach to the transition in order to promote safety and euglycemia	Expert opinion Level 7	NA	Low Level	Identifies a significant opportunity for knowledge expansion in the area of transitioning from IV to SQ insulin	Realistic use for identifying barriers and need for further research
Clinical insulin dosing software programs in the inpatient setting						
Neubauer (2015). Standardized Glycemic Management with a	To evaluate the safety, efficacy and usability of standardized glycemic	Open, noncontrolled intervention study;	99 patients	(P=0.02)	Percentage of blood glucose (BG) measurements in the range of 70–140 mg/dL,	Realistic use

Computerized Workflow and Decision Support System for Hospitalized Patients with Type 2 Diabetes on Different Wards	management by a CDSS for non-critically ill hospitalized patients with DM Type 2	Low Level 3			occurred in 50.2±22.2% of all measurements.	
Kalfon (2014). Tight computerized versus conventional glucose control in the ICU: a randomized controlled trial.	Assess the new generation of CDSSs	Non-blinded parallel-group RCT trial: Level 2	2,684 patients	95% CI	Significant higher rate of severe hypoglycemia in the tight glycemic control group (p<0.001).	Realistic use
Mader (2014). Efficacy, usability and sequence of operations of a workflow-integrated algorithm for basal-bolus insulin therapy in hospitalized type 2 diabetes patients.	To evaluate glycemic control and usability of a workflow-integrated algorithm for basal-bolus insulin therapy	Controlled, non-randomized Level 3	Algorithm based treatment was implemented on one ward and compared to standard glycemic management at the other ward.	p <0.001	Algorithm blood glucose levels in the algorithm group were significantly reduced and had a higher level of in-range glucose levels	Realistic use, although this was a paper algorithm, it provides a similar construct to how a computerized algorithm would be utilized
Van Herpe (2013). LOGIC-Insulin Algorithm-Guided Versus Nurse-Directed Blood Glucose Control During Critical Illness.	To validate clinically LOGIC-Insulin relative to tight glycemic control by experienced nurses.	Prospective parallel-group, randomized controlled clinical trial: Level 2	300 critically ill patients	p<0.001	Compared to expert nurses, LOGIC-Insulin improved efficacy of tight glycemic control without increasing the rate of hypoglycemia.	Validating algorithm for intravenous insulin dosing algorithm
Mann (2011). A computer decision support software safely improves glycemic control in the burn intensive care unit: Randomized	To determine the safety and efficacy of a computer decision support software (CDSS) to control serum glucose concentration in a burn	Prospective-paired randomization crossover trial; Level 2	18 adult burn/trauma patients	P <0.05	The patients in the computer protocol arm of the study spent 47 +/- 17% of time in target range (80-110 mg/dL) compared with 41 +/- 16% of time for the	Small sample size, one setting, pilot study, realistic use.

controlled clinical study.	intensive care unit				paper protocol arm	
Cochran (2006) EndoTool Software for Tight Glucose Control for Critically Ill Patients	To evaluate safety and efficacy of sophisticated feedback mathematics applied to the control of a two variable, quadratic insulin dosing curve	Retrospective, Observational: Level 4	2510 patients, ICU patients, 95,793 blood glucose readings		Program provided safe and effective BG control, minimal hypoglycemia, improved documentation	Limited by retrospective, observational nature of the study: specific to this project's CDSS
Igneri (2016) Evaluation of Glycemic Control with EndoTool Glucose Management System for Insulin Infusion Therapy	To assess glycemic control in critically-ill patients administered IV insulin infusion with EndoTool compared to traditional protocol	Retrospective cohort analysis: Level 4	155 critically ill patients	$p<0.001$	Time to glycemic control BG <150 was significantly shorter in EndoTool cohort, hypoglycemia episodes were significantly less; chi-square and Wilcoxon rank-sum tests	Limited by retrospective nature of the study; specific to this project's CDSS
Saur (2013) Software-Guided Insulin Dosing: Tight Glycemic Control and Decreased Glycemic Derangements in Critically Ill Patients	To determine if glycemic derangements are more effectively controlled using software-guided insulin dosing compared with paper-based protocols.	Prospective, nonrandomized, before and after cohort: Low Level 3	197 critically ill patients	$P<.001$	Patients in the software guided group were dc'd from ICU more often with a normalized BG compaired to those on paper-based insulin dosing regimen. Less hypoglycemia in the software-guided cohort.	Small sample size, pilot trial at a single institution

Appendix C

Definition of Terms

Clinical Decision Support Software. Rule or algorithm-based software integrated with electronic health records and evidence-based knowledge (Moja et al., 2014).

Dysglycemia. Glucose levels out of normal range, hypoglycemia or hyperglycemia (American Diabetes Association, 2016).

Hypoglycemia. Any blood glucose less than 70 mg/dL (American Diabetes Association, 2016).

Multi-modal Insulin Regimen. A a combination of long-acting basal insulin, usually administered once or twice daily, and short-acting insulin administered three times daily with meals with the option of correctional insulin (American Diabetes Association, 2016).

Severe Hypoglycemia. Any blood glucose less than 40 mg/dL (American Diabetes Association, 2016).

Appendix D

Theory to Application Diagram
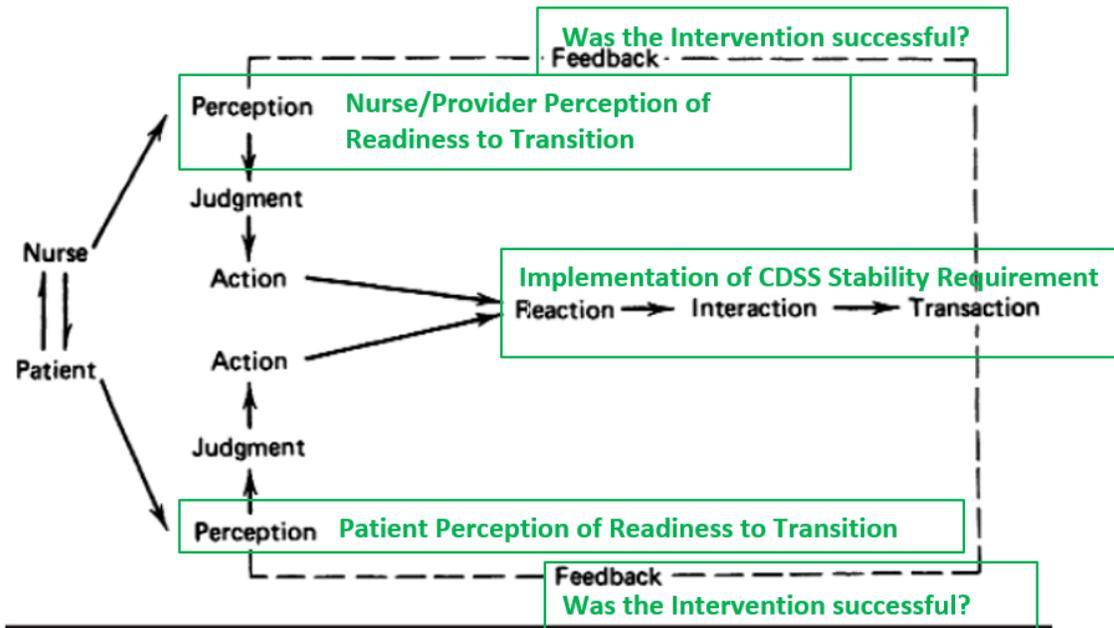
Figure 2. A Model of Transactions

NOTE: From *A Theory for Nursing: Systems, Concepts, Process* (p. 145), by I. M. King, 1981, Albany, NY: Delmar. Copyright 1995 by I. M. King.

Appendix E

IRB Approval Letter

UMKC
Office of Research Services

UMKC
5319 Rockhill Road
Kansas City, MO 64110
TEL: (816) 235-5927
FAX: (816) 235-5602

NOT HUMAN SUBJECTS RESEARCH DETERMINATION

Principal Investigator: Dr. Lyla Lindholm
UMKC Health Sciences Building
Kansas City, MO 64108

Protocol Number: 16-549
Protocol Title: The Effects of a Clinical Decision Support Software Program Stability Requirement on Glycemic Outcomes
Type of Review: Not Human Subjects Determination

Date of Determination: 01/31/2017

Dear Dr. Lindholm,

The above referenced study, and your participation as a principal investigator, was reviewed and determined to be Not Human Subjects Research (NHSR). As such, your activity falls outside the parameters of IRB review. You may conduct your study, without additional obligation to the IRB, as described in your application.

The NHSR Determination is based upon the following Federally provided definitions:

"Research" is defined by these regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

The regulations define a **"Human Subject"** as "a living individual about whom an investigator (whether professional or student) conducting research obtains: data through intervention or interaction with the individual, or identifiable private information."

Attachments include the following:
Attachments
    Stafos, UMKC Project Approval Letter 12 16 2016
    Data Collection Worksheet IV To SQ
    Data Use Agreement

All Human Subjects Research must be submitted to the IRB. If your study changes in such a way that it becomes Human Subjects Research, please contact the Research Compliance office immediately for the appropriate course of action.

Please contact the Research Compliance Office (email: umkcirb@umkc.edu; phone: (816)235-5927) if you have questions or require further information.

Thank you,

[signature]

Appendix F

Data Collection Template

A	B	C	D	E	F	G	H	I	J	K
ID	Cohort	LOS	Gende	Age	DM	Cr	A1c	BMI	DKA_HHS	Transition_Orders

L	M	N	O	P	Q	R
Total_Patient_Days_IV	Patient_Days_IV1	Patient_Days_IV2	Patient_Days_Trans	Patient_Days_SQ1	Patient_Days_SQ2	Patient_Days_SQ3

S	T	U	V	W	X	Y
RegIV2_NurseUnit	RegIV2_AveBG	RegIV2_WithinRange	RegIV2_40	RegIV2_70	RegIV2_180	RegIV2_300

Z	AA	AB	AC	AD	AE	AF
RegIV1_NurseUnit	RegIV1_AveBG	RegIV1_WithinRange	RegIV1_40	RegIV1_70	RegIV1_180	RegIV1_300

AG	AH	AI	AJ	AK	AL	AM
RegTrans_NurseUnit	RegTrans_AveBG	RegTrans_WithinRange	RegTrans_40	RegTrans_70	RegTrans_180	RegTrans_300

AN	AO	AP	AQ	AR	AS	AT
RegSQ1_NurseUnit	RegSQ1_AveBG	RegSQ1_WithinRange	RegSQ1_40	RegSQ1_70	RegSQ1_180	RegSQ1_300

AU	AV	AW	AX	AY	AZ	BA
RegSQ2_NurseUnit	RegSQ2_AveBG	RegSQ2_WithinRange	RegSQ2_40	RegSQ2_70	RegSQ2_180	RegSQ2_300

BB	BC	BD	BE	BF	BG	BH
RegSQ3_NurseUnit	RegSQ3_AveBG	RegSQ3_WithinRange	RegSQ3_40	RegSQ3_70	RegSQ3_180	RegSQ3_300

Appendix G

Intervention Explanation

How a CDSS doses insulin:

Message that Appears if Patient has **not** met the Stability Requirement:

Message that Appears if Patient has met the Stability Requirement:

Examples of patients that meet and do not meet the criteria for stability:
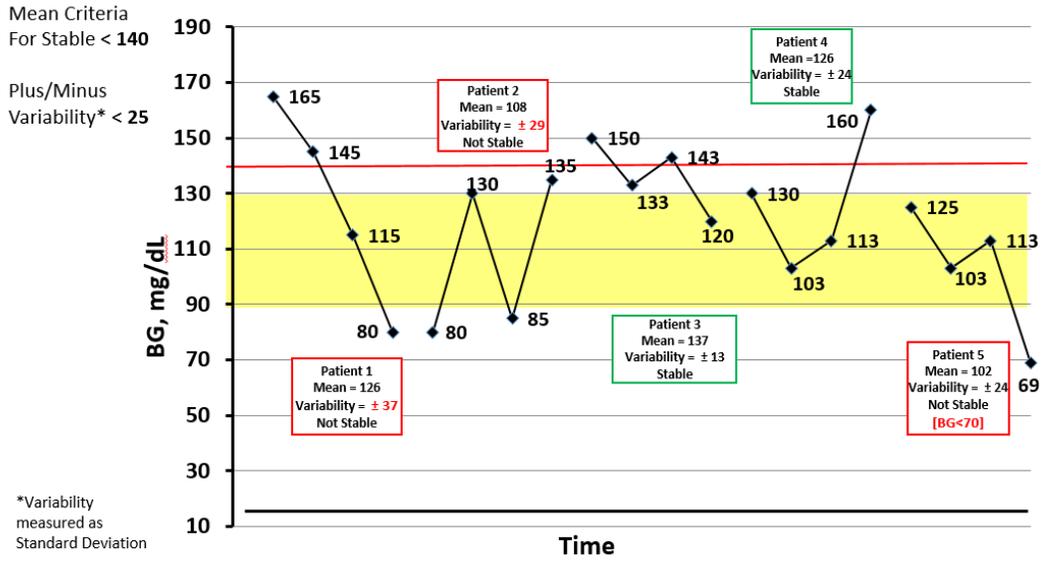
Appendix H

Project Timeline Flow Graphic

	2016		2017						
	Nov	Dec	Jan	Feb	March	April	May	June	July

IRB Submission
Release of Info from OCE
UMKC Approval

Collect and analyze data after IRB
approval received

Disseminate Results
Submit Final DNP Project
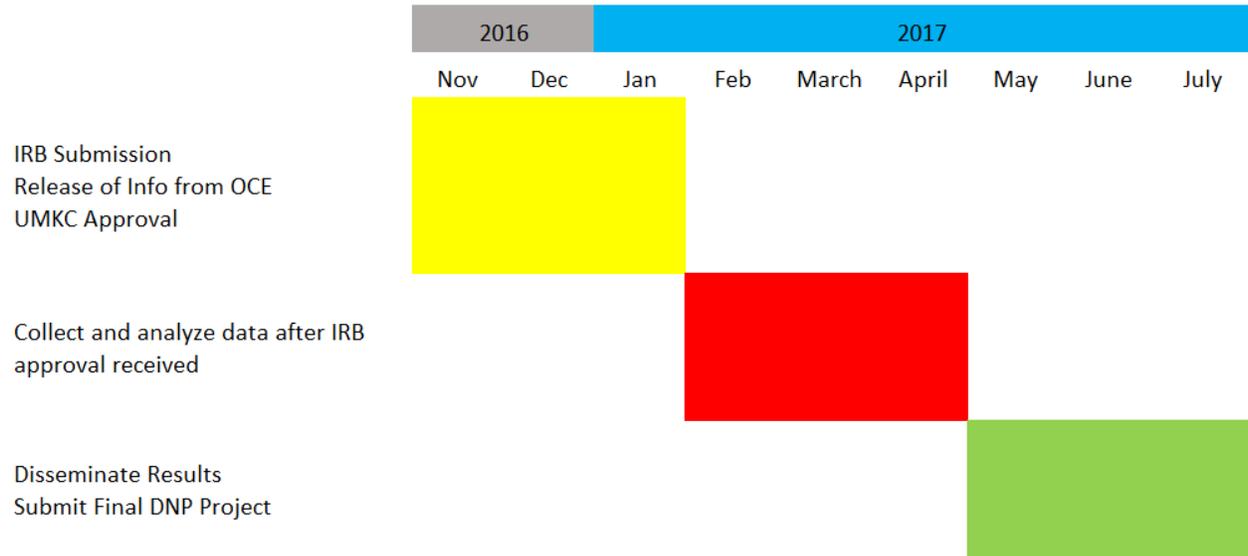
Appendix I

Intervention Flow Diagram

Intervention Steps to be Completed by Student Investigator:

Obtain IRB and UMKC Approval

Obtain Release of Information from OCE

Collect and Analyze retrospective data

Disseminate Results

Submit Final DNP Project
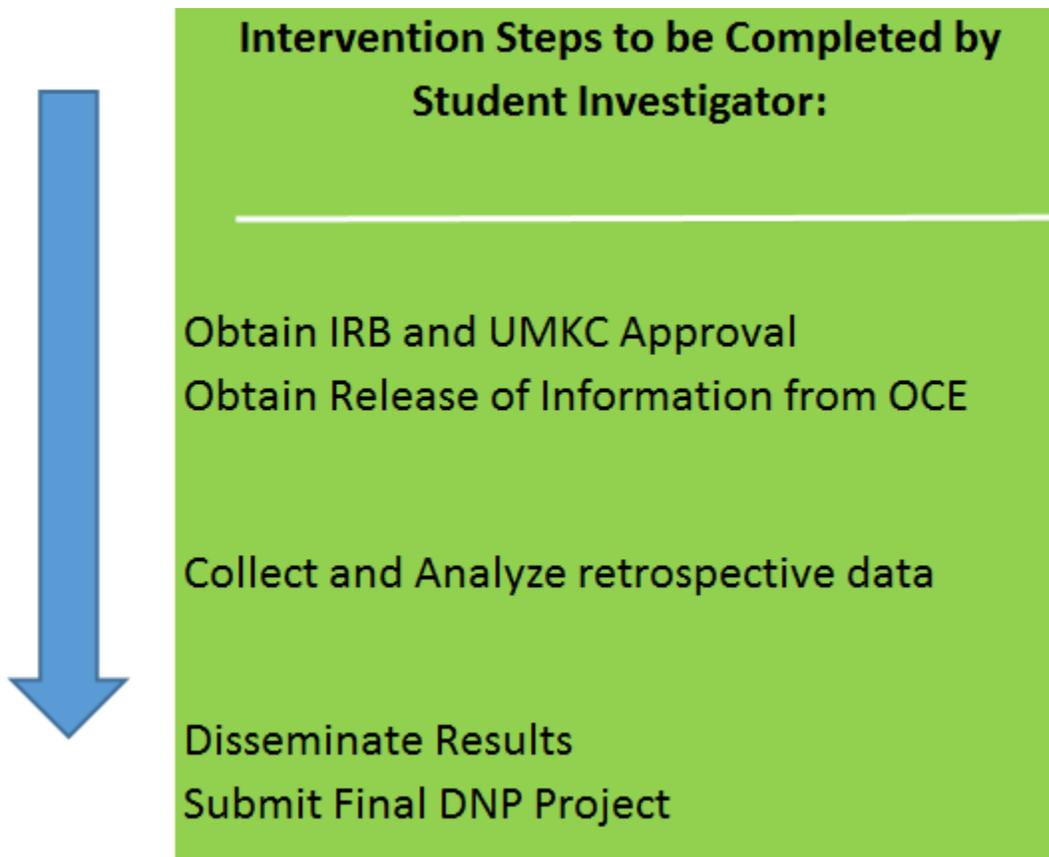
Appendix J

Statistical Analysis

Continuous Variables Presented as Mean +/- Standard Deviation

Group Statistics

	Cohort	N	Mean	Std. Deviation	Std. Error Mean
Hospital Length of Stay (Days)	Provider Discretion	103	7.95	6.007	.592
	Stability Requirement	104	6.61	4.846	.475
Age	Provider Discretion	103	58.08	16.067	1.583
	Stability Requirement	104	56.51	16.610	1.629
Serum Creatinine at Admission	Provider Discretion	103	1.437	1.4434	.1422
	Stability Requirement	104	1.357	1.2467	.1223
Hemoglobin A1c	Provider Discretion	92	8.89	2.404	.251
	Stability Requirement	91	8.37	2.256	.237
Body Mass Index	Provider Discretion	103	30.3615	8.58196	.84561
	Stability Requirement	104	31.7327	11.04052	1.08261
Hospital Days with IV Insulin	Provider Discretion	103	1.81	1.651	.163
	Stability Requirement	104	1.59	1.196	.117
Average Blood Glucose- IV-Insulin Reg 2 Days Pre-Transition	Provider Discretion	49	191.43416	121.316441	17.330920
	Stability Requirement	44	198.30429	118.034021	17.794298
Average Blood Glucose- IV-Insulin Reg 1 Day Pre-Transition	Provider Discretion	99	176.05848	76.225161	7.660917
	Stability Requirement	99	178.45173	71.268830	7.162787
Average Blood Glucose- IV-Insulin Reg Day of Transition	Provider Discretion	103	142.24140	27.631560	2.722618
	Stability Requirement	104	142.25717	26.053577	2.554763
Average Blood Glucose- SQ-Insulin Reg Day 2 Post-Transition	Provider Discretion	83	141.74856	40.001267	4.390710
	Stability Requirement	74	154.91345	49.388207	5.741262
Average Blood Glucose- SQ-Insulin Reg Day 1 Post-Transition	Provider Discretion	103	155.45187	44.607369	4.395295
	Stability Requirement	103	155.28556	56.931842	5.609661

Continuous Variables: Significance Tests

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means					95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Hospital Length of Stay (Days)	Equal variances assumed	2.366	.126	1.775	205	.077	1.346	.758	-.149	2.841
	Equal variances not assumed			1.773	195.450	.078	1.346	.759	-.151	2.843
Age	Equal variances assumed	.319	.573	.690	205	.491	1.568	2.272	-2.911	6.047
	Equal variances not assumed			.690	204.887	.491	1.568	2.271	-2.910	6.046
Serum Creatinine at Admission	Equal variances assumed	.405	.525	.428	205	.669	.0802	.1874	-.2893	.4497
	Equal variances not assumed			.427	200.186	.670	.0802	.1875	-.2897	.4500
Hemoglobin A1c	Equal variances assumed	.689	.407	1.492	181	.137	.514	.345	-.166	1.195
	Equal variances not assumed			1.493	180.507	.137	.514	.345	-.165	1.194
Body Mass Index	Equal variances assumed	1.623	.204	-.997	205	.320	-1.37124	1.37536	-4.08291	1.34043
	Equal variances not assumed			-.998	194.072	.319	-1.37124	1.37372	-4.08057	1.33809
Hospital Days with IV Insulin	Equal variances assumed	.863	.354	1.095	205	.275	.219	.200	-.175	.614
	Equal variances not assumed			1.093	185.808	.276	.219	.201	-.176	.615
Average Blood Glucose-IV-Insulin Reg 2 Days Pre-Transition	Equal variances assumed	.070	.793	-.276	91	.783	-6.870126	24.876492	-56.284222	42.543970
	Equal variances not assumed			-.277	90.400	.783	-6.870126	24.839441	-56.215034	42.474783
Average Blood Glucose-IV-Insulin Reg 1 Day Pre-Transition	Equal variances assumed	.068	.795	-.228	196	.820	-2.393248	10.487858	-23.076785	18.290289
	Equal variances not assumed			-.228	195.121	.820	-2.393248	10.487858	-23.077364	18.290868
Average Blood Glucose-IV-Insulin Reg Day of Transition	Equal variances assumed	.283	.595	-.004	205	.997	-.015772	3.732495	-7.374772	7.343229
	Equal variances not assumed			-.004	204.045	.997	-.015772	3.733560	-7.377076	7.345532
Average Blood Glucose-SQ-Insulin Reg Day 2 Post-Transition	Equal variances assumed	2.432	.121	-1.843	155	.067	-13.164887	7.141635	-27.272381	.942607
	Equal variances not assumed			-1.821	140.558	.071	-13.164887	7.227754	-27.454050	1.124276
Average Blood Glucose-SQ-Insulin Reg Day 1 Post-Transition	Equal variances assumed	.664	.416	.023	204	.981	.166311	7.126494	-13.884718	14.217340
	Equal variances not assumed			.023	192.957	.981	.166311	7.126494	-13.889518	14.222140

Categorical Data Presented as Numeric Counts of Percentages: Cohort by Sex

Crosstab

			Sex		Total
			Male	Female	
Cohort	Provider Discretion	Count	56	47	103
		Expected Count	53.7	49.3	103.0
	Stability Requirement	Count	52	52	104
		Expected Count	54.3	49.7	104.0
Total		Count	108	99	207
		Expected Count	108.0	99.0	207.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.396[a]	1	.529		
Continuity Correction[b]	.240	1	.624		
Likelihood Ratio	.396	1	.529		
Fisher's Exact Test				.579	.312
Linear-by-Linear Association	.394	1	.530		
N of Valid Cases	207				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 49.26.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2_1 = .396$; P=.529

Categorical Data Presented as Numeric Counts of Percentages: Cohort by Diabetes Status

Crosstab

			Diabetes Status			
			No History of DM	Type 1 Diabetes	Type 2 Diabetes	Total
Cohort	Provider Discretion	Count	17	17	69	103
		Expected Count	16.9	21.4	64.7	103.0
	Stability Requirement	Count	17	26	61	104
		Expected Count	17.1	21.6	65.3	104.0
Total		Count	34	43	130	207
		Expected Count	34.0	43.0	130.0	207.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	2.371[a]	2	.306
Likelihood Ratio	2.386	2	.303
Linear-by-Linear Association	.597	1	.440
N of Valid Cases	207		

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 16.92.

Note. Interpretation: $X^2_2 = 2.371$; P=.306

Categorical Data Presented as Numeric Counts of Percentages: Cohort by DKA or HHS

Crosstab

| | | | DKA or HHS | | | |
			No DKS or HHS	DKA	HHS	Total
Cohort	Provider Discretion	Count	64	37	2	103
		Expected Count	63.7	36.8	2.5	103.0
	Stability Requirement	Count	64	37	3	104
		Expected Count	64.3	37.2	2.5	104.0
Total		Count	128	74	5	207
		Expected Count	128.0	74.0	5.0	207.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	.195[a]	2	.907
Likelihood Ratio	.197	2	.906
Linear-by-Linear Association	.042	1	.837
N of Valid Cases	207		

a. 2 cells (33.3%) have expected count less than 5. The minimum expected count is 2.49.

Note. Interpretation: $X^2_2 = .195$; P=.907

Day of Transition: Number of Patient Days Within Range

Cohort * Within Range Blood Glucose-IV-Insulin Reg Day of Transition Crosstabulation

			Within Range Blood Glucose-IV-Insulin Reg Day of Transition		Total
			No	Yes	
Cohort	Provider Discretion	Count	8	63	71
		Expected Count	6.1	64.9	71.0
	Stability Requirement	Count	3	54	57
		Expected Count	4.9	52.1	57.0
Total		Count	11	117	128
		Expected Count	11.0	117.0	128.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.451[a]	1	.228		
Continuity Correction[b]	.787	1	.375		
Likelihood Ratio	1.517	1	.218		
Fisher's Exact Test				.344	.189
Linear-by-Linear Association	1.440	1	.230		
N of Valid Cases	128				

a. 1 cells (25.0%) have expected count less than 5. The minimum expected count is 4.90.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2_1 = 1.451$; P=.228

Day of Transition: Number of Patient Days with a Blood Glucose <40 mg/dL

Blood Glucose < 40 SQ-Insulin Reg Day of Transition

	Observed N	Expected N	Residual
56.00	55	63.0	-8.0
71.00	71	63.0	8.0
Total	126		

Test Statistics

	Blood Glucose < 40 SQ-Insulin Reg Day of Transition
Chi-Square	2.032[a]
df	1
Asymp. Sig.	.154

a. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 63.0.

Note. Interpretation: $X^2_1 = 2.032$; P=.154

Day of Transition: Number of Patient Days with a Blood Glucose <70 mg/dL

Crosstab

			Blood Glucose < 70 IV-Insulin Reg Day of Transition		Total
			No	Yes	
Cohort	Provider Discretion	Count	66	5	71
		Expected Count	64.3	6.7	71.0
	Stability Requirement	Count	50	7	57
		Expected Count	51.7	5.3	57.0
Total		Count	116	12	128
		Expected Count	116.0	12.0	128.0

Crosstab

			Blood Glucose < 70 IV-Insulin Reg Day of Transition		Total
			No	Yes	
Cohort	Provider Discretion	Count	66	5	71
		Expected Count	64.3	6.7	71.0
	Stability Requirement	Count	50	7	57
		Expected Count	51.7	5.3	57.0
Total		Count	116	12	128
		Expected Count	116.0	12.0	128.0

Note. Interpretation: $X^2_1 = 1.021$; P=.312

Day of Transition: Number of Patient Days with a Blood Glucose >180 mg/dL

Crosstab

| | | | Blood Glucose > 180 IV-Insulin Reg Day of Transition | | Total |
			No	Yes	
Cohort	Provider Discretion	Count	28	43	71
		Expected Count	31.1	39.9	71.0
	Stability Requirement	Count	28	29	57
		Expected Count	24.9	32.1	57.0
Total		Count	56	72	128
		Expected Count	56.0	72.0	128.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.205[a]	1	.272		
Continuity Correction[b]	.844	1	.358		
Likelihood Ratio	1.205	1	.272		
Fisher's Exact Test				.288	.179
Linear-by-Linear Association	1.196	1	.274		
N of Valid Cases	128				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 24.94.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2_1 = 1.205$; P=.272

Day of Transition: Number of Patient Days with a Blood Glucose >300 mg/dL

Crosstab

			Blood Glucose > 300 IV-Insulin Reg Day of Transition		Total
			No	Yes	
Cohort	Provider Discretion	Count	64	7	71
		Expected Count	66.0	5.0	71.0
	Stability Requirement	Count	55	2	57
		Expected Count	53.0	4.0	57.0
Total		Count	119	9	128
		Expected Count	119.0	9.0	128.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.951[a]	1	.163		
Continuity Correction[b]	1.100	1	.294		
Likelihood Ratio	2.089	1	.148		
Fisher's Exact Test				.297	.147
Linear-by-Linear Association	1.935	1	.164		
N of Valid Cases	128				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 4.01.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2_1 = 1.951$; P=.163

Subcutaneous Insulin Regimen Day 1: Number of Patient Days Within Range

Crosstab

			Within Range Blood Glucose-SQ-Insulin Reg Day 1 Post-Transition		Total
			No	Yes	
Cohort	Provider Discretion	Count	24	47	71
		Expected Count	20.1	50.9	71.0
	Stability Requirement	Count	12	44	56
		Expected Count	15.9	40.1	56.0
Total		Count	36	91	127
		Expected Count	36.0	91.0	127.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	2.360[a]	1	.124		
Continuity Correction[b]	1.790	1	.181		
Likelihood Ratio	2.401	1	.121		
Fisher's Exact Test				.165	.090
Linear-by-Linear Association	2.342	1	.126		
N of Valid Cases	127				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 15.87.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2{}_1 = 2.360$; P=.124

Subcutaneous Insulin Regimen Day 1: Number of Patient Days with a Blood Glucose <40 mg/dL

Blood Glucose < 40 SQ-Insulin Reg Day of Transition

	Observed N	Expected N	Residual
56.00	55	63.0	-8.0
71.00	71	63.0	8.0
Total	126		

Test Statistics

	Blood Glucose < 40 SQ-Insulin Reg Day 1 Post-Transition
Chi-Square	1.772[a]
df	1
Asymp. Sig.	.183

a. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 63.5.

Note. Interpretation: $X^2_1 = 1.772$; P=.183

Subcutaneous Insulin Regimen Day 1: Number of Patient Days with a Blood Glucose <70 mg/dL

Crosstab

			Blood Glucose < 70 SQ-Insulin Reg Day 1 Post-Transition		Total
			No	Yes	
Cohort	Provider Discretion	Count	66	5	71
		Expected Count	64.3	6.7	71.0
	Stability Requirement	Count	49	7	56
		Expected Count	50.7	5.3	56.0
Total		Count	115	12	127
		Expected Count	115.0	12.0	127.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.090[a]	1	.296		
Continuity Correction[b]	.545	1	.460		
Likelihood Ratio	1.081	1	.298		
Fisher's Exact Test				.366	.229
Linear-by-Linear Association	1.081	1	.298		
N of Valid Cases	127				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 5.29.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2_1 = 1.090$; P = .296

Subcutaneous Insulin Regimen Day 1: Number of Patient Days with a Blood Glucose
>180 mg/dL

Crosstab

| | | | Blood Glucose > 180 SQ-Insulin Reg Day 1 Post-Transition | | Total |
			No	Yes	
Cohort	Provider Discretion	Count	34	37	71
		Expected Count	32.4	38.6	71.0
	Stability Requirement	Count	24	32	56
		Expected Count	25.6	30.4	56.0
Total		Count	58	69	127
		Expected Count	58.0	69.0	127.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.319[a]	1	.572		
Continuity Correction[b]	.149	1	.700		
Likelihood Ratio	.320	1	.572		
Fisher's Exact Test				.595	.350
Linear-by-Linear Association	.317	1	.574		
N of Valid Cases	127				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 25.57.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2_1 = .319$; P=.572

*Subcutaneous Insulin Regimen Day 1: Number of Patient Days with a Blood Glucose
>300 mg/dL*

Crosstab

| | | | Blood Glucose > 300 SQ-Insulin Reg Day 1 Post-Transition | | Total |
			No	Yes	
Cohort	Provider Discretion	Count	65	6	71
		Expected Count	64.9	6.1	71.0
	Stability Requirement	Count	51	5	56
		Expected Count	51.1	4.9	56.0
Total		Count	116	11	127
		Expected Count	116.0	11.0	127.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.009[a]	1	.924		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.009	1	.924		
Fisher's Exact Test				1.000	.583
Linear-by-Linear Association	.009	1	.925		
N of Valid Cases	127				

a. 1 cells (25.0%) have expected count less than 5. The minimum expected count is 4.85.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2_1 = .009$; P = .924

Subcutaneous Insulin Regimen Day 2: Number of Patient Days Within Range

Crosstab

			Within Range Blood Glucose-SQ-Insulin Reg Day 2 Post-Transition		Total
			No	Yes	
Cohort	Provider Discretion	Count	13	44	57
		Expected Count	13.5	43.5	57.0
	Stability Requirement	Count	10	30	40
		Expected Count	9.5	30.5	40.0
Total		Count	23	74	97
		Expected Count	23.0	74.0	97.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.062[a]	1	.803		
Continuity Correction[b]	.000	1	.994		
Likelihood Ratio	.062	1	.803		
Fisher's Exact Test				.813	.494
Linear-by-Linear Association	.062	1	.804		
N of Valid Cases	97				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 9.48.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2_1 = .062$; P=.803

Subcutaneous Insulin Regimen Day 2: Number of Patient Days with a Blood Glucose <40 mg/dL

Blood Glucose < 40 SQ-Insulin Reg Day 2 Post-Transition

	Observed N	Expected N	Residual
40.00	40	48.5	-8.5
57.00	57	48.5	8.5
Total	97		

Test Statistics

	Blood Glucose < 40 SQ-Insulin Reg Day 2 Post-Transition
Chi-Square	2.979[a]
df	1
Asymp. Sig.	.084

a. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 48.5.

Note. Interpretation: $X^2_1 = 2.979$; P=.084

Subcutaneous Insulin Regimen Day 2: Number of Patient Days with a Blood Glucose <70 mg/dL

Crosstab

			Blood Glucose < 70 SQ-Insulin Reg Day 2 Post-Transition		Total
			No	Yes	
Cohort	Provider Discretion	Count	45	12	57
		Expected Count	47.6	9.4	57.0
	Stability Requirement	Count	36	4	40
		Expected Count	33.4	6.6	40.0
Total		Count	81	16	97
		Expected Count	81.0	16.0	97.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	2.085[a]	1	.149		
Continuity Correction[b]	1.359	1	.244		
Likelihood Ratio	2.193	1	.139		
Fisher's Exact Test				.175	.121
Linear-by-Linear Association	2.063	1	.151		
N of Valid Cases	97				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 6.60.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2_1 = 2.085$; P=.149

Subcutaneous Insulin Regimen Day 2: Number of Patient Days with a Blood Glucose >180 mg/dL

Crosstab

| | | | Blood Glucose > 180 SQ-Insulin Reg Day 2 Post-Transition | | Total |
			No	Yes	
Cohort	Provider Discretion	Count	29	28	57
		Expected Count	28.8	28.2	57.0
	Stability Requirement	Count	20	20	40
		Expected Count	20.2	19.8	40.0
Total		Count	49	48	97
		Expected Count	49.0	48.0	97.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.007[a]	1	.932		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.007	1	.932		
Fisher's Exact Test				1.000	.548
Linear-by-Linear Association	.007	1	.933		
N of Valid Cases	97				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 19.79.

b. Computed only for a 2x2 table

Note. Interpretation: X^2_1 = .007; P=.932

*Subcutaneous Insulin Regimen Day 2: Number of Patient Days with a Blood Glucose
>300 mg/dL*

Crosstab

| | | | Blood Glucose > 300 SQ-Insulin Reg Day 2 Post-Transition | | Total |
			No	Yes	
Cohort	Provider Discretion	Count	55	2	57
		Expected Count	54.6	2.4	57.0
	Stability Requirement	Count	38	2	40
		Expected Count	38.4	1.6	40.0
Total		Count	93	4	97
		Expected Count	93.0	4.0	97.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.132[a]	1	.716		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.130	1	.718		
Fisher's Exact Test				1.000	.548
Linear-by-Linear Association	.131	1	.718		
N of Valid Cases	97				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 1.65.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2_1 = .132$; P=.716

Subcutaneous Insulin Regimen Day 3: Number of Patient Days Within Range

Crosstab

| | | | Within Range Blood Glucose-SQ-Insulin Reg Day 3 Post-Transition | | Total |
			No	Yes	
Cohort	Provider Discretion	Count	9	34	43
		Expected Count	8.7	34.3	43.0
	Stability Requirement	Count	5	21	26
		Expected Count	5.3	20.7	26.0
Total		Count	14	55	69
		Expected Count	14.0	55.0	69.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.029[a]	1	.865		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.029	1	.865		
Fisher's Exact Test				1.000	.561
Linear-by-Linear Association	.029	1	.866		
N of Valid Cases	69				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 5.28.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2_1 = .029$; P=.865

Subcutaneous Insulin Regimen Day 3: Number of Patient Days with a Blood Glucose <40 mg/dL

Blood Glucose < 40 SQ-Insulin Reg Day 3 Post-Transition

	Observed N	Expected N	Residual
26.00	26	34.5	-8.5
43.00	43	34.5	8.5
Total	69		

Test Statistics

	Blood Glucose < 40 SQ-Insulin Reg Day 3 Post-Transition
Chi-Square	4.188[a]
df	1
Asymp. Sig.	.041

a. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 34.5.

Note. Interpretation: $X^2_1 = 4.188$; P=.041

Subcutaneous Insulin Regimen Day 3: Number of Patient Days with a Blood Glucose <70 mg/dl

Crosstab

| | | | Blood Glucose < 70 SQ-Insulin Reg Day 3 Post-Transition | | Total |
			No	Yes	
Cohort	Provider Discretion	Count	34	9	43
		Expected Count	36.1	6.9	43.0
	Stability Requirement	Count	24	2	26
		Expected Count	21.9	4.1	26.0
Total		Count	58	11	69
		Expected Count	58.0	11.0	69.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	2.119[a]	1	.145		
Continuity Correction[b]	1.246	1	.264		
Likelihood Ratio	2.319	1	.128		
Fisher's Exact Test				.188	.131
Linear-by-Linear Association	2.088	1	.148		
N of Valid Cases	69				

a. 1 cells (25.0%) have expected count less than 5. The minimum expected count is 4.14.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2_1 = 2.119$; P=.145

Subcutaneous Insulin Regimen Day 3: Number of Patient Days with a Blood Glucose
>180 mg/dl

Crosstab

			Blood Glucose > 180 SQ-Insulin Reg Day 3 Post-Transition		Total
			No	Yes	
Cohort	Provider Discretion	Count	22	21	43
		Expected Count	22.4	20.6	43.0
	Stability Requirement	Count	14	12	26
		Expected Count	13.6	12.4	26.0
Total		Count	36	33	69
		Expected Count	36.0	33.0	69.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.047[a]	1	.829		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.047	1	.829		
Fisher's Exact Test				1.000	.513
Linear-by-Linear Association	.046	1	.830		
N of Valid Cases	69				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 12.43.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2{}_1 = .047$; P=.829

*Subcutaneous Insulin Regimen Day 3: Number of Patient Days with a Blood Glucose
>300 mg/dL*

Crosstab

| | | | Blood Glucose > 300 SQ-Insulin Reg Day 3 Post-Transition | | Total |
			No	Yes	
Cohort	Provider Discretion	Count	39	4	43
		Expected Count	39.3	3.7	43.0
	Stability Requirement	Count	24	2	26
		Expected Count	23.7	2.3	26.0
Total		Count	63	6	69
		Expected Count	63.0	6.0	69.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.053[a]	1	.818		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.054	1	.817		
Fisher's Exact Test				1.000	.594
Linear-by-Linear Association	.052	1	.819		
N of Valid Cases	69				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 2.26.

b. Computed only for a 2x2 table

Note. Interpretation: $X^2_1 = .053$; P=.818

Use of transition orders by provider

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Cohort * Transition Orders Used by Physician	207	100.0%	0	0.0%	207	100.0%

Cohort * Transition Orders Used by Physician Crosstabulation

			Transition Orders Used by Physician		
			No Transition Orders	Transition Orders Used	Total
Cohort	Provider Discretion	Count	32	71	103
		Expected Count	39.3	63.7	103.0
	Stability Requirement	Count	47	57	104
		Expected Count	39.7	64.3	104.0
Total		Count	79	128	207
		Expected Count	79.0	128.0	207.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	4.375[a]	1	.036		
Continuity Correction[b]	3.797	1	.051		
Likelihood Ratio	4.395	1	.036		
Fisher's Exact Test				.045	.026
Linear-by-Linear Association	4.353	1	.037		
N of Valid Cases	207				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 39.31.

b. Computed only for a 2x2 table

Influence of Cohort Group on Hospital Length of Stay

Group Statistics

	Cohort	N	Mean	Std. Deviation	Std. Error Mean
Hospital Length of Stay (Days)	Provider Discretion	71	7.27	5.412	.642
	Stability Requirement	57	6.67	4.501	.596

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Hospital Length of Stay (Days)	Equal variances assumed	.180	.672	.672	126	.503	.601	.894	-1.168	2.370
	Equal variances not assumed			.686	125.826	.494	.601	.876	-1.133	2.335

Note. Interpretation $t_{(126)}$ = .679, P = .503

Relationship between hemoglobin A1c for individuals with or without transition orders by cohort

group

Estimates

Dependent Variable: Hemoglobin A1c

Cohort	Transition Orders Used by Physician	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
Provider Discretion	No Transition Orders	7.835	.410	7.027	8.644
	Transition Orders Used	9.421	.292	8.845	9.998
Stability Requirement	No Transition Orders	8.341	.344	7.662	9.020
	Transition Orders Used	8.402	.333	7.745	9.059

Pairwise Comparisons

Dependent Variable: Hemoglobin A1c

Cohort	(I) Transition Orders Used by Physician	(J) Transition Orders Used by Physician	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
						Lower Bound	Upper Bound
Provider Discretion	No Transition Orders	Transition Orders Used	-1.586[*]	.503	.002	-2.579	-.593
	Transition Orders Used	No Transition Orders	1.586[*]	.503	.002	.593	2.579
Stability Requirement	No Transition Orders	Transition Orders Used	-.061	.479	.898	-1.006	.883
	Transition Orders Used	No Transition Orders	.061	.479	.898	-.883	1.006

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

Univariate Tests

Dependent Variable: Hemoglobin A1c

Cohort		Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Provider Discretion	Contrast	51.691	1	51.691	9.927	.002	.053
	Error	932.109	179	5.207			
Stability Requirement	Contrast	.085	1	.085	.016	.898	.000
	Error	932.109	179	5.207			

Each F tests the simple effects of Transition Orders Used by Physician within each level combination of the other effects shown. These tests are based on the linearly independent pairwise comparisons among the estimated marginal means.
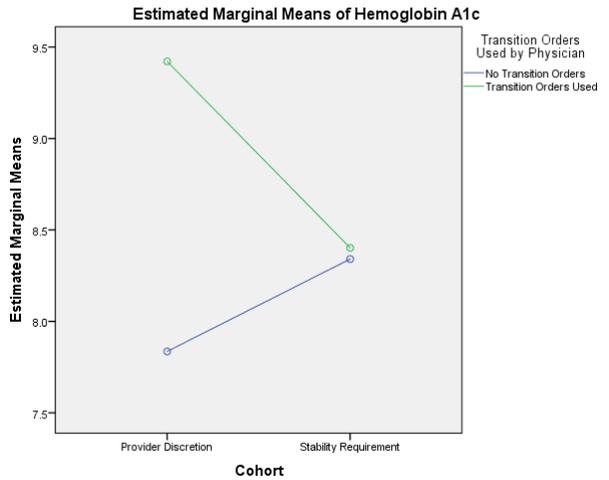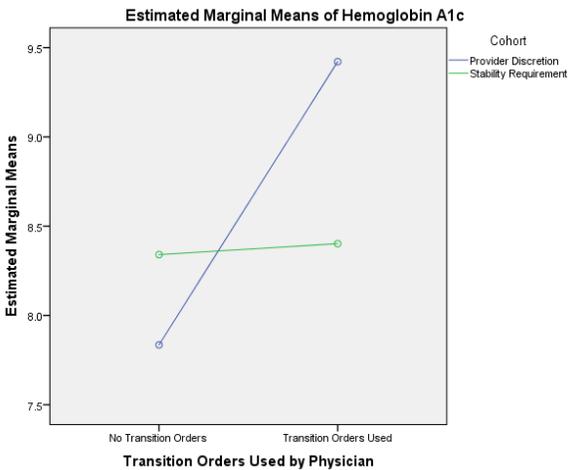
Interaction between Cohort and the Writing of Transition Orders when Measuring Patient Days

with IV Insulin

Between-Subjects Factors

		Value Label	N
Cohort	1	Provider Discretion	103
	2	Stability Requirement	104
Transition Orders Used by Physician	0	No Transition Orders	79
	1	Transition Orders Used	128

Descriptive Statistics

Dependent Variable: Hospital Days with IV Insulin

Cohort	Transition Orders Used by Physician	Mean	Std. Deviation	N
Provider Discretion	No Transition Orders	2.00	2.553	32
	Transition Orders Used	1.72	1.031	71
	Total	1.81	1.651	103
Stability Requirement	No Transition Orders	1.47	1.266	47
	Transition Orders Used	1.68	1.136	57
	Total	1.59	1.196	104
Total	No Transition Orders	1.68	1.898	79
	Transition Orders Used	1.70	1.075	128
	Total	1.70	1.441	207

Tests of Between-Subjects Effects

Dependent Variable: Hospital Days with IV Insulin

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	5.442[a]	3	1.814	.872	.457	.013
Intercept	560.932	1	560.932	269.587	.000	.570
Cohort	3.807	1	3.807	1.830	.178	.009
Transition_Orders	.051	1	.051	.025	.876	.000
Cohort * Transition_Orders	2.945	1	2.945	1.415	.236	.007
Error	422.384	203	2.081			
Total	1023.000	207				
Corrected Total	427.826	206				

a. R Squared = .013 (Adjusted R Squared = -.002)

1. Cohort

Dependent Variable: Hospital Days with IV Insulin

Cohort	Mean	Std. Error	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
Provider Discretion	1.859	.154	1.556	2.162
Stability Requirement	1.576	.142	1.296	1.856

2. Transition Orders Used by Physician

Dependent Variable: Hospital Days with IV Insulin

Transition Orders Used by Physician	Mean	Std. Error	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
No Transition Orders	1.734	.165	1.408	2.060
Transition Orders Used	1.701	.128	1.448	1.954

Appendix K

December 16, 2016

Institutional Review Board

IRB,

This letter serves to provide documentation regarding Andrea Stafos' Doctor of Nursing Practice (DNP) Project proposal. Ms. Stafos obtained approval for her project proposal, The Effects of a Clinical Decision Support Software Program Stability Requirements on Glycemic Outcomes, from the School of Nursing DNP faculty committee on December 16, 2016.

If I can provide any further information, please feel free to contact me.

Sincerely,

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