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Improving the Transition from Intravenous to Subcutaneous Insulin

in Critically Ill Hospitalized Patients

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Abstract

Many critically ill patients experience hyperglycemia as a result of physiological stress or as a consequence of diabetes mellitus. Once the condition of the critically ill hospitalized patient has stabilized, it is imperative to transition this patient from intravenous to subcutaneous insulin. The American Association for Clinical Endocrinologists, the American College of Endocrinologists and the American Diabetes Association have all provided guidelines for this transition process.

A quality improvement project was conducted by a team of Clinical Nurse Leader (CNL) students from the University of San Francisco at a metropolitan medical center in California. The team created and implemented an evidence-based protocol for transitioning hospitalized patients from intravenous to subcutaneous insulin. Due to time limitations and the vast scope of the project, the team was unable to fully implement the protocol. The team did conduct a microsystem assessment, root cause analysis, and literature review, and authored a final draft of the evidence-based transition protocol. Future CNL cohorts will engage in full implementation and evaluation of the protocol, which will include staff education and training, integration into the electronic health record and data collection regarding the protocol's effectiveness.

Keywords: intravenous to subcutaneous insulin transition, transition protocol

Improving the Transition from Intravenous to Subcutaneous Insulin

in Critically Ill Hospitalized Patients

Our team of five CNL students from the University of San Francisco engaged in a quality improvement project at a 250-bed acute care hospital facility in metropolitan California (henceforth referred to as "the Hospital"). The goal of the project was to safely and efficiently transition patients from intravenous (IV) to subcutaneous (SQ) insulin using a standard protocol. The project was assigned to our team by the Diabetes Educator Team at the Hospital in response to excess nursing effort and recent safety events that occurred as a result of the current Hospital practices.

Of particular concern to the Hospital was the control of hyperglycemia for all patients, and specifically for patients transitioning to subcutaneous insulin. The importance of aggressive glycemic control has been well documented in the literature. The 2001 landmark randomized controlled study by Van den Berghe and colleagues changed the way the medical community addresses hyperglycemia in critical illness (Van den Berghe et al., 2001). This study found that maintaining blood glucose between 80 and 110 mg/dL, when compared to the conventional wisdom of the time that called for blood glucose levels between 180 - 200 mg/dL, could significantly decrease morbidity and mortality (Van den Berghe et al., 2001). Over a 12 month period using the lowered blood glucose goal range, the researchers were able to decrease mortality during intensive care from 8% to 4.6%, with the most significant reductions occurring in the number of deaths from multiple organ failure with sepsis (Van den Berghe et al., 2001, p. 1364). Since the advent of this research, the medical community has placed great emphasis on maintaining aggressive glycemic control in the inpatient setting.

Protocols in particular have been found to be effective at controlling hyperglycemia, especially during the IV to SQ transition. One retrospective study in a large community hospital compared the use of an IV to SQ insulin transition protocol to the transition process without the use of a protocol. (Jacobson, Jerguson, Spiva & Fraser, 2012). The study found that following a standardized protocol significantly improved glycemic control, with fewer hyperglycemic events, less use of correctional sliding scale insulin, and no significant increase in the number of hypoglycemic events (Jacobson et al., 2012, p. 49). It is key to initiate the transition process from IV to SQ insulin as soon as patients are stable; this is especially important for those who are ready to start eating, as patients receiving oral intake while on IV insulin infusions have a significantly increased rate of hyperglycemic and hypoglycemic events (Smiley, et al., 2010).

Thus, at the request of the Lead Diabetes Educator, and in accordance with the above considerations, our team began the process of investigating the microsystem and the literature in order to develop an effective IV to SQ transition protocol.

Methods & Need

The Microsystem

The microsystem on which this quality improvement project took place is a Cardiovascular Progressive Care unit (CVPCU) at the Hospital. The purpose of the unit is to provide cost effective, high quality, and safe care while bridging the gap between the Cardiovascular Intensive Care unit (CVICU) and a Medical-Surgical/Telemetry unit (Stacy, 2011).

Patients on the unit are recovering from cardiovascular surgeries or events, including thoracic or esophageal surgeries, the placement of carotid stents, transcatheter aortic valve

replacements, and other cardiovascular procedures (Hospital, 2018). These patients require telemetry monitoring, vasoactive and antiarrythmic agents, and may require epicardial or transcutaneous cardiac pacing (Hospital, 2018). These patients have been transferred out of the CVICU as they stabilize, but still require more surveillance and nursing care than is provided on a Medical-Surgical unit. The unit has 22 patient beds.

The professionals of significance for this project are, first, the nurses. Nurses on the CVPCU require greater training and experience than a nurse on a Medical-Surgical unit. Nurses must have acute care experience and be skilled at caring for post-operative patients. Nurses must be certified at telemetry monitoring and management, and in Advanced Cardiac Life Support (ACLS) by the American Heart Association (Hospital, 2018). As the CVPCU is a progressive care unit in California, nurses have a maximum nurse-to-patient ratio of 1:3, compared to a telemetry unit nurse-to-patient ratio of 1:4, or a Medical-Surgical unit nurse-to-patient ratio of 1:5. (Kasprak, 2004).

Other professionals on the unit include physicians (MDs) and physician's assistants (PAs) who place the orders for patient care and medication management. Additionally, the unit hosts certified nursing assistants (CNAs), case managers, speech & physical therapists, respiratory therapists, nutritionists, social workers, and palliative care specialists.

The final group of professionals that operates on the mesosystem that includes this microsystem is the Diabetes Educator Team. The Diabetes Educator Team is staffed by 2.5 full time equivalent (FTE) registered nurses (RNs) and nurse practitioners (NPs) with specialized diabetes training. The Diabetes Educator Team provides patient teaching, training for health care professionals related to the disease, and consultations for providers regarding plans of care,

including the transition from IV to SQ insulin. Thus the Diabetes Educator Team has a wide and varied job description that encompasses the care of a large number of patients both in and out of this microsystem.

The process of particular note on this unit is the transition from IV insulin infusion to SQ insulin. Most patients on the CVICU receive intravenous insulin post-operatively to combat stress hyperglycemia. Some of these patients are diabetic at admission, and may require SQ insulin or oral hypoglycemics upon discharge. Regardless of diabetic status at admission, any patient on IV insulin must be transitioned off of IV insulin before discharge. This transition process is the focus of my analysis and of our team's quality improvement project on the microsystem.

This process of transitioning patients from IV to SQ insulin was brought to our attention by the Lead Diabetes Educator at the Hospital. Currently the Hospital does not have a standardized protocol for transitioning patients from one route of insulin to the other. Instead, providers who wish to transition their patients from IV to SQ insulin first call the Diabetes Educator Team and receive a consult with one of the educators (Lead Diabetes Educator, Personal Communication, February 13, 2018).

The pattern that has been brought to the attention of our team is the range of order sets used when transitioning patients from IV to SQ insulin. Though the current process includes consulting with the Diabetes Educator Team, this does not always occur. Often, each provider (MD or PA) determines whether to initiate a consultation or to place the order independently. This has led to significant variance in treatment, and to sentinel events that have compromised patient safety. Though this quality improvement project will be most applicable to the microsystem of the CVPCU, which hosts the bulk of patients receiving IV insulin infusions who are ready to transition to SQ insulin, the final result of the project will be a standardized transition protocol to use for all patients moving from IV to SQ insulin. This protocol will be used across the Hospital and throughout the Hospital system. Because of the desire for a Hospital-wide standardized protocol, implementation and evaluation will take place on the microsystem, in other units, and at another hospital.

The Need

The current practices of the microsystem regarding the IV to SQ insulin transition are messy and unstandardized. Three primary causes for the disarray were discovered in an initial root cause analysis (RCA) completed by our team. They include an unsustainable case load for the Diabetes Educator Team, two recent sentinel events that indicate compromised patient safety, and excess nursing effort required to engage in current Hospital practices.

Case load. In 2015, the Hospital had approximately 10,500 inpatient admissions (OSHPD, 2015). The Lead Diabetes Educator stated anecdotally that 50% percent of admitted patients have an underlying diagnosis of diabetes (Lead Diabetes Educator, Personal Communication, January 29, 2018). This places approximately 5,000 patient encounters under the purview of the Diabetes Educator Team. Though not all of these patients will require a consult with a diabetes educator regarding the transition from IV to SQ insulin, these numbers demonstrate the overwhelming case load of the Diabetes Educator Team. This case load is especially substantial as the Diabetes Educator Team is only staffed by 2.5 FTE.

Recent data specific to the microsystem also indicate the considerable case load carried by the diabetes educators. One report generated by the Program Manager of Medication Safety in the Pharmacy department of the Hospital indicated that 34 patients in the CVPCU received intravenous insulin in the month of January (see Appendix A). These 34 patients are only a subset of the total number of patients who would require a consultation with the Diabetes Educator Team to transition from IV to SQ insulin before discharge. Additionally, consulting on the IV to SQ transition is only one of many duties that must be fulfilled by the diabetes educators. For these reasons, the current process used to transition patients from IV to SQ insulin is unsustainable and unrealistic for the sparsely staffed Diabetes Educator Team. The process must be standardized to reduce the workload of the diabetes educators and to prevent potential patient safety events.

Sentinel events. Two sentinel events (see Appendix B for details) occurred in the second half of 2017 and prompted the Diabetes Educator Team to seek the establishment of a transition protocol in order to improve patient safety and quality of care. The Joint Commission defines a sentinel event as "a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in any of the following: [d]eath, [p]ermanent harm, [s]evere temporary harm," (The Joint Commission, 2017). In these two instances the sentinel event was the same: severe temporary harm due to hospital-acquired diabetic ketoacidosis (DKA), caused by ending the infusion of intravenous insulin without first safely transitioning the patients to subcutaneous basal insulin. Not only are these events sentinel events, but they are also hospital-acquired conditions, and are therefore not reimbursed by the Centers for Medicare and Medicaid Services (CMS, 2008).

In each sentinel event, the patient had an underlying diagnosis of diabetes mellitus type I (DM I). One patient was undergoing a surgical procedure and was placed on an IV insulin infusion before surgery that continued into the postoperative period. The second patient came to the emergency department with a malfunctioning insulin pump and hyperglycemia without ketoacidosis, and was placed on an IV insulin infusion. Both patients were removed from the IV insulin infusion during their treatment. In both cases the IV insulin infusion was not reinitiated; nor was SQ basal insulin given to manage their underlying DM I. Both patients developed hospital-acquired DKA as a direct result of the removal of the IV insulin infusion without appropriate replacement with SQ basal insulin. (See Appendix B for details about each of these sentinel events).

There are a multitude of factors that contributed to these sentinel events. However, in each case, insulin (in IV or appropriate SQ form) was not reinitiated in a timely manner, leading to hyperglycemia and DKA. In each event the Diabetes Educator Team was not called to assist with the transition to SQ insulin after the patient was removed from IV insulin. In each event providers failed to appropriately transition the patients. In order to prevent another sentinel event or patient safety event, the Diabetes Educator Team has tasked our team with developing an evidence-based protocol to safely transition any patient receiving an IV insulin infusion to SQ insulin.

Current hospital insulin orders and nursing effort. The Hospital has three intravenous insulin infusion order sets that can be used for patients requiring IV insulin: a critical care order set, a medical/surgical order set, and a cardiac surgery order set. The differences between each order set are minimal, and are found primarily in differing blood glucose goal ranges and slight

differences in hourly infusion rates. Because the microsystem in question is the CVPCU, I will focus my attention on the cardiac surgery IV insulin infusion order set (detailed in Appendix C).

The cardiac surgery IV insulin infusion order set demonstrates the significant amount of nursing effort that is required to maintain and monitor IV insulin infusions. Blood glucose must be measured every hour while the measurement is greater than 150 mg/dL; this state can persist for a number of days post surgery, due to stress hyperglycemia and/or a prior diagnosis of diabetes (Furnary & Braithwaite, 2006). Once a patient measures within blood glucose goal range (110 - 150 mg/dL), the blood glucose must still be measured every two hours while the patient remains on an IV insulin infusion. Not only are frequent blood glucose measurements required, but at each measurement the nurse must determine if the rate of infusion needs to be adjusted, and she must determine the patient's insulin sensitivity. Though adjustments to the infusion rate are relatively straightforward, determining insulin sensitivity involves calculating percentages and performing mathematical computations, which adds to the time required. Thus, with hourly to bi-hourly blood glucose measurements and infusion rate calculations and adjustments, IV insulin management takes significant nursing time. Additionally, CVPCU nurse can be assigned up to three patients at a time, so this effort can be doubled or tripled.

In order to determine the average nursing time spent monitoring IV insulin infusions, our team intended to meet with the CVPCU unit council. We hoped to collect data and gain insight, as well as receive permission to do a time-in-motion observation of CVPCU nurses caring for patients with IV insulin infusions. However, after multiple inquiries through multiple points of contact, the unit council chair did not respond to our requests, and we were unable to pursue this avenue of inquiry.

Though we were unable to collect our own data related to the nursing effort needed to continually monitor blood glucose and IV insulin infusions, one study of a level I trauma center in the Southeastern United States collected such data (Aragon, 2006). The study was conducted across 58 beds and focused primarily on intensive care units and areas for recovery from open heart surgery (Aragon, 2006, p. 372). 21 nurse observations, using a time-in-motion design, were conducted to measure the amount of time required to measure blood glucose levels and adjust IV insulin doses according to facility standards (Aragon, 2006, p. 374). The nursing time needed ranged from 3 minutes, 22 seconds to 8 minutes, 53 seconds, with an average of 4 minutes, 43 seconds (Aragon, 2006, p. 374). Aragon (2006) states that:

Some of the longer times involved finding blood glucose monitors, troubleshooting the monitoring device, and obtaining measurements in patients with isolation precautions. In some of the shorter times, some of the potential steps were omitted, such as hand hygiene or wearing gloves, and other shortcuts were taken (p. 374)

Aragon's research (2006) serves as an estimate of the amount of nursing time spent monitoring blood glucose and adjusting IV insulin infusions. Other research paints a similar picture, with the complete insulin management process - point of care glucose testing with a glucometer, documenting the blood glucose measurement, and adjusting the insulin infusion - taking up to 10 minutes out of every hour (Goldberg & Inzucchi, 2005, p. 29). With this evidence in mind, I estimate that IV insulin management could require one to two hours of nursing effort per patient over the course of a 12 hour nursing shift on the CVPCU.

In contrast, the Hospital subcutaneous order set, though more complicated in appearance, is much simpler in practice than the IV insulin infusion (see Appendix D for a sample order set).

IV TO SQ TRANSITION

Blood glucose monitoring is done, at maximum, five times in a 24-hour period (before each meal, at bedtime, and at 0200). Basal insulin is given once or twice per day (at bedtime or at breakfast and bedtime), and bolus insulin is given before meals and, if needed, at bedtime and at 0200. With this regimen, blood glucose monitoring and administration is much simpler, and thus requires less nursing time to implement. Therefore, with a safe and effective transition protocol from IV to SQ insulin, the nursing effort required to monitor and administer insulin would decrease; patient insulin monitoring would be decreased from a maximum of 24 times in a 24 hour period to five times in a 24 hour period.

Each of these factors - the Diabetes Educator Team case load, the recent sentinel events, and the nursing time requirements - contribute to the urgency with which this project was initiated. The development of a IV to SQ insulin transition protocol will be key in promoting patient safety and reducing the nursing effort and Diabetes Educator time needed for effective inpatient glycemic management.

Results & Protocol

In response to the need for an IV to SQ insulin transition protocol, our team completed an in-depth literature review to determine best practice on the subject. Searches were completed through PubMed, a database hosted by the National Center for Biotechnology Institute and the U.S. National Library of Medicine, and CINAHL, the Cumulative Index of Nursing and Allied Health Literature. Searches were conducted primarily in February of 2018, with additional searches as the project progressed.

Expert Recommendations

I first researched the current recommendations from the experts in the field of diabetes: the American Association of Clinical Endocrinologists (AACE), the American College of Endocrinology (ACE), and the American Diabetes Association (ADA). Three publications of note provided a basis on which to build our protocol.

First, the 2015 collection of clinical practice guidelines for the management of diabetes mellitus (DM), compiled and published by the AACE and ACE gave the backdrop for why tight glycemic management is key in an inpatient setting, stating, "[i]t is well established that hyperglycemia in patients with or without a prior diagnosis of DM increases both mortality and disease-specific morbidity in hospitalized patients" (Handelsman et. al., 2015, p. 49). In this publication the AACE and ACE also establish that scheduled SQ insulin regimens that combine basal and bolus dosing are recommended, while discouraging the use of sliding scale insulin as the sole method of glycemic control (Handelsman et. al., 2015, p. 50).

This same publication indicated that any transition from IV to SQ insulin should ideally occur when the patient has a stable infusion rate, and blood glucose levels within the appropriate goal range (Handelsman et al., 2015, p. 50). The guidelines do not indicate how long an infusion rate should remain stable before beginning the transition.

The 2015 AACE and ACE guidelines (Handelsman et al.) also recommend the appropriate percentage of IV insulin that should be given as SQ insulin, stating, "[s]everal studies recommended starting at a daily insulin dose ~80% of the intravenous insulin used in the preceding 12 to 24 hours and splitting it into basal and bolus insulin." (p. 50) This recommendation is supported by an earlier consensus statement from the AACE and the ADA on

inpatient glycemic control, which indicated that 75 - 80% of the total daily IV insulin infusion dose should be proportionately divided into basal and bolus doses of SQ insulin (Moghissi et al., 2009, p. 1123). This statement is also supported by an earlier publication from the ACE Inpatient Diabetes and Metabolic Control Consensus Conference of 2004, which stated that the correct SQ insulin dose can be determined by taking 80% of the amount of IV insulin given over the past 24 hours (Bode, Braithwaite, Steed & Davidson, 2004, p.75). Bode and colleagues also endorsed using the 80% conversion factor for patients receiving all types of intake, including minimal oral intake, normal oral intake, and minimal IV dextrose, defined as less than or equal to 125 ml/hr of 5% dextrose (D5W) (Bode et al., 2004, p. 50).

The 2015 clinical guidelines also account for patients who may not require transitioning from IV to SQ insulin. Specifically, "[n]ondiabetic patients with stress or newly diagnosed hyperglycemia who have required an insulin rate ≤ 1 to 2 units/hour at the time of transition may not require a scheduled subcutaneous insulin regimen" (Handelsman et al., 2015, p.50). Instead, these patients can be treated with correctional sliding scale insulin until their stress hyperglycemia has resolved.

Finally, the 2009 consensus statement from the AACE and the ADA emphasized that SQ insulin must be given one to four hours before discontinuing the IV insulin infusion in order to prevent hyperglycemia (Moghissi et al., 2009, p. 1123).

Each of these components - that patients be at a stable infusion rate, that ~80% of daily IV insulin be given as SQ insulin, that SQ insulin be given in basal/bolus dosing, that certain patients may not require basal insulin, and that the first dose of SQ insulin must be initiated at

least one hour before discontinuing the IV infusion - were integrated into our protocol. These guidelines also formed the backbone of many of the other protocols I found in my research.

Additional Research

Though the AACE, ACE and ADA provided general guidelines for the transition process from IV to SQ insulin, their recommendations did not provide sufficient specifics out of which to develop a complete transition protocol. Further research was required to determine best practices that arose out of relevant studies in healthcare settings similar to the Hospital.

First, I aimed to discover the best SQ insulin regimen to use once patients are removed from IV insulin. Numerous studies have been done to determine the insulin analog that best mimics the body's interprandial (basal) production of insulin in patients without diabetes; the two best candidates are insulin glargine and insulin detemir (Poon & King, 2010). Both detemir and glargine have a peakless duration of action of 23 and 24 hours, respectively (Poon & King, 2010, p. 217). Glargine is best prescribed as a once daily dose, while detemir is most effective with twice daily use (Poon & King, 2010, p. 217).

Though glargine and detemir best mimic the body's production of interprandial insulin, there are some specific clinical situations in which using natural protamine Hagedorn (NPH) insulin is appropriate. The pharmacokinetics of NPH closely mimic the effects of steroids on glucose in the body, and so NPH could be useful in patients who are receiving glucocorticoid therapy (Krieder & Lien, 2015, p. 5). However, as our protocol is to be a general guideline for providers in a number of patient scenarios, we chose to promote glargine and detemir, leaving the administration of NPH to the discretion of the provider. Next, I aimed to clarify the AACE and ADA consensus that basal insulin should be given between one and four hours before the termination of the IV insulin infusion (Moghissi et al., 2009, p. 1123). In fact, detemir has been found to have an onset of action of one hour (Goldman-Levine & Lee, 2005, p.503). Glargine has been found to have an onset of action of 1.5 hours, with the metabolic activity of glargine reaching a plateau between three and four hours (Lepore et al., 2000; Poon & King, 2010.) Therefore, to prevent hyperglycemia and to achieve the full onset of action of the insulin analogs, glargine or detemir should be given at least two hours before the discontinuation of the IV insulin infusion.

I also wanted to address the question of weight-based dosing in the IV to SQ insulin transition, posed to us by the Lead Diabetes Educator (personal communication, January 30, 2018). The Hospital initially began the process of developing an IV to SQ insulin transition in 2013, but its progress was halted by a number of factors, including a system-wide transition to a new electronic medical record (Lead Diabetes Educator, personal communication, January 30, 2018). This initial protocol used patient weight as factor in determining the total daily SQ dose after transition. This was once a common method of calculating transitional SQ insulin doses that has since been replaced by determining SQ doses from prior IV insulin infusion rates (Clement et al., 2004; Leahy, 2006).

More recent research has found that weight-based dosing of SQ insulin is less aggressive and less effective than a calculation that determines the SQ dosage from the IV insulin infusion rates prior to the transition. One academic medical institution described by Ramos and colleagues (2010) developed a protocol that transitioned patients to an SQ dose of 80% of their daily IV insulin infusion. This institution compared the total daily SQ dose of insulin based on (a) the protocol, (b) individual provider preference (non-protocol dosing), and (c) patient weight (Ramos et al., 2010). The protocol-based dosing provided the most aggressive and effective glycemic management, with weight-based dosing and non-protocol dosing being much less aggressive and less effective; while hypoglycemia occurred at the same rate regardless of SQ dosing practice, hyperglycemia occurred much less often when the protocol was followed, and much more often when less aggressive SQ doses were given (Ramos et al., 2010, p. 450). This study, and further recommendations from the AACE, ACE and ADA, all demonstrate that the most effective way to determine the total daily SQ dose of insulin when transitioning from an IV infusion is not by using weight, but by using the historical IV insulin infusion rates (Handelsman et. al., 2015; Moghissi et al., 2009).

Evidence-Based Protocols

With the recommendations of the AACE, ACE and ADA, and my further research, I began to look for protocols that had the following features:

- Patients are at a stable IV insulin infusion rate before transition.
- Most patients receive SQ insulin with basal/bolus administration.
- Glargine or detemir is used as the basal insulin analog.
- Basal insulin is given at least one hour before the discontinuation of IV insulin.
- SQ basal insulin dosing is determined by IV insulin rates, not by weight.

The results of my literature search for protocols that have these features are summarized in Table 1.

Table 1

Summary of IV to SQ Protocols

Protocol Setting	Date ^a	Authors	Patient Features	IV Dose Calculat ion	Timing of Basal ^b	% IV Given as Basal	Other Features
University of Wisconsin (UW) Health System	2017	UW Hospitals and Clinic Authority	IV infusion ≥ 24 hours, controlled blood glucose; no high dose steroids or TPN	Average; past 8 hours	4 hours prior	*Full nutrition: 40% (+ 40% prandial) Minimal nutrition: 80%	If no history of DM & IV < 1 unit/hr: sliding scale only
Local teaching and research hospital	2015	Diabetes Manage ment Specialist	Most patients (including resolving DKA); no post- cardiovascular surgery	Last hour's rate	2 hours prior	*40% (+ 40% prandial)	Prandial is premeal or based on carbohydrate intake
Ohio State Medical Center	2015	Dungan, Hall, Schuster & Osei	48 hours post- cardiothoracic surgery; off pressors and stable	Average; past 8 hours	4 hours prior	Randomized to 50%, 65%, 80%. Titrated daily (+ prandial)	Found 50% to be best. Prandial: based on carbohydrate intake
University of Pittsburgh Medical Center (UPMC)	2010	UPMC	Most patients except patient without history of DM and <2 units/ hour IV insulin	Average; past 8 hours	4 hours prior	*35% (+ 35% prandial; hold if NPO)	If first dose basal and prandial are given together, discontinue IV after 1 hour
University of California, San Diego	2010	Ramos et al.	Diagnosis of DM or A1c \ge 6; in medical, cardiovascular or surgical ICU	Average; past 6 hours	2 hours prior	*Full nutrition: 40% (+ 40% prandial) Minimal nutrition: 80%	Compared to patients transitioned without protocol (at providers' discretion)
Cleveland Clinic	2009	Olansky et al.	Post-operative cardiac patients in Cardiovascular ICU	Average; past 8 hours	2 hours prior	50% (+50% sliding scale or prandial)	Most patients were not eating at transition, received sliding scale and not prandial insulin
Northwestern Memorial Hospital	2006	Scmeltz et al.	In cardiovascular or surgical ICU	Average; past 6 hours	2 hours prior	Randomized to 40%, 60%, 80%. (+ prandial)	Found 80% to be best. Prandial: at provider discretion

Notes: *These protocols employ a 'conversion safety factor' of 70-80% to convert IV to SQ insulin dosages; the resulting SQ dose is then divided into basal and prandial doses. ^aDate of publication or revision. ^b Hours prior to discontinuation of IV insulin.

Specific protocol features. As demonstrated by the protocols summarized in Table 1, the

literature shows varied protocols that have been effective in different settings. Though each

protocol differs slightly in its patient population, calculation of SQ insulin, timing of the first SQ

dose, and the percentage of insulin given as basal, there are some themes that arise from these

protocols.

First, all protocols except one calculate the daily IV insulin dosage by taking the average rate over the past six to eight hours. This was done with the understanding that the patient should be relatively stable, as recommended by the AACE and ACE, and is used as an estimate of effective glycemic control (Handelsman et al., 2015, p. 50; Schmeltz et al., 2006, p. 642). Our protocol (described in detail in Appendix E) employs a six hour average based on these results.

Second, all protocols gave the first dose of SQ basal insulin two to four hours before discontinuing the IV insulin infusion. This narrows down the window suggested by the AACE and ADA, and takes into account the time of onset for both glargine and detemir (Goldman-Levine & Lee, 2005; Moghissi et al., 2009; Poon & King, 2010). Our protocol (Appendix E) suggests giving basal insulin a minimum of two hours before discontinuing the IV insulin infusion based on these results.

Third, all but one protocol found the safest and most effective basal dose to be between 35% and 50% of the prior IV insulin daily dosage. These results bolster the recommendations of the AACE, ACE and ADA that propose ~80% of the daily IV insulin dose be split equally into basal and bolus insulin, meaning 40% as basal insulin and 40% as prandial or sliding scale insulin (Handelsman et al., 2015; Moghissi et al., 2009). Dungan and colleagues (2011), Ramos and colleagues (2010), and Olansky and colleagues (2009) all report better glycemic control, fewer cases of hyperglycemia, and minimals cases of hypoglycemia when compared with other dosages of basal. The one exception to this theme was published by Schmeltz and colleagues (2006); though randomized, their sample was small (75 patients), and the study was published 12 years ago. Thus, our team used the better supported and more recent findings of the 35 - 50% range to develop our protocol (Appendix E).

Fourth, four of the seven protocols used a 'conversion safety factor' to calculate the total SQ insulin dose, and then divided that result evenly into basal and bolus insulin. This also follows the recommendation of the AACE, ACE, and ADA, and leads to better clarity and readability when publishing a protocol (Handelsman et al., 2015; Moghissi et al., 2009). We did the same in the development of our protocol (Appendix E).

Features of the patient population. Each of the protocols found in our research was used in specific patient populations. The results of these protocols, as well as evidence from other studies, provided guidance to our team as we determined which patients in the Hospital could safely transition with this IV to SQ protocol.

First, protocols like the one used at the Cleveland Clinic were effective in diabetic and non-diabetic patients alike. 77% of the patients studied in this prospective, non-interventional study were not diabetic, and only one patient of 99 developed mild hypoglycemia (Olansky et al., 2009, p. 481). Likewise, levels of insulin resistance between patients with and without a prior diagnosis of diabetes mellitus were similar in the immediate cardiothoracic postoperative period (Liao et al., 2008, p. 232). This indicates that patients with and without diabetes prior to a surgical event require similar amounts of insulin postoperatively, and can be treated using the same IV to SQ transition protocol (Liao et al., 2008, p. 232).

Second, six of the seven protocols included patients who were recovering from cardiovascular surgeries. In each of these protocols there was no difference in outcomes for patients with or without recent cardiovascular events (Dungan et al., 2011; Olansky et al., 2009; Ramos et al., 2010). These results indicate that the protocol can be applied to patients with or without cardiovascular events or diagnoses. This is significant for the Hospital, as many of the patients requiring a transition from IV to SQ insulin will be post-cardiovascular surgery and receiving care in the CVPCU.

Third, the Diabetes Educator Team at the Hospital was especially concerned about the use of this protocol in patients with diabetic ketoacidosis (Lead Diabetes Educator, personal communication, February 13, 2018). However, the research demonstrates that if the patient is receiving a moderate amount of dextrose (≤ 125 ml/hr), the transition to SQ insulin can still be accomplished using the same protocol (Bode et al., 2004, p. 75). D5W in doses of ≤ 125 ml/hr is the common dosage a patient in the Hospital with resolving DKA would receive at the point of transition from IV to SQ insulin (Lead Diabetes Educator, personal communication, February 21, 2018). Hence, our protocol can be also be used with patients whose DKA is resolving.

Fourth, the use of pressors while in the ICU and before the transition from IV to SQ insulin did not have an impact on the SQ dose of insulin given at the transition, nor did they predispose the patient to a higher risk of hyperglycemia (Olansky et al., 2009, p. 482). This again widens the patient population and allows the protocol to be used in most clinical scenarios.

These findings suggest that the protocol we have developed for the Hospital (Appendix E) can be used for a wide patient population, including patients who do not have DM, patients post-cardiovascular surgery, patients with resolving DKA, and patients who received pressors prior to the IV to SQ transition.

The Protocol for the Hospital

The final protocol we developed for the Hospital compiles the best practices from the evidence, while incorporating the current practices of the Hospital. The full protocol can be found in Appendix E. A flowchart representing the protocol is presented in Figure 1.

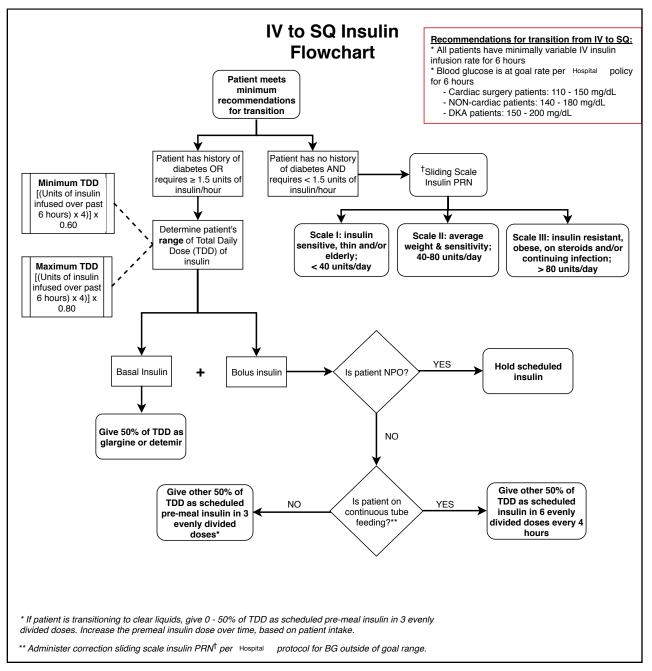


Figure 1. A flowchart of the IV to SQ transition protocol developed for the Hospital.

Key features of the protocol include the following:

• All hospitalized patients can be transitioned with this protocol, including patients post-

cardiovascular surgery or with resolving DKA (Bode et al., 2004; Dungan et al., 2011;

Olansky et al., 2009; Ramos et al., 2010);

- Patients' blood glucose measurements prior to the transition should be within the blood glucose goal rates relevant to their condition (per Hospital policy);
- Patients' IV insulin infusions should have minimally variable rates for the preceding six hours (Handelsman et al., 2015);
- Patients with no history of DM and with minimal IV insulin requirements do not require basal insulin (Handelsman et al., 2015);
- The total daily dose of SQ insulin is calculated by extrapolating the 24 hour IV insulin requirement from the past 6 hours of IV insulin (Ramos et al., 2010; Schmeltz et al., 2006);
- The conversion safety factor to calculate the daily SQ dosage from the daily IV dosage ranges from 60 80% (Handelsman et al., 2015; Moghissi et al., 2009);
- The SQ insulin is split evenly between basal and bolus insulin (Handelsman et al., 2015; Moghissi et al., 2009);
- Basal insulin must be given at least two hours before discontinuing the IV insulin infusion (Goldman-Levine & Lee, 2005; Moghissi et al., 2009; Poon & King, 2010);
- Glargine or detemir are the basal insulin analogs of choice (Poon & King, 2010);
- Dosing of prandial insulin depends on the patient's nutrition status, and is adjusted according to Hospital guidelines (UW Hospitals, 2017; Diabetes Management Specialist, 2015; UPMC, 2010);
- Sliding scale insulin is given as correctional insulin on an as needed basis (per Hospital policy; Handelsman et al., 2015)

Implementation & Evaluation

Due to time limitations and the vast scope of the project, our team was unable to fully implement the protocol. Implementation was stalled after receiving approval from the interdisciplinary Cross Campus Endocrine Team. Other steps toward implementation were taken, but full integration into Hospital policy will need to be completed by future cohorts. Below I describe the actions our team took, and outline suggestions for implementation and evaluation for future cohorts.

Implementation

The final protocol in Appendix E is the fourth draft of the evidence-based protocol our team developed. We presented the first draft of the protocol to the Lead Diabetes Educator in person on February 13, 2018. She suggested some edits based on current Hospital policies, and we sent the second draft of the protocol to the Diabetes Educator Team on March 6, 2018. We received further feedback from the Lead Diabetes Educator via email, and sent the third draft of the protocol to the Diabetes Educator Team on March 20, 2018. This draft was sent in preparation for the upcoming Cross Campus Endocrine Team.

The Cross Campus Endocrine Team (CCET) is composed of RNs, NPs, pharmacists, and endocrinologists, and meets on a monthly basis. Each participant engages in quality improvement of the Hospital's practices related to endocrinology, and especially related to diabetes mellitus. The CCET engages in RCAs, failure mode and effects analyses (FMEAs) and plan-do-study-act (PDSA) cycles to improve systems and promote patient safety related to endocrinology order sets and hospital practices. We presented our third draft of the protocol to the CCET on March 28, 2018, at the request of the Lead Diabetes Educator. We had planned to present the protocol at the previous CCET on February 28, 2018, but the evaluation of a DM-related order set took precedence in the agenda. Our presentation on March 28 included a summary of the research that was used in the protocol's development, and an overview of the key points of the protocol.

Overall, the feedback on the protocol was positive. The CCET was appreciative of the work we had put in to develop the protocol, and found the details of the protocol to correspond with their theoretical and practical knowledge of the IV to SQ transition. We received two pieces of feedback that led to our fourth and final draft. First, to align with Hospital policy, we changed the frequency of insulin administration for patients receiving continuous tube feeding from every six hours to every four hours. Second, we were instructed that the Hospital is "very conservative" in its insulin dosing, and did not feel comfortable using an 80% conversion safety factor for all patients. Therefore, we were required by the CCET to allow for a range of conversion safety factors, with the SQ dosage ranging from 60% to 80% of the daily IV insulin requirement (Personal communication, Lead Diabetes Educator, March 28, 2018). This range is represented in our flowchart in Figure 1, and in our complete protocol in Appendix E.

Though our team, and the evidence we found, supports an 80% conversion safety factor, we were not able to convince the CCET that this was a percentage associated with patient safety and improved outcomes. Prior to the CCET, the Lead Diabetes Educator expressed concerns about the 80% conversion safety factor (personal communication, March 20, 2018), so we were prepared for this possible point of divergence. Though our team still holds that the 80%

conversion safety factor is best practice, we recognize that we must work within the constraints of the Hospital and its practices.

The CCET also gave our team some next steps: (a) complete our final draft and send it to the Diabetes Educator Team; (b) send our final draft to the CVPCU Nurse Educator and CVPCU unit council for review and approval; and (c) once reviewed by the CVPCU, send the completed protocol to the physician leading the efforts to integrate protocols and clinical pathways into the electronic health record using a program called AgileMD.

Our final draft of the protocol (found in Appendix E) was sent to the Diabetes Educator Team and the CVPCU Nurse Educator on April 5, 2018. On April 24, 2018 we received feedback from the Lead Diabetes Educator that we will need to pause the protocol implementation process and allow the next cohort of students working at the Hospital to complete the quality improvement project. Due to our upcoming graduation, and pressing issues regarding current Hospital order sets that the CCET must first attend to, our team will be unable to complete the approval process this semester.

Prior to the CCET meeting on March 28, our team attempted to contact the CVPCU unit council. We had hoped to collect data on the nursing effort required to monitor IV insulin infusions in preparation for a cost-benefit analysis of the protocol. Unfortunately, after multiple inquiries through multiple points of contact, we did not receive a response. Our next communication with the CVPCU team occurred at the CCET meeting on March 28, 2018. We then emailed the final draft of the protocol to the CVPCU Nurse Educator on April 5, 2018, but we have not yet received any feedback. The review of the protocol by the CVPCU unit council will be passed on to the next cohort of students working at the Hospital. Concurrent to the development of our protocol we pursued its integration into the electronic health record (EHR) using AgileMD. AgileMD is a combination of software, services, and content subscriptions that can be integrated into a hospital's electronic health record to provide seamless access to clinical pathways, protocols and order sets (AgileMD, 2018). The Hospital currently subscribes to its services, and is pushing for widespread use and adherence by prescribing providers - specifically, MDs, PAs, and NPs. The Lead Diabetes Educator tasked us with contacting the physician leading the Hospital's AgileMD efforts (Personal communication, January 30, 2018).

On February 7, 2018, our team met with the physician leading the usage of AgileMD in the Hospital. She presented AgileMD and its functionality within the Hospital's electronic health record (EHR). The flowchart in Figure 1 is an approximation of the provider view of the protocol within the EHR through AgileMD. AgileMD will also be able to integrate calculators and any needed pop-up and hover-over details into the flowchart within the EHR.

Currently, the Hospital is underutilizing AgileMD (Physician leading AgileMD efforts, personal communication, February 7, 2018). Before this protocol can be effective, physicians throughout the Hospital system will require training and instruction on how and when to use AgileMD within the EHR (Cross Campus Endocrine Team, Personal Communication, March 28, 2018). This training will be led by the physician leading the utilization of AgileMD, and supported by the next cohort of students working at the Hospital.

Future Implementation

Further steps of implementation will be completed by the next cohort of students working at the Hospital. Had our team been able to fully implement and evaluate the use of this protocol at the Hospital, I expect that our steps would have been similar to the plan that follows.

First, we would seek and receive approval from the CVPCU unit council. If needed, our team would present the protocol at one of their monthly meetings and make any required edits.

Second, we would focus on the integration of the protocol into AgileMD. We would first send the protocol to the physician leading the usage of AgileMD, who would then send it on to the company. AgileMD would then be able to incorporate the protocol into the EHR in approximately two weeks (Physician leading AgileMD at Hospital, personal communication, February 7, 2018). During this time we would also work with the lead physician to confirm that all the relevant providers have access to AgileMD.

Third, once the protocol was integrated into the EHR, we would create a video demonstration of how to use this protocol specifically, and how to use the features of AgileMD more generally. This video demonstration would be included in the required learning modules for all inpatient MDs, PAs, and NPs. The video demonstration would also be integrated into new hire training for MDs, PAs and NPs who begin work at the Hospital.

Fourth, we would provide in-person education regarding the use of AgileMD and the protocol. The demonstration and instruction of the use of this protocol and AgileMD would be incorporated into provider team meetings and grand rounds, especially for providers with an intensive care focus. These training sessions would be led by members of the CCET and the physician leading the AgileMD adoption, with support from our team. These meetings would

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highlight how to use the protocol through AgileMD and include an overview of the research that led to the protocol. Similar education regarding the key points of the protocol would be given to nurses in the ICU and the CVPCU through short inservice trainings and morning huddles. In particular, education regarding the specifics of the protocol would include:

- timing the discontinuation of the IV insulin to be at least two hours after the administration of the first dose of basal insulin (glargine or detemir);
- timing the first dose of basal insulin to be given in the morning at 0900;
- calculating the correct dose of SQ insulin based on the selected conversion safety factor;
- the importance of giving basal insulin in combination with regularly scheduled bolus insulin for most patients;
- the importance of glycemic control and the effectiveness of the basal/bolus dosing in minimizing hyperglycemia;
- the low rates of hypoglycemia associated with evidence-based IV to SQ protocols.

In addition to these topics, it would be key to dispel the myths of hypoglycemia. Many providers hold unrealistic fears of inducing hypoglycemia (Goldberg & Inzucchi, 2005, p. 31). In order to increase protocol adherence, we would need to emphasize the evidence showing that protocols like this one do not increase rates of hypoglycemia (Dungan et al., (2011); Olansky et al., 2009; Ramos et al., 2010). At the same time, we can highlight hypoglycemia prevention strategies, which include point of care glucose testing and protocols for rectifying hypoglycemia, both of which the Hospital has (AACE, 2014).

Future Evaluation

Evaluation of this protocol's effectiveness would involve a interdisciplinary team, incorporating providers, nurses, and pharmacists. It would also involve collecting data from information technology (IT) or AgileMD. The primary goals of the protocol's implementation are preventing hypoglycemia, reducing cases of hyperglycemia and any related sentinel events or near misses, and decreasing the nursing effort required to maintain patient glycemic control. The secondary goals of this protocol include decreasing the case load of the Diabetes Educator Team, and increasing provider use of AgileMD.

First, it would be critical to collect data on the number of patients who were transitioned using the protocol. This data will come from IT or AgileMD, and it will indicate if any positive results are truly due a protocol-managed transition, or to other coinciding factors. If the number of patients transitioned per protocol is low, the future cohort would need to determine the cause of low adherence, and develop a plan to improve protocol usage rates.

Second, we would collect data on the number of patients transitioned from IV to SQ insulin who experienced hypoglycemia or severe hyperglycemia. This data is collected by the Pharmacy department, and would indicate if the protocol is maintaining glycemic control as expected. If cases of hypoglycemia and hyperglycemia increase in patients transitioned using the protocol, the future cohort would need to complete an additional RCA or a PDSA to determine the cause.

Third, we would determine if the number of sentinel events or near misses related to the IV to SQ transition has decreased. Pharmacy, and especially the Medication Safety officer, would be able to track sentinel events and near misses before and after the institution of the protocol.

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The Diabetes Educator Team, who audits the charts of patients who experience diabetes related adverse events, would also give insight into whether any insulin-related sentinel events are due to the IV to SQ transition. If sentinel events were to remain the same or increase, this would indicate a need to do an additional RCA to determine the cause of the events.

Fourth, we would determine if the nursing effort required for managing insulin on the CVPCU has decreased because of this protocol. This would first involve collecting data on the number of patients receiving an IV insulin infusion on the CVPCU; these numbers can be collated by Pharmacy. Protocol effectiveness would be supported if the number of patients receiving IV insulin had decreased. We would also survey nurses and ask them to self-evaluate their workload. Questions would be qualitative, and would cover topics such as (a) if a change in workload has been felt since the initiation of the protocol, (b) if they think rates of hyperglycemia or hypoglycemia have changed, and (c) whether the protocol is effective for their patients.

Fifth, we would track the number of consultations the Diabetes Educator Team receives for patients transitioning from IV to SQ insulin. If the protocol is effective, the number of consultations should decrease, allowing the diabetes educators to fulfill other aspects of their job descriptions. This would be tracked by the Diabetes Educator Team (for consultation requests by phone) and IT (for consultation requests made via the EHR). If the number of consultations decreases but the number of patients transitioned via the protocol is low, then the future cohort would need to identify the break in the chain of communication.

Finally, we would collect data on the number of providers accessing and using AgileMD. This data would be collected from IT or AgileMD. This information would be especially significant to the physician leading the Hospital's AgileMD efforts, and any actions to increase provider usage would be led by her.

Cost Analysis

Because our team is unable to fully implement the protocol, a full cost and benefit analysis cannot be completed at this time. Implementation will be in the hands of the next cohort of students working at the Hospital, and they will determine the true costs and benefits of protocol implementation.

However, there are some economic benefits that can be anticipated at this stage in the process. In particular, the reduction in nursing time spent monitoring IV insulin infusions and the reduction in instances of hospital acquired DKA will lead to significant savings.

First, the nursing effort required to monitor and adjust IV infusions would likely decrease as a result of the protocol. Though our team was unable to collect site-specific data regarding the nursing effort needed to continually monitor blood glucose and IV insulin infusions, Aragon's 2006 study in a level I trauma center in the Southeastern United States provided such data. In units similar to the CVPCU and the CVICU, Aragon determined that the nursing time required to monitor blood glucose and adjust the IV insulin infusion rate ranged from 3 minutes, 22 seconds to 8 minutes, 53 seconds, with an average of 4 minutes, 43 seconds (Aragon, 2006, p. 374).

At the Hospital, IV insulin infusion protocols (Appendix C) require that a patient's blood glucose be tested approximately once every hour. Applying the average nursing time from Aragon (2006) of 4 minutes and 43 seconds for each blood glucose measurement, a CVPCU nurse who works a standard 12 hour shift could spend, on average, 56 minutes and 36 seconds.

Thus approximately one hour of nursing effort is needed for each patient requiring IV insulin infusion management on the CVPCU.

However, once a patient has been transitioned to SQ insulin, the average number of blood glucose measurements required in a 12 hour shift decreases from 12 to three. Though Aragon (2006) does not provide data on the average time required to monitor blood glucose and provide SQ insulin, I posit that the time required is equivalent or slightly higher than the average Aragon observed for IV insulin. With a slightly higher nursing time requirement of 6 minutes to complete the blood glucose measurement and SQ insulin administration, the time required over a 12 hour shift decreases from one hour with IV insulin to 18 minutes with SQ insulin - a decrease of 70%.

This decrease in nursing time could lead to savings in nursing salary and benefits, and a decrease in overtime usage and payment. In a Hospital system as large as this, the savings could be in the hundreds of thousands of dollars over the course of a year. Similarly, the cost of supplies would decrease, as the need for glucose testing strips and lancets would drop. Unfortunately, our team was not given access to the unit budget, so these savings cannot be quantified at this time.

Second, the benefits related to a decrease in patients with hospital-acquired diabetic ketoacidosis could lead to increased revenue and reimbursement. Since 2009, the Centers for Medicare and Medicaid Services (CMS) no longer reimburse for medical services rendered to treat complications of hospital care - known as preventable, hospital-acquired complications, or 'never events' (O'Rourke & Hershey, 2009). "Manifestations of poor control of blood sugar

levels" are considered never events; this includes hospital-acquired DKA (O'Rourke & Hershey, 2009).

This protocol was developed in part to combat hospital-acquired DKA. If this protocol is successful in reducing the rates of hospital-acquired DKA, it could lead to savings for the Hospital; under current CMS rules, the Hospital pays for all care for patients with hospital-acquired DKA (O'Rourke & Hershey, 2009). Though I was unable to find Hospital-specific data related to the cost of care and treatment for patients with DKA, some cost estimates do exist in the literature.

One U.S. study conducted in 1997 found that the average total cost of an episode of DKA was \$6,444 (Javor et al., 1997). In 2018 dollars, this amounts to \$9,997 when inflation is considered (Alioth Finance, 2018). More recent studies on the cost of an episode of DKA were conducted in Spain and in the United Kingdom; the average per patient cost was 1,476.8 Euros in Spain and 2,064 Euros in the U.K. (Barranco et al., 2017; Dhatariya, Skedgel & Fordham, 2017). In U.S. dollars, this becomes \$1,787 in Spain and \$2,497 in the U.K. (Transferwise, 2018). However, since U.S. healthcare expenditures are, on average, 301% higher than Spain and 236% higher than the U.K., the U.S. equivalent cost to Spain and the U.K. would be \$5,379 and \$5,893, respectively (OECD, 2016).

Based on these results and calculations, the cost savings per patient per episode of DKA would be between \$5,379 and \$9,997. In January 2018 on the CVPCU alone, 34 patients received IV insulin infusions and had the potential to improperly transfer to SQ insulin. If even one of 34 patients experienced hospital-acquired DKA each month on the CVPCU, this could

cost the hospital up to \$119,964 each year. When considering the wider Hospital patient population, and the patient population of the Hospital system, the yearly savings is significant.

Additionally, the Hospital receives reduced Medicare reimbursement through the Hospital-Acquired Condition (HAC) Reduction Program (Hospital Compare, 2018). The HAC Reduction Program reduces reimbursements to hospitals based on their rankings among other hospitals in terms of how often patients are diagnosed with hospital acquired conditions (CMS, 2015). Hospitals that are among the worst-ranking are reimbursed 99% of what CMS would have otherwise paid (CMS, 2015).

The HAC Reduction Program compiles data based on six indicators, including the Agency for Healthcare Research and Quality (AHRQ) patient safety indicator (PSI) 90 composite measure. The PSI 90 includes PSI 10: "Postoperative physiologic and metabolic derangement rate" (AHRQ, 2016). This category includes diabetes related complications after surgery, and would include post-surgical hospital-acquired DKA due to improper transition from IV to SQ insulin. Hence, decreasing the rate of hospital-acquired DKA by using this protocol would improve the Hospital's total HAC score, and could lead to increased CMS reimbursement. Though I was unable to find data on the proportion of the Hospital's operating income that comes from CMS, the total operating income of the Hospital system in 2015 was approximately 1.5 billion dollars (Hospital, 2015). Thus, any change in CMS reimbursement could be equivalent to at least hundreds of thousands of dollars each year.

Finally, the anticipated costs of implementing this protocol are low. There is no additional cost to incorporate this protocol into AgileMD, as the Hospital has already purchased and subscribed to AgileMD services. Additionally, the Hospital had already budgeted for AgileMD

training to increase usage among providers; this protocol can function as a case study for the training that is intended, so no additional costs will be incurred. There may be minor costs associated with educating nurses about the protocol, though the majority of the teaching will occur during regularly scheduled huddles and rounds. Similarly, there may be a minor time cost for nurses to complete the survey regarding their experience with the protocol; to mitigate this, the survey would be short so the time cost would be negligible. The remaining monitoring and data collection will occur within the job descriptions of the professionals involved, and will not add additional costs.

Future Directions and Sustainability

From the perspective of a clinical nurse leader (CNL), this project epitomizes the importance and the difficulty of working with an interdisciplinary team. Though we anticipated the process of developing a new clinical protocol to be lengthy, we had hoped to be further along before handing the project over to the next cohort. Unfortunately, the work load of many of the key players, including the Diabetes Educator Team and the CVPCU staff, is very high, and their responsiveness was lower than expected. Additionally, the Cross Campus Endocrine Team is in the midst of editing multiple order sets and internal systems, and so our project was one of many that required attention. The complexity of developing a protocol for use on a unit and across a hospital system is significant, and the number of people involved is vast. Change does not occur quickly in a large metropolitan hospital.

Because this quality improvement project is not yet complete, sustainability will entail engaging in the future implementation and evaluation actions described above. With teaching, training, and determining effectiveness of the protocol, the next cohort of students will be well on their way to completing this project. However, if effectiveness of the protocol remains unclear after initial data collection, I suggest that the next cohort and the Cross Campus Endocrine Team engage in a deeper root cause analysis that looks beyond the initial root causes that led to this protocol's development.

In future years and with future CNL students there is space for continued refinement of the protocol itself. Internal data should be collected regarding the best conversion safety dose. This protocol should be evaluated for effectiveness in specific patient populations. The protocol should be updated as the evidence continues to evolve regarding inpatient glycemic control. This protocol should not be a stagnant document - it should change as patient needs change.

Discussion

Though this protocol was developed within one microsystem, it is also intended to be generalized to the Hospital and to the Hospital system. In fact, this protocol could easily be generalized to other hospitals and healthcare organizations in a number of different settings. With the exception of the 60% conversion safety factor and the specifics of the bolus insulin dosing, this protocol is not specific to the Hospital. Its key features come directly from the evidence, and have been tried and tested within numerous patient populations.

When stripped down to its most basic features, the protocol highlights the need for timely IV to SQ insulin transitions, the benefits of basal insulin, the timing of basal administration and IV discontinuation, and the safety and efficacy of giving patients 80% of their IV insulin in a SQ dose. These key points can be translated and used in any inpatient setting, whether as a protocol, order set, clinical pathway or general standard of practice. Patients will benefit from the application of the protocol. Providers will benefit from the standardization of the process. Hospitals will benefit from the money saved by transitioning patients quickly and safely.

Conclusion

In conclusion, evidence-based intravenous to subcutaneous insulin protocols are needed to safely and efficiently transition patients. The protocol we developed will prevent hypoglycemia, reduce hyperglycemia, and decrease the nursing effort required to maintain patient glycemic control. Though the implementation of this protocol at the Hospital is incomplete, its creation and development has placed the Hospital on the path toward standardized best practice and improved patient outcomes.

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Appendix A

Use of Intravenous Insulin (Regular Insulin, 150 Units in 150 milliliter Infusion) in Hospital from January 1, 2018 - February 6, 2018 Source: Program Manager of Medication Safety, Pharmacy Department

Unit	Antihyperglycemic	Date Initiated
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/29/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/19/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/29/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/29/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/30/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/15/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/16/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/17/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/16/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/16/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/17/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/17/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/26/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/24/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/23/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/24/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/26/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/25/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/25/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/23/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/15/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/14/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/11/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/14/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/9/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/11/2018

CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/8/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/8/2018
CVPCU	1/11/2018	
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/8/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/9/2018
CVPCU	CVPCU insulin regular 150 Units in NS 150 mL infusion	
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/9/2018
CVPCU	insulin regular 150 Units in NS 150 mL infusion	1/10/2018
CVICU	insulin regular 150 Units in NS 150 mL infusion	1/22/2018
CVICU	insulin regular 150 Units in NS 150 mL infusion	2/5/2018
CVICU	insulin regular 150 Units in NS 150 mL infusion	2/1/2018
CVICU	insulin regular 150 Units in NS 150 mL infusion	2/1/2018
CVICU	insulin regular 150 Units in NS 150 mL infusion	2/6/2018
Oncology	insulin regular 150 Units in NS 150 mL infusion	1/18/2018
Oncology	insulin regular 150 Units in NS 150 mL infusion	1/17/2018
Oncology	insulin regular 150 Units in NS 150 mL infusion	1/14/2018
Orthopedics	insulin regular 150 Units in NS 150 mL infusion	1/6/2018
Orthopedics	insulin regular 150 Units in NS 150 mL infusion	1/7/2018
Orthopedics	insulin regular 150 Units in NS 150 mL infusion	1/7/2018
ICU	insulin regular 150 Units in NS 150 mL infusion	1/8/2018
ICU	insulin regular 150 Units in NS 150 mL infusion	1/7/2018
ICU	insulin regular 150 Units in NS 150 mL infusion	1/20/2018
Telemetry	insulin regular 150 Units in NS 150 mL infusion	1/24/2018
Metabolic	insulin regular 150 Units in NS 150 mL infusion	1/17/2018
Metabolic	insulin regular 150 Units in NS 150 mL infusion	2/2/2018
Cardiovascular	insulin regular 150 Units in NS 150 mL infusion	1/12/2018
Cardiovascular	insulin regular 150 Units in NS 150 mL infusion	1/7/2018
Cardiovascular	insulin regular 150 Units in NS 150 mL infusion	1/7/2018
Cardiovascular	insulin regular 150 Units in NS 150 mL infusion	1/10/2018

Appendix B Sentinel Events: Cases 1 & 2 Source: Chart review

Case 1:

84 year old male with long-standing, well managed DM I. Admitted to ED with hyperglycemia, possibly due to malfunctioning insulin pump.

Timeline:

Day 1:

Admitted with hyperglycemia (blood glucose of 436 mg/dL)

2100 - IV insulin infusion started

Day 2:

0722 - Blood glucose of 32 mg/dL

2011 - Blood glucose of 243 mg/dL

2013 - IV insulin infusion stopped

2100 - Sliding scale subcutaneous insulin given

*No basal insulin given in addition to sliding scale

Day 3:

0200 - Blood glucose of 471 mg/dL; Sliding scale insulin given

0900 - Diabetic ketoacidosis confirmed with chem panel

0915 - IV insulin infusion restarted

Day 4:

Insulin pump with basal/bolus regimen restarted **Patient discharged home**

Day 6:

2040 - Patient readmitted to ED (blood glucose of 143 mg/dL)

2102 - Insulin pump removed

* No IV insulin infusion started

* No basal insulin given

Day 7:

0200 - Blood glucose of 367 mg/dL

0800 - Blood glucose of 457 mg/dL

* RN contacted Diabetes Educator

* Diabetes Educator contacted MD for order of basal insulin

0909 - First subcutaneous basal insulin dose given; prandial subcutaneous insulin given with breakfast

Day 8:

Patient discharged home

IV TO SQ TRANSITION

Case 2

27 year old male with uncontrolled DM I. Admitted for surgical treatment of osteomyelitis.

Timeline:

Day 1:

Patient admitted day before surgical procedure

Patient placed on subcutaneous basal insulin and prandial subcutaneous insulin

Day 2:

IV insulin infusion started preoperatively

Surgical procedure occurs

Patient remains on IV insulin infusion

Day 3:

0020 - Blood glucose of 84 mg/dL

0100 - IV insulin infusion stopped

* No basal insulin started

1300 - Diabetic ketoacidosis confirmed with chem panel; Blood glucose of 306 mg/dL

* RN contacted Diabetes Educator

* Diabetes Educator contacted MD for order of basal insulin

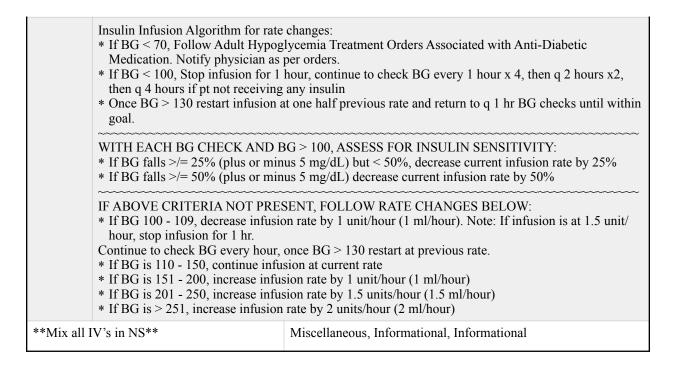
1348 - First subcutaneous basal insulin dose given; sliding scale insulin given while 4353patient is NPO

Day 4:

Diabetes ketoacidosis resolved Patient now followed by Diabetes Educator Plan of care created for patient upon discharge

Appendix C Cardiac Surgery Intravenous Insulin Infusion Order Set Source: The Hospital Computerized Physician Order Entry System*

Genera	ป			
Nursing Interventions				
Goal range for blood glucose (BG): 110 - 150		Until discontinued, Starting today		
Order stat blood glucose rather than using the meter for Hct < 20 or > 65		Bedside blood glucose meter can be inaccurate for Hct < 20 or > 65 . Resume bedside glucose monitoring when Hct $>/= 20$ or $.$		
Contact the Diabetic Educator		Details		
Notify P	hysician			
Notify physician managing insulin infusion if:		Routine, Until discontinued, Starting today, Insulin infusion rate > 14 units/hr and BG not in goal range x2 consecutive hours. Hypoglycemia when infusion is = 1 unit/hour.<br Unable to reach goal range within first 16 hours of anesthesia end time. Another treating physician changes diet, IV fluids or orders steroids or starts alternate diabetes treatment.		
Lab				
General				
POC Blood Glucose		Routine, Every hour. Starting today with First Occurrence Include Now Goal range for blood glucose (BG): 110 - 150 MG/DL Check every hour until in goal range for 3 consecutive hours, then check every 2 hours. If patient falls out of goal range, test every hour until returns to goal range for two hours, then continue to check every 2 hours.		
Hemoglobin a1c		Routine, Once		
Medication				
Insulin I	nfusion			
insulin (HUMA N R) infusion for Type II Diabetic	 JMA CARDIAC SURGERY IV INSULIN INFUSOIN Initial infusion rate for patients NOT on an insulin infusion. If insulin infusion stopped per change algorithm do NOT use this table to restart infusion. Blood Glucose Infusion Rate 			



* The hypoglycemia component of Cardiac Surgery IV Insulin Infusion order set was not included here as it was not relevant in the development of the transition protocol. All other details, including any grammatical or typographical errors, are directly quoted from END IP Cardiac Surgery IV Insulin Infusion.

Appendix D Insulin Subcutaneous Order Set Source: The Hospital Computerized Physician Order Entry System*

Labs				
Lab - HgbA-1c				
Hemoglobin A1C	Routine, Once			
Labs - Point of Care				
POC Blood Glucose - If patient is eating	Routine, 4 times daily before meals and at bedtime. BG checks AC & at bedtime and 0200 for patients who receive insulin at dinner and/or bedtime or patients who have ANY hypoglycemia (BG<70)in the past 24 hours. Use same scale 1, 2, or 3 in Bedtime and 0200 table that was ordered for AC.			
Medications				
Guideline: Starting insulin dose 0.2 units/kg basal insulin q 24 hr and 0.05 units/kg Novolog before each meal. It is recommended that scheduled / basal insulin be used in combination with supplemental insulin.				
Basal Insulin				
insulin detemir (LEVEMIR PEN) injection	Subcutaneous, Nightly at bedtime, Nightly at bedtime			
Scheduled Pre-Meal-Insulin				
insulin aspart (NovoLOG PEN) injection - individual dose TID AC				
Pre-breakfast insulin aspart (NovoLOG PEN) injection	Subcutaenous, Daily before breakfast, Daily before breakfast			
Pre-lunch insulin aspart (NovoLOG PEN) injection	Subcutaenous, Daily before lunch, Daily before lunch			
Pre-dinner insulin aspart (NovoLOG PEN) injection	Subcutaenous, Daily before dinner, Daily before dinner			
Sliding Scale Insulin (AC, HS and 0200 Coverage)				
Scale I (sensitive, thin, elderly)	< 40 units/day			

insulin aspart (NovoLOG PEN) injection	 0-12, Subcutaneous. 3 times daily antidiabetic, 3 times daily antidiabetic Scale I If BG >/= 350 mg/dL, give appropriate insulin per dose algorithm and call physician. BG < 70 mg/dL: Follow Hypoglycemia Orders BG 70 - 110 mg/dL: No insulin BG 111 - 150 mg/dL: No insulin BG 151 - 200 mg/dL: 2 units BG 201 - 250 mg/dL: 4 units BG 301 - 350 mg/dL: 8 units BG 351 - 400 mg/dL: 10 units (Call physician) BG > 400 mg/dL: 12 units (Call physician)
insulin aspart (NovoLOG PEN) injection	 0-6, Subcutaneous, Bedtime and 0200 scheduled, Bedtime and 0200 scheduled Scale I If BG >/= 350 mg/dL, give appropriate insulin per dose algorithm and call physician. Check 0200 BG for patients who received insulin at dinner and/or bedtime, or patient who have had ANY hypoglycemia (BG <70) in the past 24 hours. BG < 70 mg/dL: Follow Hypoglycemia Orders BG 70 - 110 mg/dL: No insulin BG 151 - 200 mg/dL: 1 unit BG 201 - 250 mg/dL: 2 units BG 301 - 350 mg/dL: 4 units BG 351 - 400 mg/dL: 5 units (Call physician) BG > 400 mg/dL: 6 units (Call physician)

* This order set represents a sample of what would be selected for an individual patient eating three meals each day and receiving Scale I (of Scale I, II, or III) sliding scale insulin. The complete order set found in the electronic health record also includes instructions for patients with different nutritional needs and/or receiving different sliding scale insulin amounts. The 'General' section (which includes when to notify the physician, nursing interventions related to diabetic ketoacidosis, and ancillary consultations) and the 'Hypoglycemia'' section were removed for brevity. All other details, including any grammatical or typographical errors, are directly quoted from END IP Insulin Subcutaneous.

Appendix E Protocol: Transition from IV to SQ Insulin Draft 4, 4/3/2018

Patient Recommendations:

* All patients have minimally variable IV insulin infusion rate for 6 hours

* Blood glucose is at goal rate per John Muir policy for 6 hours

- Goal for Cardiac Surgery Patients: BG 110 150
- Goal for non-cardiac patients: BG 140 180
- Goal for DKA patients: BG 150-200

Timing of the transition:

- Give initial basal dose at 0900
 - Stop IV insulin drip *at least* two hours after first dose of basal insulin.
 - Give pre-meal and/or sliding scale insulin before lunch
 - For patients requiring > 50 U/day of basal insulin, split the dosing of the basal
 - Give half of the daily basal dose at 0900
 - Give half of the daily basal dose at 2100 the night before transition to basal/bolus insulin.

1. Patients with history of diabetes or requiring \ge 1.5 units/hour

- Determine the patient's total daily dose (TDD) of SQ insulin:
 - a. Determine the total units of IV insulin infusion over previous 6 hours
 - b. Multiply this total by 4 to calculate total average daily IV insulin infusion dose
 - c. Multiply the total average daily IV insulin infusion dose by any factor between 0.6 0.8 to convert to a safe SQ dosage
 - Patients will receive between 60% 80% of IV insulin infusion dose, as determined by the provider

<u>Math:</u> Total SQ Dosage (units/day) = *Minimum:* = (insulin infusion total over 6 hours) x (4) x (0.6) *Maximum:* = (insulin infusion total over 6 hours) x (4) x (0.8)

- **Basal Insulin:** Give 50% of TDD as long acting glargine (Lantus) or detemir (Levemir) insulin
 - Give regardless of oral intake
 - Give <u>at least</u> 2 hours prior to discontinuation of IV insulin infusion
- Bolus Insulin

- Patient on PO intake:
 - Give 50% of TDD as scheduled pre-meal insulin in 3 evenly divided doses
 insulin aspart (NogoLOG pen)
 - If patient is transitioning to clear liquids, give 0 50% of TDD as scheduled pre-meal insulin in 3 evenly divided doses.
 - Increase the premeal insulin dose over time, based on patient intake.
 - Hold scheduled insulin if patient is NPO.
 - Administer correction sliding scale insulin PRN per John Muir protocol for BG outside of goal range
 - Scale I: sensitive, thin, elderly; <40 units insulin/day
 - Scale II: average weight; 40 80 units insulin/day
 - Scale III: resistant, obese, steroids, or continued infection; >80 units insulin/day
- Patient on Continuous Tube Feed:
 - Give 50% of TDD as scheduled insulin in 6 evenly divided doses, every 4 hours
 - If tube feedings are stopped, hold scheduled insulin.
 - Administer correction sliding scale insulin PRN per John Muir protocol for BG outside of goal range
 - Scale I: sensitive, thin, elderly; <40 units insulin/day
 - Scale II: average weight; 40 80 units insulin/day
 - Scale III: resistant, obese, steroids, or continued infection; >80 units insulin/day

2. Patients without history of diabetes <u>and</u> requiring < 1.5 units/hour

- No basal dose of insulin is needed
- Order correction sliding scale insulin PRN per John Muir protocol for BG outside of goal range
 - Scale I: sensitive, thin, elderly; <40 units insulin/day
 - Scale II: average weight; 40 80 units insulin/day
 - Scale III: resistant, obese, steroids, or continued infection; >80 units insulin/day