HOSPITAL ACQUIRED HYPO/HYPERGLYCEMIA: A CLINICAL ISSUE

by

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Abstract

Hypo- and hyperglycemia related to improper timing of mealtime insulin occurs frequently in the in-patient setting. The timing of mealtime insulin administration is affected by many variables such as blood glucose meter availability, meal delivery and patient's willingness and desire to eat. The purpose of this collaborative multidisciplinary evidence-based project was to improve the timing of mealtime insulin administration related to point of care fingerstick blood glucose monitoring and meal delivery to decrease the rate of hypo- and hyperglycemia. The average time between point of care fingerstick blood glucose monitoring and insulin delivery on the medical unit where this project was conducted was 57.44 minutes. In addition, mealtime insulin administration was not consistently documented, and timing between meal tray delivery and mealtime insulin administration was not a documented task. The John Hopkins Nursing Evidence-based Practice Model served as the conceptual framework for the project, and the use of the Six Sigma Methodology served as the practice method. The findings or this project proved food delivery notification enabled the nursing staff to efficiently administer mealtime insulin in coordination with point of care fingerstick blood glucose monitoring and the delivery of meals. In addition, 100% of point of care fingerstick blood glucose monitoring was administered within the best practice window of 30 minutes, 100% of mealtime insulin administration was documented, and 76% of patients received mealtime insulin within the recommended 15-minute window. Secondary outcome metrics of reducing rates of hypo/hyperglycemia by 10% was achieved for recurring hypoglycemia; however, hyperglycemia rates remained unchanged.

Keywords: mealtime insulin, prandial insulin administration, nutritional insulin, Inpatient, coordinated mealtime insulin delivery, coordinated meal delivery.

Hospital Acquired Hypo/Hyperglycemia: A Clinical Issue

Management of hospital acquired hypo- and hyperglycemia has become an important quality indicator in the in-patient environment. Both conditions are associated with adverse outcomes, including complications and death (American Diabetes Association, 2018). The American Diabetes Association (ADA) Standards of Medical Care-2017 promote and support proper timing between point of care fingerstick blood glucose monitoring, mealtime insulin administration, and meal delivery to reduce episodes of both hypo- and hyperglycemia. The ADA considers improving the timing of these three patient care interventions a crucial step in the safe and effective care of patients with diabetes (American Diabetes Association, 2018).

The focus of this quality improvement project was to answer the PICOT question; in hospitalized adult patients with diabetes receiving mealtime insulin, how does a collaborative multi-disciplinary approach to improve documentation and timing of mealtime insulin administration, compared to present practice, decrease hypo- and hyperglycemia rates, over eight weeks? The goal was to improve the timing of point of care finger stick blood glucose monitoring, mealtime insulin administration, and meal delivery in the inpatient setting.

Project Description

The current state and practices were assessed by interviewing nurse managers and nursing staff, as well as generated electronic medical record (EMR) reports relating to fingerstick glucose testing, mealtime insulin administration, and meal tray delivery. Fingerstick glucose testing occurring within 30-minute of insulin administration and mealtime insulin administration occurring within 15-minutes of the start of the meal is recommended by the American Association of Clinical Endocrinologists (AACE) and the American Diabetes Association (ADA 2017). A retrospective chart review revealed the average time between fingerstick glucose and

insulin delivery was 57.44 minutes, which is outside the 30-minute best practice recommendation. Mealtime insulin administration was not consistently documented, with only 59% of mealtime insulin administration documented in the EMR. Timing between meal tray delivery and insulin administration was not a documented task prior to project implementation. Observational data revealed eight patients (62%) received their mealtime insulin outside the 15-minute best practice recommendation. Furthermore, the overall average time between insulin administration and meal delivery was 29.54 minutes, which could compromise patient safety, increase patient risk for hypo- and hyperglycemia, and other serious consequences (Brutsaert, Carey, & Zonszein, 2014).

Research supports that both hypo- and hyperglycemia are linked to increased length of stay, mortality, and costs to organizations (Gosmanov, 2016). Therefore, better coordination of mealtime insulin practice is crucial to optimize patient outcomes. There are many factors that affect proper timing in delivering these three tasks. Multiple patient responsibilities by nursing staff, inadequate supply of insulin on the units, unavailable POC glucose meter, wide variation in the kitchen to unit meal tray delivery schedule, and the patient's inability or lack of desire to eat are amongst the most common. In this project leader's hospital, a combination of varied meal delivery time, lack of coordination of meal delivery, and insulin administration among two disciplines (nurses and dietary aids) affected the proper timing of insulin administration.

Improper timing of mealtime insulin administration on this hospital has been associated with glucose variability resulting in hypo- and hyperglycemia. Both hypo- and hyperglycemia are acute complications which can lead to further sequelae such as morbidity, mortality, patient, dissatisfaction and increased length of stay (ADA, 2017).

Recurring hypoglycemia has been identified as a consistent challenge by this project leader's Glycemic Management Team. In the month prior to project implementation, the recurring episodes of hypoglycemia rates were 37.5% which ranks this hospital in the 85th percentile for recurring hypoglycemia. The percent weight daily mean >180 mg/dl for this hospital was 27.7% which ranks this hospital at the 58 percentile out of 100 hospitals for hyperglycemia days >180 mg/dl. This data indicates that 85% of hospitals report fewer episodes of recurring hypoglycemia and 58% report fewer episodes of hyperglycemia per patient days. The end-goal of this quality improvement project is to improve recurring hypoglycemia and hyperglycemia days in this project leader's hospital by 10%. Unit specific goals include documentation of meal delivery by nursing staff, timing between fingerstick glucose and mealtime insulin administration to be less than 30 minutes, and mealtime insulin administration less than 15 minutes before or after the start of the meal.

Presently, there is no evidence of coordination between fingerstick glucose monitoring, insulin administration, and meal delivery. Nursing staff check glucose levels when glucometers are available, which can result in glucose measurements greater than an hour before meals or after the patient has eaten their meal. Insulin is administered with the mid-day medications without regard for timing of glucose or meals. The nursing assistant delivers patient meals unaware if the patient's glucose has been measured or if the patient had received their mealtime insulin. Lastly, there is no policy standardizing the mealtime insulin administration to ensure the delivery of evidence-based practice.

Available Knowledge

To conduct a literature search, the use of electronic databases (Pubmed, Sage, Ovid and the American Association of Diabetes Educators) was used. Keywords used were: *mealtime insulin*,

prandial insulin administration, nutritional insulin, insulin analogs, inpatient, adult patients, coordinated mealtime insulin delivery, coordinated meal delivery. Exclusion criteria included continuous subcutaneous insulin infusion, insulin pump therapy, basal insulin administration, adolescences and children. Years searched were from July 1, 2001, to July 1, 2016. The initial search using inclusion criteria of (a) mealtime insulin resulted in 2,407 articles. Conducting the search again with the additional inclusion criteria of (b) insulin analogs resulted in 1,192 relevant articles. A third search using inclusion criteria of (c) inpatient resulted in 162 relevant articles. A subsequent search by (d) adult patients resulted in 110 relevant articles. To further drill down to additional articles a search using coordinated mealtime insulin delivery and coordinated meal delivery was used. Combining the search with exclusion criteria of insulin pump therapy and articles versus research studies resulted in 37 studies; however, 20 studies met the inclusion criteria for inpatient mealtime insulin administration for adult patients assigned to a non-critical care unit. Research evidence was selected, reviewed, critiqued, and synthesized to identify its support of this project.

Mealtime Insulin Administration

The inpatient environment poses particular challenges to achieving best practice management of patients with diabetes. Such challenges as unanticipated changes in nutrition, medication changes, use of insulin resistant medications such as corticoid steroids, psychological and physical stress, and changes in activity are often associated with inpatient diabetes care and management (Draznin, Gilden, Golden, & Inzucchi, 2013). Coordination of mealtime insulin delivery is a crucial step to achieving safe and effective care for patients with diabetes. Chen et al. (2016) supports this project with a similar study they conducted using electronic records to assess timeliness of glucose measurements compared to insulin administration and meal delivery.

This project leader used similar reports from the EMR to measure and record outcomes over the eight week project period.

In contrast, Muller et al. (2013) used a prospective, randomized, open-label, single-center, crossover study to examine the necessity of the injection-to-meal interval (IMI) in patients with type 2 diabetes in a general practice setting. The results of this study concluded that an IMI was not necessary. Interestingly, the authors only observed patients with type 2 diabetes on regular insulin that has a longer onset, peak and duration that the rapid acting insulin analogs used in this project leader's study. By the nature of the pharmacokinetics of regular insulin, a wider prandial coverage period would be noted, however in a hospital setting, with fixed meals and the use of rapid acting insulin, a shorter duration of insulin action time occurs. This difference in insulin action time would require a tighter window of administration time as replicated in this project leader's study.

Collaborative Approach to Implementing Change

Nurses remain the primary care givers for hospitalized patients. As the prevalence of diabetes grows so does the number of hospitalized patients admitted with diabetes. This increase presents a demand for nursing knowledge of diabetes care to grow (Freeland, Penprase, & Anthony, 2011). Initial and ongoing educations regarding onset, peak, and duration of the action of mealtime insulin, the effect of improper timing of mealtime insulin administration, and common causes of hypo- and hyperglycemia in the inpatient setting were provided to ensure project implementation and sustainability. Including patients in the practice change can foster best practice self-care measures to be continued upon discharge. Camacho, Johnson, Bonner, and Glass (2016) conducted research examining the benefit to including patients in hospital based practice change. Their study demonstrated mealtime insulin administered by patients with

diabetes, taught be certified diabetes educators can prove to be a safe and effective method of the administration of mealtime insulin. The authors examined ways to mitigate the complexities associated with insulin administration and assist patients to reach their glycemic goals and reduce the complications associated with improper mealtime insulin administration. Providing patients and their family education and information regarding a quality improvement strategy to improve care and encouraging them to assist the nurses to achieve outcome goals can be an effective project strategy (Camacho et al., 2016; Gilman, 2001). Having patients and their family witness best practice in regard to proper timing of fingerstick glucose, mealtime insulin administration and meal consumption can increase adherence to therapy when the patient returns to self-care measures at home (Camacho et al., 2016; Gilman, 2001).

Similarly, Houck, Tirumalesetty, and Meadow (2013) implemented a study using the plan-do-act performance improvement method to improve timing of glucose monitoring, insulin administration, meal delivery, and patient outcomes. The authors recognize the coordination of glucose testing, nutrition delivery, and insulin administration is integral to the safe management of hyperglycemia and diabetes in the hospital; however, found the synchronization of these three patient care tasks significantly challenging. In addition to nursing and dietary staff education, Houch et al. (2013) also concluded it is critical to educate the patient and patient family on the process improvement measures and best practice guidelines.

Research by Eiland, Goldner, Drincic, and Desouza (2014) support a system wide collaborative approach to preventing hypoglycemia in the inpatient setting. The positive outcomes of this study support a larger scale approach to mealtime insulin administration.

Hardee et al. (2015) also studied a variety of inpatient processes to improve patient outcomes and

transitions in care. The authors determined that establishing standardized processes provided consistent, high-quality transitional care for all patients with diabetes.

Prevention of Complications

Proper timing of mealtime insulin is attributed to avoidance of hypo- and hyperglycemia and other acute and chronic complications (Manning & Jackson, 2005). Insulin therapy is the treatment of choice to manage glucose control in the inpatient setting over oral antidiabetic medications (American Diabetes Association, 2018). Insulin therapy is associated with improved control when administered safely and correctly (American Diabetes Association, 2018). Establishing the optimal mealtime insulin dose when using basal-bolus insulin therapy can be challenging because it often depends on multiple factors such as fingerstick glucose, target blood glucose level, insulin-to-carb ratios, the total carbohydrate content of the meals, and other medications the patients are prescribed (Bergenstal et al., 2008). Gosmanov (2016) reported that variable caloric intake is a clinical factor in need of strong consideration. Variations in carbohydrate content in each meal was eliminated as a variable in this project by implementing a carbohydrate consistent meal plan for patients prescribed mealtime insulin.

The timing of fingerstick glucose in relation to meal consumptions has been a concern for many nursing and health care providers (Trotter et. al., 2013). Understanding this relationship and appreciating the direct effect that proper timing of fingerstick glucose has on insulin calculations can prevent unnecessary complications (Trotter et al., 2013). Insulin is a high alert drug and all positive safety measures that can be put in place, as well as practice changes necessary to ensure proper calculations of mealtime insulin, must be implemented into practice (Ridge, 2007). Eiland et al. (2014) confirmed the reasons behind the frequency and severity of

hypoglycemia is numerous; however, the timing of diet and medication regimen is considered critical to preventing detrimental consequences.

Coordinated Approach to Mealtime Insulin Delivery

A coordinated and timely approach to mealtime insulin administration, although challenging to achieve, is a necessary element to achieving optimum glucose control for the patient with diabetes in the hospital setting (Chen et al., 2016). Bao et al. (2011) conducted a comparison study to compare a novel algorithm on the use of the food insulin index (FII), for estimating mealtime insulin dose with carbohydrate counting in adults with type 1 diabetes. This study took a slightly different approach to mealtime insulin as it examined the impact of nutrition on mealtime insulin calculations and dosing. Similarly, it supports the important relationship between mealtime insulin and meal contents in regard to glycemic control. This study also demonstrates the need for proper insulin administration in relation to the meal in order to maintain normoglcyemia and prevent the acute complications of both hypo- and hyperglycemia. Moreover, it reinforces the need to consider the quality of the food being consumed in relation to the insulin being administered and the timing that insulin is being administered. This critical piece in the safe delivery of mealtime insulin will be included in the staff education portion of this project.

A similar study conducted by Dungan, Sagrilla, Arde-Rasoul, and Osei (2013) examined the role carbohydrates have in calculating the mealtime insulin dose. This randomized study explored the relationship between the variations in carbohydrates in each meal. This study examined the use of a fixed carbohydrate meal planning system to assist in mitigating the variable of different carbohydrate contents at each meal. This study proved, the ability to decrease this variable using fixed carbohydrate meals (consistent carbohydrates), will narrow the

effect on glycemic control, namely hypo- and hyperglycemia on the timing of insulin and dose. This study, in comparison to Bao et al. (2011) supports the need to consider the nutritional content of a meal in addition to the timing of the meal in order to prevent glucose excursions. The project leader's hospital administration supports this best practice by offering carbohydrate controlled meals to all patients with diabetes.

In contrast to this project leader's outcomes, results from a similar study conducted on four cardiology units in two hospitals by Lampe et al. (2014) revealed a low achievement of ideal practices. Their study included 64 patients, using a goal of one hour between glucose measurements insulin administration and 15 minutes between insulin administration and meal delivery. Unfortunately, the study ended with only 14% of patients receiving glucose measurement and meal delivery within the best practice time window. They concluded that the approach used to synchronize tasks among various patient caregivers was not well coordinated.

Nurse-led Process Change

This project focused on a nurse-led process change to improve the timing of fingerstick glucoses, mealtime insulin administration, and meal delivery. Empowering the nursing staff has been proven to be an effective means to improve patient care and outcomes. Engle, Ferguson, and Fields (2016) implemented a quality improvement project with the aim to redesign a hospital meal delivery process in order to shorten the time between blood glucose monitoring, corresponding mealtime insulin administrations, and improve glycemic control. The implications of this process improvement study revealed that nurse-led coordination of POC glucose monitoring, mealtime insulin administration, and meal delivery lead to improved glycemic control for the inpatient population. The results of this study, which revealed the percentage of patients receiving meal insulin within 30-minutes of blood glucose measurement, demonstrated

an increase of 35% at study implementation to 73% at study conclusion. This study provides an example demonstrating a nurse-led process change can effectively improve timing between these two critical patient care practices.

Nurse-led initiatives have been the focus of other research studies as well. Corl et al. (2015) conducted a 14-week retrospective chart audit on 254 hyperglycemic (>180mg/dl) acute care patients. This quality improvement project was designed to evaluate the effect of bedside diabetes education provided by staff nurses on readmission rates of patients requiring insulin. The study demonstrated that diabetes education performed by the nursing staff resulted in a significant reduction in early seven day readmission rates with a trend in improving 14- and 30-day readmission rates. This study was also able to demonstrate that focusing on the nursing staff to implement best practice around diabetes care issues can result in quantifiable outcomes both during the inpatient stay and after discharge.

Varaei, Salsali, Cheraghi, Tehrani, and Heshmat (2013) provides support to this project with the results of their quasi-experimental study using a before and after design. This study consisted of 19 baccalaureate nurses working on an inpatient unit caring for patients with diabetes. These nurses were taught and provided an evidence-based approach to implementing care and education to the patients assigned to the study ward. A statistically significant difference in knowledge, attitude, and practice of nurses before and after the intervention (p = 0.001) was noted. Although this project leader did not measure nurse attitude or knowledge before and after, a significant difference in knowledge, attitude, and practice was noted among the staff on this project unit during daily morning huddles.

Adjusting nursing work patterns to improve patient care is the goal of a patient centered initiative. This project utilized a nurse driven approach to mealtime insulin delivery by adjusting

nursing patterns to prevent acute complications such as hypo- and hyperglycemia. This approach is proven effective in the LOGIC-1 study designed by Van Herpe et al. (2016). The LOGIC-1 study is a prospective, parallel-group, randomized, controlled clinical trial. Using a nurse driven focus the researchers studied a heterogeneous mix of 300 critically ill patients randomized to either nurse-directed glycemic control (Nurse-C) or algorithm-guided glycemic control (LOGIC-C). Glycemic penalty index (GPI), a measure that penalizes both hypoglycemic and hyperglycemic deviations from normoglycemia, was the efficacy outcome measure, and incidence of severe hypoglycemia (<40 mg/dl) was the safety outcome measure. A critical piece to their study was the ability to achieve best practice for the delivery of insulin by the use of an electronic glycemic management system as effectively as a skilled and knowledgeable nursing staff.

To further examine the need for proper timing between fingerstick glucose, mealtime insulin administration and meal delivery, other studies were collected and synthesized. Duran-Valdez et al. (2017) confirmed, from their 40 patient randomized control study, that insulin timing requires a patient-centered translation approach to improve patient care outcomes such as improved A1C and prevention of acute complications such as hypo- and hyperglycemia.

Educational Tools

Eight and a half by eleven sized laminated informational cards and graphs were distributed to the nursing staff on the project unit each week during morning huddles each Monday. These educational tools were placed on each nurse's work station on wheels (WOW). The education tools were used to enhance staff education throughout this project. Krall, Donihi, Hatam, Koshinsky, and Siminerio (2016) utilized similar educational tools to enhance staff education in his study to improve nursing interventions that impact glycemic control in hospitalized patients with diabetes. The use of educational tools, unit-based flyers, laminated

cards, audit graphs and monthly meetings are a few examples Krall et al. (2016) found to be effective in demonstrating a change in nursing practice.

In the hospital environment limitations and challenges exist even in spite of nursing staff education and instrumental teaching tools such as laminated instruction cards (Freeland et al., 2011). Gilman (2001) noted the most common reason for variances in insulin timing as reported in nurse notes was either the nurse or the patient was otherwise occupied at the usual mealtime and the insulin was given later than usual. Improvement in coordination and documentation of meal delivery at the project leader's hospital has been assessed as a need and included in the project goals. Krall et al. (2016) also noted that improved processes and tools assisted in relieving the work load of the nurse, allowing more time to educate patients and provide timely diabetes care and education.

Other studies were conducted to examine the effectiveness of tools to foster practice change. Warren et al. (2016) studied implementing evidence-based nursing practice across a diverse 9-hospital system. The authors positioned transformational nursing leaders within the organizations to collectively analyze resources and created a system-wide online evidence-based education plan with tools to successfully change nursing practice. Chen et al. (2016) used EMR reports and educational tools to assist in a practice change around mealtime insulin delivery. The author's use of EMR reports as tools designed to guide the nursing staff to implement best practice were similar to the EMR reports used by this project leader. Tools, especially electronic tools, aid in the clarity of the treatment order and often have built in aids for the care provider to ensure accuracy in prescribing and administration (Chen et al., 2016). This project leader implemented a new process change in relation to documenting meal delivery with the use of

visual and electronic tools. Visual reminders where placed on the nursing unit to assist the nursing staff in documenting meal delivery.

Six Sigma Methodology

The fundamental objective of the Six Sigma methodology is the implementation of a measurement-based strategy that focuses on process improvement and variation reduction. Six Sigma design is a disciplined, data-driven approach and methodology often used within healthcare facilities for process improvement. Lampe et al. (2014) conducted an observational descriptive design study designed to evaluate the timing and practices of blood glucose testing and rapid-acting insulin administration around mealtimes using the Six Sigma methodology. Lampe et al. (2014) examined 64 mealtime practices performed by nurses assigned to four medical oncology step-down units at two hospitals within a large community hospital health system.

Liberatore (2013) noted several inpatient care areas for which the Six Sigma Methodology has been applied. These areas include; hospital admission, discharge, medication administration, operating room, and in both cardiac care and intensive care. Application of the Six Sigma Methodology initially improved key process changes by 67%, however only 10% reported sustained improvement (Liberatore, 2013).

Nayar, Fetrick, and Nguyen (2016) studied the use of the Lean Sigma Methodology to improve medication administration in the VA hospital setting. Using this quality improvement study method, the authors were able to identify the root cause behind medication delays and where able to improve processes. This study offers tremendous worth to the practice for patients with diabetes receiving mealtime insulin. Similar to Six Sigma methodology, authors Nayar et

al. (2016) used a method of process mapping to define process weaknesses in order to focus on the target of improvement.

Summary of Review of Literature

Numerous authors have discussed the benefits of a coordinated approach to proper timing between point of care glucose monitoring, mealtime insulin administration and meal delivery, on reducing both hypo- and hyperglycemia for the hospitalized patient with diabetes. Each of the authors concluded that a coordinated and timely approach to mealtime insulin administration, although challenging to achieve, is a necessary element to achieving optimum glucose control for the patient with diabetes in the hospital setting. This body of evidence supports this quality improvement project's aim to improve the timing of mealtime insulin administration, with the end goal of realizing a decrease in hypo- and hyperglycemia rates.

Rationale

The conceptual framework used for this project was the John Hopkins Nursing Evidence-based Practice Model. This evidence-based model was developed and tested by a team of nurses and faculty at The Johns Hopkins Hospital and The Johns Hopkins School of Nursing. The model incorporates three critical elements inherent to the profession of nursing. The three critical elements are: practice, education, and research. The element of practice is the basic component which represents the foundation of nursing. Furthermore, the Johns Hopkins Nursing Evidence-based Practice Model consists of a practical guide for the bedside nurse. This model provides tools for process and critique; including question development, evidence rating scale, and research and non-research evidence appraisal which is applicable to a variety of healthcare settings (Schaffer et al., 2012). By design, the Johns Hopkins Nursing Evidence-based Practice Model lends itself to the staff nurse. This conceptual framework was chosen because it relates to

nurse driven research and projects. This conceptual framework was the foundation for the preimplementation education process, the development of the tools used in this project, and the daily critique that occurred with the nursing staff during morning huddle each day. Furthermore, the elements of this nursing model aligned congruently with team decision-making, and the overall project focus of implementing an effective system wide multidisciplinary collaborative approach to mealtime insulin administration.

Project Variables

The independent variable in this project was the revised and implemented schedule for fingerstick glucose monitoring, insulin administration, and meal delivery. The dependent variables were episodes of hypo- and hyperglycemia. Confounding variables that affected the results include staffing for both nursing and dietary departments and study population due to constant fluctuation in the medical-surgical patients admitted to the project unit with varying degree of blood sugar control. Furthermore, the patient's willingness and desire to eat is also considered a confounding variable. Appetite varied widely, both between and across subjects, which was beyond the scope of this project. Additional project variables such as the timing of fingerstick glucose, mealtime insulin administration, and meal delivery were minimized and coordinated during the eight-week project.

Study Assumptions

It was assumed that the nursing and dietary staff had a sincere interest in participating in this study. All staff participants are motivated by best practice and best patient outcomes. All patients included in this study have type 1 diabetes, type 2 diabetes, or insulin requiring stress induced hyperglycemia. Lastly, hospital glucometers results are accurate as all hospital medical equipment is regularly inspected and quality controls are performed per protocol.

Specific Aim

The aim of this study was to establish the prevalence of hypo- hyperglycemia episodes in hospitalized adult patients and determine if implementing a multidisciplinary approach to improving timing between fingerstick glucose, mealtime insulin, meal delivery, could decrease in-patient hypo-and hyperglycemia rates.

Context

The host hospital for this project is a 400-bed community hospital in New York State. This project leader joined the administrative team of this hospital in May 2016 to fulfill a vision of creating and implementing an outpatient diabetes education center and improving inpatient care for patients with diabetes. The need to improve the current culture of diabetes care, management, and education was identified and listed as a hospital goal by the board of directors for 2016. A committed administrative team supports many inpatient initiatives such as this quality improvement project to improve inpatient glycemic control. Administrative stakeholders such as the Chief Nursing Officer, Chief Medical Officer, Director of Nutrition and Dietetics, and the nurse manager on the project unit conveyed support and were eager to begin project implementation. Their commitment to this project remains steadfast even throughout the months following project completion.

Benefits of implementing this performance improvement project far reach beyond patient care. The Joint Commission expects hospitals to develop a comprehensive approach to performance improvement (Murray, 2016). Implementing measures to improve the timing of fingerstick glucose, mealtime insulin administration, and meal delivery to prevent hypo- and hyperglycemia correspond precisely to the Joint Commission standards of care. The avoidance of hypo- and hyperglycemia is paramount for patient safety and the avoidance of complications,

seizures, falls, and infections. Episodes such as hypo- and hyperglycemia can affect the length of stay and the use of unnecessary medications and resources, translating to a significant cost to the hospital (Draznin, Gilden, Golden, & Inzucchi, 2013).

The administrative leadership team at this project leader's hospital provided full support to this project. The implementation of best practice standards of care is paramount to the mission and vision of this organization. Furthermore, in efforts to support a commitment to quality and performance improvement, this hospital participates in a voluntary national diabetes care quality improvement program where benchmarking against hospitals of similar size and geographic characteristics is reported monthly. This program also graphs trends in care and over designated periods of time. This hospital has already realized improvement in some aspects of care for the patient with diabetes. Ultimately the safe and proper care of all patients with diabetes is of the utmost importance. Additionally, the financial reward for safely and appropriately caring for these patients is equally as important for the financial success for the hospital.

Intervention

Project intervention entailed a collaborative multi-disciplinary approach to improve documentation and timing of mealtime insulin administration. The implementation strategy consisted of several phases including pre-implementation, implementation, analysis, and evaluation. The intervention behind a new process surrounding ensuring best practice performing mealtime insulin administration began with the dietary staff.

This new process design begins with the dietary staff flagging the patient specific meal trays and loaded them onto a separate meal cart. Immediately before the meal trays leave the dietary office, the dietary clerk calls the unit clerk on the project unit to make them aware that the meal trays for patients with diabetes are leaving the kitchen. The project unit clerk then uses

the unit intercom system to notify the nursing staff, the meal trays are in route and that they should begin performing fingerstick glucose. When the meal trays arrive to the unit (breakfast, lunch, and dinner) the nursing staff delivers the meal trays to each patient receiving mealtime insulin. The nurse considers the fingerstick glucose performed within the past 30-minutes along with the patient's desire and ability to eat, to calculate a mealtime insulin dose. The multidisciplinary departmental change in practice was successful in narrowing the window of time for which the meal trays arrived on the floor and assisted the nursing staff to better coordinate fingerstick glucose procedures.

The project unit nursing staff also implemented a new documentation process created by this project leader. This new process allows the staff nurse to document the delivery of the meal tray in the patient's EMR. This new intervention captured the time of meal delivery which was critical in evaluating best practice adherence.

With the conceptual framework in place, the interventions were defined and implemented. Project interventions were nurse driven as two of the tasks; fingerstick glucose, mealtime insulin administration are nursing responsibilities. Meal delivery before the project was implemented was the responsibility of the nursing assistants. With the evidence to support the proper timing of mealtime insulin in relation to meal delivery, a practice change was initiated to divorce this task from the role and responsibilities of the nursing assistants and marry it to the professional nurse's role and responsibilities. This new task reassignment allowed for the professional nurse to own all the interventions involved in mealtime insulin administration, allowing for a decrease in the gap or lag time between each task. In addition, using the Johns Hopkins Nursing Evidence-based Practice Model, tools for documentation were developed and implemented into the EMR system for documenting meal delivery. In addition, the staff was able

to connect the education provided during the pre-implementation phase and throughout the project with the daily improvement in the timing of mealtime insulin that was illustrated in the daily reports generated from the EMR displayed each day during morning huddle.

The project interventions, which included meal tray notification and the reassignment of the meal tray delivery proved highly effective in achieving best practice timing between fingerstick glucose, mealtime insulin administration, and meal delivery. To this end, it is recommended to continue this practice change beyond the project period to ensure sustainability of outcomes. Fortunately, nursing leadership and front-line nursing staff were able to appreciate the importance of the interventions and continue to incorporate these best practice recommendations when caring for their patients with diabetes receiving mealtime insulin.

Pre-implementation phase

During the one-week pre-implementation phase this project leader developed a new streamlined collaborative multistep process of mealtime insulin administration. This new process was presented to the project unit nursing and ancillary staff during specific project education sessions throughout the week prior to project implementation. These education sessions took place during morning huddles between 8:45 am and 9:00 am. Handouts describing the project goal, best practice guidelines regarding the timing of mealtime insulin administration, and proposed changes in both practice and meal delivery documentation were reviewed.

Education for the dietary staff was also provided in collaboration with the Dietary Manager one week prior to project implementation and ongoing during the project implementation phase. Education strategy and tools included discussion, handouts, and laminated reminder cards. The education focused on the specific change in practice for the dietary staff.

Implementation phase

Implementing the collaborative, multidiscipline team approach to mealtime insulin administration required a change in the process flow that was implemented over an eight-week period. The project unit nursing staff quickly engaged in the project and their commitment to the project mission was evident in the daily results. Each day the nursing staff would ask pointed questions regarding the project to gain a deeper understanding of the protocol and desired outcomes. The connection between the timing of fingerstick glucose, mealtime insulin administration, and meal delivery gained ongoing appreciation and understanding which was also evident by the nursing staff actions and by the outcome reports. These reports were presented to the project unit nursing staff on a daily basis and the weekly laminated reports were posted on the unit.

Study of Interventions

Before implementation of the intervention, a retrospective chart audit was performed by using specific reports designed to reveal timing of fingerstick glucose and insulin administration. To establish a baseline and benchmark, two random weeks of data was collected and analyzed. A one-week retrospective chart review was conducting during a week of April 2016 and another in August 2016. These two months were specifically selected to eliminate variables related to weather or staffing.

For the month prior to project implementation, daily reports containing fingerstick glucose, mealtime insulin, and meal delivery were collected for the specific study unit. During the study period, documentation of meal delivery was added to the EMR reports. These reports were collected and analyzed daily over the eight-week study period. Final evaluation of the project was conducted by using the rate of recurring hypoglycemic and hyperglycemia before

and after the study.

Measures

Quality improvement studies are very important to the nursing profession. The Six Sigma quality improvement methodology has been selected as the project design method for data collection and analysis. The fundamental objective of the Six Sigma methodology is the implementation of a measurement-based strategy that focuses on process improvement and variation reduction. The Six Sigma design is a disciplined quantitative approach to quality improvement. DMAIC is an acronym for the five phases that make up the QI process: The letters in the acronym DMAIC are as illustrated: Define the problem with a process, measure the defect, analyze causes, improve the process performance to remove the causes, and control the process to make sure defects do not reoccur (Liberatore, 2013). The Six Sigma design is a disciplined, data-driven approach and methodology often used within healthcare facilities for process improvement.

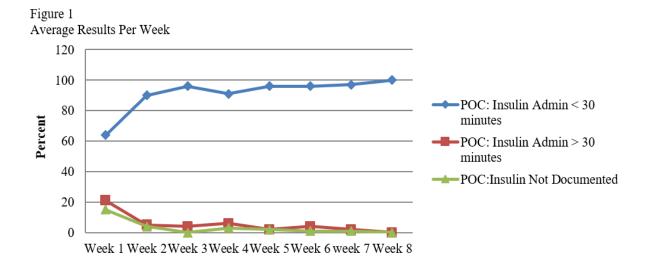
To track and report ongoing project data, a variety of graphs and statistical analysis such as cause-and-effect diagrams (also known as fishbone or Ishikawa diagrams), process mapping, Failure Modes and Effects Analysis (FMEA), and a stakeholders analysis. An excel spread sheet was used to capture the medical unit, timing of fingerstick glucoses, mealtime insulin administration and meal delivery. This report was able to reveal all measured data points such as fingerstick glucose, mealtime insulin, and meal delivery between the hours of 6:00 am and 9:00 pm. This time sequence eliminated the possibility of including bedtime insulin administration which is not applicable to this project. Using the Six Sigma methodology, the root cause of poor timing between fingerstick glucose, mealtime insulin administration, and meal delivery was due to a process issue. The three tasks were divided among three disciplines without a collaborative

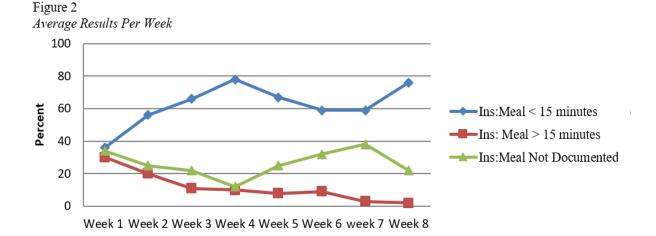
understanding of the role each played in the process. In order to improve the process, these three tasks needed to be "married" and coordinated by one discipline. A Fishbone Diagram, Stakeholders Communication Chart, and Meal Delivery and Mealtime Insulin Administration Observation Table, along with other daily timing reports were used in the Define, Measure, Analyze, Improve, and Control phases. The daily reports captured the timing of fingerstick glucose, mealtime insulin administration, and meal delivery. The project leader reviewed the daily reports with the project unit nurse manager and nursing staff each morning during morning huddle. In addition, these daily reports were reviewed with the nurse preceptor weekly. Furthermore, progress graphs depicting unit progress were displayed on the unit to serve as a visual reminder and motivational strategy for the staff. The goal of using frequent and various teaching methods is to promote collaboration, engagement, and stir the passion for this project. Monthly reports were also shared with the hospital wide Endocrine Disease Committee members, during the regularly scheduled Endocrine Disease Committee meeting which occurs on the first Wednesday of each month from 8:00 am to 9:00 am. As evident by these reports, the Control Phase was achieved by week five showing the process was hardwired into practice and sustainability was achieved.

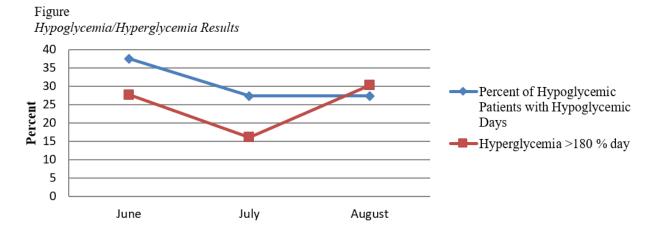
Analysis

Quantitative data was collected and analyzed for this project. The analysis phase of the DMAIC Six Sigma methodology began at the completion of the first day of the project and continued to be a daily process throughout the eight-week project period. Three reports were generated each day; timing of fingerstick glucose, time of mealtime insulin administration, and timing of meal delivery. In order to generate the meal delivery report, the project leader entered each patient chart and recorded the time each meal was delivered. The time between fingerstick

glucose and mealtime insulin administration was then calculated for each patient and each meal. Next, the time between insulin administration and meal delivery was calculated for each patient for each meal. A daily report was then generated combining all patients. Weekly stats were categorized and entered into a table. This table was converted to a bar graph which was laminated and displayed on the project unit. At the completion of the project all data were converted to line graph format to display trends throughout the project period (Figure 1, Figure 2, Figure 3).







To eliminate bias or variations in interpretations, the project leader was the only person to collect the data. All reports were reviewed by the project leader and project team. Weekly reports were reviewed and discussed with the project leader and preceptor. No changes were permitted to be made to any of the reporting processes to eliminate any misrepresentation of numbers, timing gaps, and to ensure the validity of the reports.

Ethical Considerations

Prior to, and throughout the study, all patient data was kept confidential and di-identified in reporting. All study activity was conducted on password protected computers and all data was stored in a locked cabinet in a secure location. The Capella University IRB determined that this project did not meet the federal regulations definition of human subject research and therefore IRB review and oversight was not needed. This hospital IRB committee also determined IRB review and oversight was not necessary.

Results

By the completion of this PI project, 100% of mealtime insulin was administered within the 30-minute best practice recommendation of fingerstick glucose measurement; 76% of patients received their mealtime insulin within the best practice recommended 15-minute window; and 100% of mealtime insulin administration was documented. Secondary outcome

metrics of reducing rates of recurring hypoglycemia by 10% was achieved (78%); however, hyperglycemia, measured as percent of patient days >180 mg/dl, remained unchanged.

Although this performance improvement project was successful in meeting outcome goal, areas for improvement were noted. Anticipated weekly rounds and reporting with the project unit nursing staff was quickly reconfigured to daily rounds due to an unanticipated overwhelming nursing interest, engagement, and request for daily feedback. The use of laminated weekly cards, result graphs, and daily unit meeting huddles were also effective in conveying project outcomes and sustaining nursing and dietary engagement throughout the eight-week project period.

Although the project interventions were effective in achieving the specific aims, one intervention, the call to the unit by the dietary office staff in advance of meal tray delivery was identified as an unsustainable intervention. After a collaborative multidisciplinary meeting with project stakeholders, it was determined the best alternative to this intervention was to assign each medical floor a specific 30-minute window for meal delivery. This alternative intervention will allow for consistency in meal delivery, eliminate a task from the dietary office staff, and is an intervention appropriate and reasonable to scale hospital wide. All stakeholders have agreed to the implementation of this new strategy for meal delivery. Project sustainability is critical to maintaining these outcome measures and will involve continued support from administration and key stakeholders such as nursing leadership, nursing staff, and dietary personnel.

To measure the effectiveness of this new meal delivery process additional study would be recommended. Currently, the second phase of this performance improvement project has begun with this revised meal service delivery intervention. A mix-study using scheduled meal times has been implemented. The study is presently in the preimplementation phase, which includes meetings with new stakeholders (nurse managers) and Chief Nursing Officer. Actual project

implementation is anticipated for January 8th, 2018 on three additional medical units. A comparison of project outcomes will be reviewed and reported to administration. Based on these findings, the best process to fully support the best practice for mealtime insulin administration will be determined and implemented house wide.

Summary

Key findings indicate that a multidisciplinary approach to mealtime insulin administration can positively impact hypoglycemia rates in the inpatient setting. Considering the many variables that affect hypo- and hyperglycemia, this project proved that implementing processes that support and enable nursing staff to measure fingerstick glucose monitoring, administer mealtime insulin, and delivery meals within the AACE and ADA's best practice recommendation of <30 minutes between fingerstick glucose and mealtime insulin administration and <15 minutes between insulin administration and meal delivery for patients with diabetes. The findings or this project proved food delivery notification enabled the nursing staff to efficiently administer mealtime insulin in coordination with point of care fingerstick blood glucose monitoring and the delivery of meals. 100% of point of care fingerstick blood glucose monitoring was administered within the best practice window of 30 minutes, 100% of mealtime insulin administration was documented, and 76% of patients received mealtime insulin within the recommended 15-minute window. Secondary outcome metrics of reducing rates of hypo/hyperglycemia by 10% was achieved for recurring hypoglycemia; however, hyperglycemia rates remained unchanged.

Interpretation

The association between the project interventions, administering mealtime insulin within the best practice time frame, and project outcomes are directly related. Although there are many variables that impact inpatient glycemic control, accurate and timely mealtime insulin administration is a critical piece in the puzzle of inpatient diabetes management. Unlike in patients without diabetes, blood glucose levels for a patient with diabetes may vary from minute to minute. In order to safely and accurately administer the correct dose of insulin, the nurse must have a timely and accurate blood glucose level. The American Diabetes Association (2017) included in the Standards of Medical Care in Diabetes-2017 that fingerstick glucose should be performed before each meal and within a recommended 30-minute window.

Similar studies, projects, and articles examining the timing between fingerstick glucose, mealtime insulin administration, and meal delivery in their relationship to hypo- and hyperglycemia have been included in this manuscript. Most resulted in similar positive patient care outcomes. These studies also corroborated the importance of improved timing on patient satisfaction, glycemic variability, patient safety, and financial impact on the organization.

Limitations

Poor timing between fingerstick glucose, mealtime insulin administration, and meal delivery are common variables that impact overall glycemic management (Engle et al., 2016). Correcting just these specific variables alone many not have quite the effect on total hypo/hyperglycemia rates as anticipated or desired. The many causes of both hypo- and hyperglycemia each can impact the rate of hypo- and hyperglycemia in different ways and degree of impact which is a limitation of this performance improvement project. All stakeholders were aware of the project variables and were supportive of any positive change resulting from the project interventions. At the very least, achieving best practice in regard to the timing of mealtime insulin administration, regardless of the effect on hypo/hyperglycemia rates over eight

weeks, would have been considered a successful project outcome by this project leader and hospital administration.

Inconsistent dietary staff was also noted as a project limitation. Although the dietary manager was fully onboard and supportive of the project, the dedicated staff was not.

Inconsistent staff resulted in the need for multiple in-services to ensure each new staff member was aware of the project, process, and goals. Furthermore, the limitation of dedicated and consistent dietary staff also as an effect on project sustainability, specifically the ability to scale this project beyond the project period throughout the hospital. The dietary staff call to the unit clerk when the trays were leaving the kitchen was determined unsustainable once the project expanded to other medical units throughout the hospital. To adjust for this limitation, it has been decided that each floor will be assigned a permanent 30- minute meal delivery time, therefore eliminating the need for a manual call to each floor. The administrative staff and nursing staff for each unit will have their assigned meal delivery time, allowing appropriate scheduling fingerstick glucose, breaks, and other patient care tasks. This will allow for continued positive outcomes in meeting best practice associated with mealtime insulin administration without added resources or responsibilities on the part of the dietary staff.

The project sample includes all patients with diabetes receiving mealtime insulin on one medical floor of this project leader's hospital. A sample size of approximately nine patients, receiving three meals a day, is anticipated. This small cohort may be considered a limitation to this project; however, the information can be translated house wide.

Conclusion

The success of this project improvement can be attributed to a multidisciplinary collaborative approach to mealtime insulin administration. The use of staff education regarding

HOSPITAL ACQUIRED HYPO/HYPERGLYCEMIA

best practice in regard to timing of fingerstick glucoses, mealtime insulin administration, and meal tray delivery, establishing and organizational support of a new process for meal notification and meal delivery, proved to improve and sustain timing between these three tasks and reduce unit rates of recurring hypoglycemia. Rates of hyperglycemia were unchanged over the eightweek project period. The overall project was very well received by this hospital administration and is in the second phase of a mix study to expand the project throughout all medical units.

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