AMERICAN UNIVERSITY OF BEIRUT

PROMOTING GLUCOSE CONTROL IN MEDICAL SURGICAL PATIENTS WITH TYPE 2 DIABETES MELLITUS AT THE AMERICAN UNIVERSITY OF BEIRUT MEDICAL CENTER

by
NOURHAN AHMAD AL SHAMI AL BAYRAKDAR

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NOURHAN AHMAD AL SHAMI AL BAYRAKDAR

Approved by:

Dr. Samar Noureddine, Professor First Reader
Hariri School of Nursing

Dr. Houry Puzantian, Assistant professor First Reader
Hariri School of Nursing

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ABSTRACT
OF THE PROJECT OF

Nourhan Ahmad Al Shami Al Bayrakdar for Master Science in nursing
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Title: Promoting Glucose Control in Medical Surgical Patients with Type 2 Diabetes Mellitus at the American University of Beirut Medical Center

Background: Diabetes mellitus (DM) is a chronic metabolic disease characterized by elevated levels of blood glucose (BG). There are two types of DM: type 1 and type 2. About one in four patients with DM is hospitalized. Thus, inpatient BG control, assessment, and management are important aspects that require attention. Glucometrics is a set of measures that aims to evaluate the effectiveness of blood sugar control in the hospital setting. The BG level is obtained by point-of-care testing (POCT) via fingerstick and subsequently reflects transient changes in BG within the acceptable BG range. To facilitate advances in this nascent field, standardized metrics for inpatient glycemic control should be developed.

Aims: The study has two aims. One is to compare glucometrics at AUBMC before and after implementation of the adult subcutaneous insulin clinical order sets and the hypoglycemia management protocol, and the second aim is to compare glucometrics after the protocols' implementation with the SHM benchmark values.

Design: A retrospective cohort study based on electronic medical record review. Glucometrics of patients with type 2 diabetes mellitus admitted to AUBMC 3 months prior to implementation were compared to those of patients admitted 3 months following implementation.

Sample: The sample consisted of 228 adult inpatients, of whom 86 were admitted before and 142 after the new protocol was implemented; all patients were 18 or older and admitted to medical-surgical units.

Procedure: IRB approval was secured. Fingerstick POCT-BG results with their timestamp for patients with T2DM in addition to their demographic and clinical characteristics. The time frame was three months before (December 2020, January 2021, and February 2021) and three months after (May, June, and July 2021) the implementation of the new protocol. The data were extracted using the Electronic Privacy Information Center (EPIC) system.

Results: There was no difference in the descriptive variables between the two groups, pre- and post-protocol. The comparison of pre- and post-protocol data revealed significantly lower sample BG values, lower hyperglycemia, and severe hyperglycemia, with somewhat higher hypoglycemia in post protocol compared to pre-protocol data.

The improvement in glucometrics was statistically significant mostly at the samples' level of analysis. Significantly lower severe hyperglycemia (BG > 299 mg/dL) was found post-protocol at all levels of analysis (patient-samples, patient-stay, and patient-day). Moreover, the results that compare the post-protocol data at AUBMC to the benchmark were all within the range of the benchmark, except for the patient day with any BG $\geq$ 180

mg/dL, which was 62.09% vs. 29.5% for the benchmark. And, also, higher than the upper limit of the benchmark's range of 12% to 45.8%, which shows that there is room for improvement for this protocol.

Conclusion: This project provided preliminary data to evaluate the effectiveness of the newly introduced protocols for glucose control. Other investigators still used different ways of analyzing the data. It is recommended to use multiple methods of analysis since no one method is considered superior. The findings show promise in terms of blood glucose control, but there is room for improvement, including more compliance with the guidelines and better documentation.

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CHAPTER I

BACKGROUND

The World Health Organization (WHO) defines diabetes mellitus (DM) as a chronic metabolic disease characterized by elevated levels of blood glucose (BG), which leads to serious damage to the heart, blood vessels, eyes, kidneys, and nerves over time (WHO, n.d). There are two types of DM; type 1 affects mostly children and adolescents, while type 2 mostly affects adults. The elevated BG in type 2 diabetes mellitus (T2DM) is caused by defects in pancreatic β-cell insulin secretion or in the response of insulin-sensitive tissues (Galicia-Garcia et al., 2020).

The incidence of DM is increasing rapidly worldwide. In fact, it has quadrupled in the past three decades and is considered the ninth major cause of death (Zheng et al., 2018). The International Diabetes Federation (IDF) stated that individuals living with DM were around 537 million in 2021, this number is estimated to increase to 643 million in 2030 and 783 million in 2045 worldwide (IDF, 2022). Furthermore, the IDF reported that roughly 3 out of every 4 diabetics live in low-and middle-income countries (IDF Diabetes Atlas, 2021). Equally important, DM has caused over 6.7 million deaths—around one death every five seconds in 2021 (IDF Diabetes Atlas, 2021). Additionally, since there are 541 million people worldwide with impaired glucose tolerance (IGT), the chance of developing diabetes has increased (IDF Diabetes Atlas, 2021). Diabetes has cost at least 966 billion USD in health-care costs, which have risen by 316% in the previous 15 years (IDF Diabetes Atlas, 2021).

In the Middle East and North Africa alone where one in six people live with DM, the IDF estimated that DM was expected to rise from 73 million in 2021 to 136 million in 2045 (Ogurtsova et al., 2022). Furthermore, one in every three people with diabetes is undiagnosed. Furthermore, in 2021, DM will have led to 796,000 deaths (IDF Diabetes Atlas, 2021).

In Lebanon, 11.3% of the population in 2005 was found to have DM, with this number rising to reach 15.8% in 2017 (Hirbli et al., 2005; Nasrallah et al., 2017). A strong link was documented between T2DM and both a higher body mass index (BMI) and a sedentary lifestyle among Lebanese people (Ahmadieh et al., 2019). In addition, a high prevalence of micro-vascular diabetic complications was found among Lebanese with DM, with at least one third having neuropathy or retinopathy, and around 50% having albuminuria. As for macro-vascular complications, 20% were found to have coronary artery disease (CAD) and peripheral vascular disease (PVD), and 4.1% had cerebrovascular disease (Ahmadieh et al., 2019).

About one in four patients with DM are hospitalized, and 9% of hospitalized patients present with complications associated with DM (Goswami et al., 2019). Hyperglycemia and hypoglycemia are both defined as adverse events that affect the clinical outcomes of hospitalized inpatients (Kyi et al., 2019). Uncontrolled hyperglycemia occurs in 32% to 38% of patients in non-critical care areas (Maynard et al., 2014). Besides, hyperglycemia commonly happens among hospitalized patients, and is associated with rising hospital complications, length of stay, and mortality rate. Of equal importance, hypoglycemia is associated with poor outcomes and rising health-care expenses (Pasquel et al., 2021).

According to Kyi et al. (2019, p.1), "Acute hyperglycemia in hospitals is linked with hospital-acquired infections because of the associated neutrophil and macrophage dysfunction, as well as with cardiovascular and renal disease secondary to pro-thrombotic changes, osmotic diuresis, and endothelial dysfunction." Similarly, acute hypoglycemia in hospitals can lead to neuroglycopenia, causing seizures, falls, and neurological injury, as well as cardiac ischemia and arrhythmia. As such, the American Association of Clinical Endocrinologists (AACE) and the American Diabetes Association (ADA) recommended insulin as an optimal treatment for hyperglycemia in hospitalized diabetic patients (Pasquel et al., 2019). Basal-bolus insulin for controlling hyperglycemia has shown better glycemic control than oral antidiabetic medications. However, the inappropriate administration of insulin may lead to a risk of hypoglycemia, which is associated with a 12–30% increase in hospital length of stay and a high mortality rate (Pasquel et al., 2019). Therefore, inpatient BG control, assessment, and management are an important aspect and are the prime of interest that require attention (Cook et al., 2012). Thus, the importance of controlling BG levels in hospital settings was highlighted in the literature, although it is not without its challenges (Kyi et al., 2019; Rogers et al., 2014). Evidence based protocols are often used to guide the treatment of patients admitted with T2DM, knowing that they may get admitted because of diabetes complications or conditions that are not related to diabetes.

Glycemic control is often measured with HbA1c in outpatients, which shows how well diabetic patients have been controlling their BG in the previous three months. Glucometrics, on the other hand, is a set of measures that aims to evaluate the effectiveness of blood sugar control in the hospital setting. BG level is obtained by

point-of-care testing (POCT) via fingerstick, and subsequently reflects transient changes in BG, with the acceptable BG range being between 70 mg/dL and 180 mg/dL and integrated in glucometrics calculation. Moreover, glucometrics are required for Joint Commission Certification in Advanced Inpatient Diabetes Care (Goldberg et al., 2006; Joint Commission Center, n.d). Glucometrics include the rates of hyperglycemia (≥180 mg/dL), severe hyperglycemia (≥299 mg/dL), hypoglycemia (≤70 mg/dL), and severe hypoglycemia (≤40 mg/dL) (Schnipper et al., 2008; Thompson & Cook., 2017).

The Society of Hospital Medicine (SHM) has reported an achievable benchmark based on data from 76 hospitals with 476 non-ICU (Maynard et al., 2014). With the increasing attention towards improving and controlling BG levels in hospitalized patients worldwide, comparing the organizations' glucometrics to standardized benchmarks allows the evaluation of the performance of hospitals in terms of glucose control (Kyi et al., 2019).

In March 2021, a multidisciplinary team at American University of Beirut Medical Center (AUBMC) developed and implemented a new evidence-based adult subcutaneous insulin clinical order set (See Appendix 1) and hypoglycemia management protocols (See Appendix 2). The aim of these protocols was to effectively control BG, by preventing hyperglycemia and managing hypoglycemia in order to maintain BG levels within acceptable range. However, the protocols' effectiveness, in improving BG control has not been evaluated. Glucometrics outcomes achieved by tracking the incidence of hypoglycemia and hyperglycemia and benchmarking them with SHM have not been done yet at AUBMC. To that end, the aims of this quality improvement project are to:

1. To compare glucometrics at AUBMC before and after implementation of adult subcutaneous insulin clinical order sets and hypoglycemia management protocol.
2. To compare glucometrics after the protocols' (adult subcutaneous insulin clinical order sets and hypoglycemia management protocol) implementation with the SHM benchmark values.

If AUBMC rates are within those set by the SHM benchmark, the effectiveness of the implemented protocols will be supported.

CHAPTER II

LITERATURE REVIEW

A vast body of literature that includes observational and prospective randomized clinical trials, showed that hyperglycemia is strongly linked to poor clinical outcomes, such as mortality, infections, and hospital complications (Corsino et al., 2015; Evans et al., 2012; Jiang et al., 2003). In a retrospective analysis of 2,030 patients admitted to a community hospital, mortality on the general wards was considerably greater in patients with newly diagnosed hyperglycemia and known history of diabetes compared to those with normal glucose readings (10% vs. 1.7% vs. 0.8%, respectively; $p < 0.01$) (Umpierrez et al., 2002). Ramos et al. (2008) found that for every 40 mg/dL increase in postoperative glucose level above 110 mg/dL, the risk of postoperative infection increased by 30%.

A. Benefits of Glycemic Control

A prospective randomized study that examined the impact of glycemic control at 1-year post liver transplant showed that 35 of the 82 patients (42.7%) with BG target of less than 140 mg/dL had any infection within 1 year, while 54 of 82 (65.9%) in the randomized group with a glycemic target of less than 180 mg/dL had an infection ($P = 0.0046$) , with a hazard ratio of being in the 140 group of 0.54, 95% confidence interval 0.35-0.83 (Wallia et al., 2017).

In the Normoglycemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation (NICE-SUGAR) trial, a randomized group of intensive care unit patients on mechanical ventilation was on intensive glycemic control, with a target

glucose level of 80 to 110 mg/dL, while the control group was on moderate glycemic control, with a target glucose level of 140 to 180 mg/dL. This trial showed that intensive glycemic control had no substantial therapeutic advantage over moderate glycemic control and the mortality rate was high in both groups (27.5% vs. 24.9%), but significantly more in the intensive treatment group, $p = 0.02$. Moreover, the intensive glycemic control group had higher rates of hypoglycemia with BG 40 mg/dL or lower (6.8% vs 0.5%), $p < 0.001$, but no difference in length of stay. The authors concluded that insulin therapy should be initiated when hyperglycemia is above 180 mg/dL and the targeted glucose level for hospitalized patients must be between 140 and 180 mg/dL (van den Berghe et al., 2001). According to the American Diabetes Association (ADA), the standards of care for patients with DM in hospital settings should follow protocols and structured order sets that include computerized physician order entry (ADA Professional Practice Committee, 2022).

B. Hyperglycemia protocols

As noted above, monitoring hospitalized patients with diabetes or new hyperglycemia is important to avoid complications and inform treatment. HbA1C should be ordered on admission for diabetic and hyperglycemic (BG>140 mg/dL) patients if they have not been tested for the past three months. A validated, computerized insulin sliding scale should be used for insulin administration according to BG levels in diabetic and hyperglycemic patients (ADA Professional Practice Committee, 2022). Also, a diabetes management specialist should be consulted for all patients with diabetes who are admitted (ADA Professional Practice Committee, 2022).

Insulin is the best choice for usage in hospital settings for patients with DM. However, in some cases, oral antidiabetic medications can be resumed in the hospital. If oral medications are withheld during the hospital stay, there should be a protocol in place for restarting them 1-2 days before discharge (ADA Professional Practice Committee, 2022).

In non-intensive care wards, managing hyperglycemia in diabetic patients by scheduling insulin regimens is recommended (Bueno et al., 2015). Furthermore, Regimens using insulin analogs and human insulin result in similar glycemic control in the hospital setting (Bueno et al., 2015). Rapid or short-acting insulin before meals or every 4-6 hours is preferred for controlling hyperglycemia for patients who are fasting or receiving continuous enteral or parenteral nutrition (Bueno et al., 2015). Moreover, for patients with poor oral intake or restricted oral intake, basal insulin or a basal and bolus correction scale are best considered (Bueno et al., 2015). Besides, for patients with good oral intake, an insulin regimen with a basal, prandial, and correction scale is recommended (Bueno et al., 2015). Regarding patients' glucose monitoring in hospitals, fingerstick is the standard method of glucose measurement. Moreover, finger sticks are used before meals for patients who tolerate oral intake and every 4-6 hours for patients who are not eating (Rice & Coursin, 2016).

C. Hypoglycemia protocols

Hypoglycemia can occur in any hospitalized patient, which may increase the mortality rate (Akirov et al., 2017). Furthermore, hypoglycemia episodes can be prevented by implementing a standardized protocol that a nurse can initiate to address situations where BG becomes less than 70 mg/dL. Hypoglycemia episodes in the

hospital should be documented and tracked in the medical record (Bogun & Inzucchi, 2013). Dendy et al. (2014) reported that hospitalized patients who experienced a severe hypoglycemic episode (<40 mg/dL) had previously experienced hypoglycemia (<70 mg/dL) during the same stay. Another study done by Ulmer et al. (2015) about hypoglycemic episodes (classified as 50 mg/dL) found that 78% of patients were taking basal insulin, with hypoglycemia occurring most frequently between midnight and 6:00 a.m. Despite being aware of hypoglycemia, 75% of patients did not have their basal insulin dosage changed before the next insulin injection.

1. Considerations for surgical patients

Diabetic patients may also be more vulnerable to complications during surgery. This is a major concern because it is expected that more than half of diabetic patients will need at least one surgical operation over their lifetime (Wang et al., 2019). Postoperative complications can extend hospital length of stays, increase the financial load, and increase mortality. Adverse glucose reactions in patients undergoing surgery have resulted in several incidents such as surgical site infection, myocardial infarction, stroke, and death due to adverse events (Wang et al., 2019). BG control in diabetic patients using evidence-based therapeutic regimen

for major cardiac surgery and orthopedic surgery has been shown in studies to significantly reduce the prevalence of glucose metabolism problems and postoperative complications, resulting in improved surgical results (Wang et al., 2019). A retrospective study done by Wang et al. (2019) of 1,525 diabetic patients included 49.9% who underwent orthopedic surgery and 50.1% who underwent general surgery. Postoperatively, 118 (7.7%) patients had adverse events. These included delayed

extubation (n = 43, 36.4%), circulatory disorder (n = 15, 12.7%), respiratory and circulatory abnormalities (n = 23, 19.5%), nonhealing of the incision (n = 11, 9.3%), infections at other sites (n = 15, 12.7%), other complications (n = 8, 6.8%), or death (n = 3, 2.5%).

The ADA recommends that BG levels in the perioperative period be between 80 and 180 mg/dL (ADA Professional Practice Committee, 2022). A study was conducted by Shah and colleagues (2019) in Canada, which included creating a Hypoglycemia During Hospitalization (HyDHo) scoring system to predict the risk of hypoglycemia during hospitalization in diabetic patients admitted to a general medical unit. This selected model included five variables: age, emergency department visit six months prior, insulin use, use of oral agents that do not induce hypoglycemia, and severe chronic kidney disease. High risk for hypoglycemia when the patients' threshold score is ≥ 9 was noted, with good sensitivity in both the derivation and the validation cohorts. However, patients who scored below this threshold had low risk for hypoglycemia. Thus, this tool can be useful to detect patients who are in need for frequent BG monitoring. Additionally, it can also help decrease the frequency of BG monitoring for patients who are at low risk of hypoglycemia which will also help in saving hospital resources.

A study done by Buchleitner et al. (2012) showed that BG levels tighter than 80 to 180 mg/dL in the perioperative period led to increase in hypoglycemic events and poorer surgical outcome. Thus, tighter control over BG levels is not recommended. Demma and colleagues (2017) also found that taking care of diabetic patients before surgery by cutting down their insulin by 25% starting the night before the surgery led to BG levels that were in the right range and a lower risk of hypoglycemia.

2. Considerations for patients on enteral or parenteral feeding

For patients receiving enteral or parenteral nutrition who require insulin, the regimen should address basal, prandial, and correctional insulin requirements (Hsia et al., 2011). Most patients on basal insulin should maintain their basal dosage while the insulin dose for the entire day is calculated as one unit of insulin for every 10-15 g of carbohydrate in the feeding formula (ADA Professional Practice Committee, 2022). Commercial ready-to-use enteral feeding formulas for enteral feeding come with different amounts of carbohydrates and may be administered at different rates. Thus, insulin dose adjustment must be considered to cover the nutritional component of enteral feeding (ADA Professional Practice Committee, 2022). The NPH insulin is to be given twice or three times per day (every 8 or 12 hours) as recommended by the diabetes specialist. In addition to adjusting insulin doses according to the feeding formula, for the correction scale human regular insulin should be given subcutaneously every six hours or rapid-acting insulin every four hours (ADA Professional Practice Committee, 2022). If enteral feeding is stopped, a 10% dextrose infusion must be started to prevent low blood sugar and give time to choose a more appropriate insulin dose (ADA Professional Practice Committee, 2022).

3. Considerations for patients receiving glucocorticoids

In hospitalized patients, the incidence of glucocorticoid treatment can exceed 10%. Therefore, these drugs can cause hyperglycemia in patients with or without diabetes (Pichardo-Lowden et al., 2011). Insulin therapy strategies must take glucocorticoid type and duration of effect into account. Short-acting glucocorticoids, such as prednisone, reach peak plasma levels in 4-6 hours but have pharmacologic

effects that last all day (Roberts et al., 2018). Patients who take steroids in the morning experience uncontrolled hyperglycemia throughout the day, but regardless of treatment, they typically achieve normal BG levels overnight (Pichardo-Lowden et al., 2011). NPH is the recommended insulin with steroid treatment, in addition to basal-bolus insulin. NPH is an intermediate-acting insulin whose action peaks at 4-6 hours after the injection. Moreover, it is preferable to administer the NPH with steroids (Kwon et al., 2013). Long-acting steroids, such as dexamethasone, require the addition of basal insulin to manage fasting BG levels (Seggelke et al., 2011). Patients on high doses of glucocorticoids may need an unusually high amount of (prandial, correction, and basal) insulin to control BG levels (Brady et al., 2014; Mathioudakis et al., 2016).

D. Glucometrics Indicators and Benchmarking

Glucometrics benchmarking is a way to assess the management of hyperglycemia and hypoglycemia in the hospital in non-critical care units (Kyi et al., 2019). Bersoux et al. (2014) have reported on glycemic control in 635 hospitals in the U.S., which was to our knowledge until today the largest published comprehensive national source of inpatient point of care-BG (POC-BG) data. The findings in the non-ICU settings were as follows: The mean POC-BG was 167 mg/dL. The prevalence of hyperglycemia (BG >180 mg/dL) was 32.3%. The proportion of days with hyperglycemia with BG > 300 mg/dL was 2.3%. The prevalence of hypoglycemia (BG <70 mg/dL) was 6.1% and the percentage of patient days with at least one POC-BG < 70 mg/dL was around 6%. The patient-day-weighted mean glucose was highest in the smallest hospitals, rural hospitals, and Northeastern hospitals compared to larger hospitals, urban hospitals, and hospitals in other geographic locations (all at $p < .01$).

Moreover, there was a significant difference in the percentage of patient days with hypoglycemia by geographic region (P <.001).

Another study done in an Australian hospital by Kyi et al. (2019) in which the results were compared to Bersoux's study documented a patient-day mean BG level that was slightly higher than that of the US hospital benchmark (171.17 mg/dL vs 167 mg/dL). The incidence of hyperglycemia was higher (37% vs. 32%). However, hypoglycemia was less than the US benchmark (4.1% vs 6.1%).

Appendix I shows the benchmarks reported for select glucometrics by Maynard et al. (2014) from non-critical care units at 76 hospitals.

Maynard et al. (2017) examined the practice variations in insulin administration and glycemic adverse events, where nine Dignity Health institutions evaluated hypoglycemia, uncontrolled hyperglycemia, and glycemic control in non-critical care areas. They compared the baseline results in 2011 with the post intervention implementation results in 2014. The intervention that was implemented included new protocols for insulin control and hypoglycemia prevention in a pilot hospital, and after that, they implemented them across the other eight hospitals. Glucometrics were used to assess the effectiveness of protocols based on the Society of Hospital Medicine (SHM) benchmarking studies. The targets were developed for each hospital's indicators with the aim to increase their performance by 10%–20% from their baseline. The results were as follows: the day-weighted mean BG for all the nine hospitals combined improved by 11.4 mg/dL (95% confidence interval [CI]: 11.0–11.8]) for the whole cohort of hospitals, and eight of the hospitals had a decrease in severe hyperglycemic days. In addition, the percentage of patient-days with BG > 299 mg/dL decreased from 11.6% to 8.8% (relative risk of 0.76 [95% CI: 0.74-0.78]) for the total cohort.

Moreover, the percentage of patient-days for hypoglycemia defined as BG < 70 mg/dL stayed unchanged at 3.6%. Finally, eight of the hospitals had either reduced hypoglycemia by 20% or reached the SHM best-quartile rates.

In summary, glycemic control is important in diabetic patients during hospitalization as both hyperglycemia and hypoglycemia can increase the risk for adverse events such as infection, mortality among others. Most diabetic patients are switched from oral hypoglycemic agents to insulin upon admission for acute conditions. Evidence based protocols were developed accounting for the stress of illness, surgery, mode of nutrition and use of medications like glucocorticoids. The adult subcutaneous insulin clinical order sets protocol was developed to control the BG levels and the hypoglycemia management protocol to manage hypoglycemic episodes during hospitalization. Outcome indicators are used to evaluate the effectiveness of these protocols in maintaining glycemic control.

CHAPTER III

METHODOLOGY

A. Design

This was a retrospective cohort study based on electronic medical record review.

B. Sample

The sample included a total of 228 adult inpatients 18 years and above, admitted to medical-surgical units (9 north, 9 south, 10 south, 10 north, and 5 south) and known to have T2DM who were hospitalized three months before (December 2020, January, and February 2021) and three months after (May, June, and July 2021) implementation of the new adult subcutaneous insulin clinical order sets and hypoglycemia management protocol. Inclusion criteria were the patients had to be admitted for at least 48 hours and have at least four POCT BG readings. Exclusion criteria included patients with type 1 diabetes mellitus (T1DM) because this population has its unique management, and patients from maternity, obstetrics, and gynecology wards. Additionally, pregnant women admitted to medical-surgical units were excluded because they sought special treatment with a different BG target. Moreover, patients admitted with Diabetes Ketoacidosis (DKA) and hyperglycemic hyperosmolar state (HHS) were excluded because their extended hyperglycemia will skew BG data. The inclusion and exclusion criteria are based on the Schnipper et al. (2008) recommendations.

After screening the medical records of all patients with T2DM who were admitted in the period indicated above, a total of 52 patients were excluded from

the sample for the following reasons: 22 patients did not have a POCT order, 12 patients had POCT order that was less than four times per day, ten patients were transferred to critical care area, six patients were admitted to the CCU, one patient was diagnosed with DKA, and another patient had T1DM.

C. Procedure

Approval of the institutional review board (IRB) was secured. The data were extracted using the Electronic Privacy Information Center (EPIC) system. Fingerstick POCT-BG results with their timestamp for all patients with T2DM who were admitted three months before the initiation of the new protocol were collected. Moreover, data were collected for three months after implementing the new protocols.

The extracted data included fingerstick POCT-BG levels of the sample taken for people who can tolerate oral intake pre-meals and at bedtime. For people who were at risk for hypoglycemic events, more information on glucose levels at 1 am was available to help detect possible hypoglycemia. Additionally, patients who were NPO, on enteral feeding, and receiving total parenteral nutrition (TPN) or peripheral parenteral nutrition (PPN) had their POCT-BG levels taken every 4 hours. Thus, the number of BG samples per day varied between patients. The BG data on the first day of hospitalization and following day 15 were not extracted because it was assumed that the patient would be in acute condition on day 1 or uncontrolled if he/she had a prolonged hospital stay beyond 14 days that would lead to his/her unstable BG and thus would the results; this was in line with the recommendations of Maynard et al. (2014).

The First day of admission was excluded because early BG control is impacted by multiple variables beyond the direct control of the clinician such as glucose control

prior to admission and severity of the presenting illness and may not realistically reflect the effect of the hospital's intervention. In addition, we excluded BG measure after day 14 for patients with prolonged hospital stay to avoid skewing caused by data from the patients with very prolonged hospital stays.

D. Measures

The variables in the data collection sheet (see Appendix 3) included: BG levels captured by date and time, gender, HbA1c results, length of stay, endocrinology team consultations, eGFR levels, insulin treatment regimen during hospital admission (no insulin, basal with or without prandial insulin, supplemental insulin only, and all of them together), Insulin type, number of antidiabetic agents used at home, comorbidities, and receipt of glucocorticoid treatment. Below is a description of the above variables.

- Length of stay (LOS) is defined as the number of days the patient was available in the hospital from admission until discharge. LOS is a significant indicator that reflects the efficacy of hospital management, patient quality of care, and functional ability of the patient. Reduction in the patients' length of stay is associated with lower risk for new infections, drug side effects, as well as better treatment outcomes and decreased mortality rate (Baek et al., 2018).
- Glycated hemoglobin (HbA1c) is indicative of BG level in the last 90 days, which is around the red blood cell's predicted half-life. HbA1c is a standard marker used to evaluate and monitor diabetic patients, especially T2DM (Sherwani et al., 2016), and is usually measured in the serum. Furthermore, HbA1c can be used to classify individuals as nondiabetic, prediabetic, or diabetic. Patients who are non-diabetic have an HbA1c of less than 5.7%, those

who are diagnosed as prediabetic have HbA1c between 5.7% and 6.4%, and diabetic patients have 6.5% and more according to the most recent practice guidelines for the management of T2DM by the American Diabetes Association [ADA] (ADA Professional Practice Committee, 2022). In addition, it is recommended to request an HbA1c test for the diabetic patients who are hospitalized and do not have a recent HbA1c test (ADA Professional Practice Committee, 2022).

- Endocrinology consultation is the evaluation of the patient by an endocrinologist upon a consultation request. Taking care of diabetic inpatients by the diabetes specialists and endocrinology team was found to result in decreasing the length of stay, optimizing glycemic control, and improving overall clinical outcomes (Mendez et al., 2015). This was measured by the endocrinologist's consultation note documented in the medical record by either the endocrinology attending or the fellow.
- Estimated glomerular filtration rate (eGFR) estimates kidney function in filtering creatinine as a waste product. It is calculated based on age, sex, serum creatinine and race (CKD Epidemiology equation used at AUBMC labs). Moreover, an important role of the kidneys is insulin metabolism. Insulin levels may depend on renal function. In people with chronic renal disease, insulin remains longer in plasma (National Kidney Foundation, 2012).
- Insulin treatment is captured in medication administration notes on EPIC. For patients who tolerate oral intake, the recommendations for insulin treatment are basal insulin, prandial insulin, and insulin based on correction scale. For patients who are unable to tolerate oral intake or are taking nothing by mouth (NPO),

basal insulin with or without a correction scale is recommended as an insulin treatment. (American Diabetes Association Professional Practice Committee, 2022).

- Glucocorticoid treatment is captured in the medication administration notes on EPIC. Hospitalized patients who receive glucocorticoids $\geq$ 40 mg/day for $\geq$ 2 days may experience hyperglycemia. Besides, glucocorticoids treatment by any route (topical, oral, inhaled, intramuscular, intravenous, or intra-articular) for diabetic patients may worsen their glycemic control (Suh & Park, 2017).
- Comorbidity is a physical or mental disorder that coexists with the primary disease of focus. The comorbidities related to T2DM vary on a spectrum from hypertension and obesity to liver disease. In one study, over 97% of patients had one comorbidity and 88.5% had at least two comorbidities in addition to their diabetes (Iglay et al., 2016).

BG levels were analyzed using equations that are based on three units of analysis: patients-day, patients-stay, and patients-sample (Thomas & Inzucchi, 2008). These units are defined as:

- Patient-day is a calendar day during which at least one BG determination was made. The mean of the BG values taken for every patient per day were calculated. Next, the mean of patient day BG means was calculated for each patient. Then, the patient-day-weighed mean was then calculated across all patient-days.
- The patient-stay is indicated by the patient's medical record number, i.e., it represents one patient. The mean of the patient-stay BG is the sum of the means for each patient divided by the number of monitored patients.

- A patient-sample is one BG sample. In this level of analysis, the mean of all equally weighted BG measurements that are done for all hospitalized patients is calculated.

The three metrics patient-stay, patient-day, and patient-sample were calculated based on the equations listed below (Thomas & Inzucchi, 2008):

n of units of analysis: patients-stays:

Glycemic exposure: Mean of all patients stay means

Percent at target: (#of patient-stay means in range/# patient -stays) *100

Adverse event rate: (# patient-stays with hypoglycemia/# patient-stays) *100,

(# Patient-stays with hyperglycemia/# patient -stays) *100

n of units of analysis: patients-days:

Glycemic exposure: Mean of all patient-day means

Percent at target: (# patient-day means in range/# patient-days) *100

Adverse event rate: (# patient-days with hypoglycemia/# patient-days) *100

(# Patient-days with hyperglycemia/# patient-days) *100

n of units of analysis: patients-samples:

Glycemic exposure: Mean of all patient samples

Percent at target: (#samples in range/# patient-samples) *100

Adverse event rate: (# samples with hypoglycemia/# patient- samples) *100

(# Samples with hyperglycemia/# patient- samples) *100

E. Data Analysis

Glucometrics were calculated on the inpatient cohort admitted during the three months before the new protocols were initiated and for the inpatient cohort of patients admitted during the three-month period after. The two cohorts' mean, median, standard

deviation (SD), and range of glucose measurements were then calculated for each of the three metrics: patient-stay, patient-day, and patient-sample. These glucometrics were analyzed with the Statistical Package of the Social Sciences (SPSS) version 28, using the independent sample t test (or its nonparametric equivalent when the data were skewed) or chi squared test to compare values at pre and post protocol implementation (Aim 1). After that, glucometrics values post protocol implementation were compared to corresponding SHM benchmark values using the one sample test (Aim 2).

CHAPTER IV

RESULTS

The total number of patients was 228, i.e., 228 patients; this consisted of 86 patients before the protocols were implemented (pre-protocol) and 142 patients after implementation of the protocol (post-protocol). The total number of BG samples drawn for all 228 patients was 4,579, including 1,742 samples before the protocol and 2,837 samples after implementation of the protocols. There was an average of 20.09 samples per patient, 20.27 pre-protocol and 19.98 post protocol. The total number of patient days was 1,196 days, including 461 days pre protocol and 735 days post protocol. The number of BG samples per patient day was 3.83. Table 1 shows the main characteristics of the total sample and by group, pre – protocol and post-protocol. The vast majority of the sample (58.3%) were male, with 54.7% males in the pre-protocol group and 60.6% males in the post-protocol group. Furthermore, the length of stay in the pre- and post-protocol groups were 7.14 days (SD 6.32) and 7.32 days (SD 6.62), respectively.

The mean HbA1c in the pre-protocol group was higher than the post-protocol (7.42% vs. 7.09%, respectively). Moreover, serum creatinine and eGFR were higher in the pre-protocol than in the post-protocol group, with 1.81 mg/dL (SD 1.89) for creatinine vs 1.63 (SD1.31), and 58.78 (SD 33.59) mL/min/1.73 m^2 for eGFR vs 55.92 (SD 30.7). Endocrinology consultations were slightly more frequent post-protocol compared to pre-protocol (22.5% vs. 20.9%). None of these differences between the two groups was statistically significant. Hypertension was the most frequent co-morbidity in the sample: 87.2% pre-protocol and 83.8% post-protocol, followed by dyslipidemia (55.8% vs 53.5%), while myocardial infarction was the least frequently

diagnosed at 2.3% pre-protocol and 3.5% post-protocol. Other co-morbidities reported by 75% of the sample include chronic obstructive pulmonary disease, anemia, Parkinson's disease, Alzheimer's disease, osteoarthritis, and rheumatoid arthritis. The only marginally significant group difference in comorbidities was in coronary artery disease, which was more frequent in the post protocol group. (p=0.084).

The insulin regimen that included only supplemental insulin administered based on regularly monitored BG levels was the most common order during hospitalization, with a significant difference between the two groups, with 74.6% in post-protocol compared to 54.7% in pre-protocol (P =0.002). On the other hand, the prandial only regimen was significantly more often prescribed in the pre-protocol group than the post protocol group (12.8% vs. 0.7%, $p < 0.001$).

Apidra was the most frequently used type of insulin; it was significantly more often used pre-protocol in 88.4% than post-protocol (64.8%) as a short acting insulin ($p < 0.001$). Humalog was significantly more often used post protocol than pre-protocol (19.7% vs 1.2%, $p < 0.001$). A similar pattern was noted for Humalin R (7.7% vs. 1.2%, $p = 0.033$). On the other hand, Lantus was the most frequently used agent among the long-acting insulins, with the average frequency almost the same pre- and post-protocol, at 25.6% and 25.4%, respectively. Treatment with glucocorticoids was 27.9% in the pre-protocol and 19% post-protocol and the difference was not statistically significant.

Table 2 Descriptive for the whole sample and by group (N = 228)

Variables	**Pre-protocol sample (N=86, 37.7%)**	**Post-protocol sample (N=142, 62.3%)**	**Total (N=228)**
Age (Mean ± SD)	73.16±10.77	73.10±12.15	73.12 ±11.62

Gender: Male (n, %)	47 (54.7%)	86 (60.6%)	133 (58.3%)
Length of stay (Mean ± SD)	7.14±6.32	7.32±6.62	7.25±6.50
HbA1C within 90 days of admission (Mean ± SD)	7.42±1.94	7.09±1.43	7.21 ±1.63
Serum Creatinine at admission (Mean ± SD)	1.81±1.89	1.63±1.31	1.70±1.56
eGFR (Mean ± SD)	58.78±33.59	55.92±30.70	57±31.80
Endocrinology consultation (n, %)	18 (20.9%)	32 (22.5%)	50 (21.9%)
Co-morbidities (n, percent):			
Hypertension	75 (87.2%)	55 (38.7%)	78(34.2%)
Other (Anemia, osteoarthritis,	68 (79.1%)	5 (3.5%)	7 (3.1%)
COPD…)	48 (55.8%)	22 (15.5%)	34 (14.9%)
Dyslipidemia	23 (26.7%)	119 (83.8%)	194 (85.1%)
Coronary artery disease$^{\perp}$	26 (30.2%)	28 (19.7%)	41 (18.0%)
Chronic renal disease	24 (27.9%)	41 (28.9%)	65 (28.5%)
Cancer	13 (15.1%)	46 (32.4%)	72 (31.6%)
Heart failure	12 (14%)	29 (20.4%)	41 (18.0%)
Stroke	18 (20.9%)	76 (53.5%)	124 (54.4%)
Thyroid disease	12 (14%)	20 (14.1%)	38 (16.7%)
Atrial fibrillation	10 (11.6%)	12 (8.5%)	22 (9.6%)
Peripheral vascular disease	2 (2.3%)	103 (72.5%)	171 (75.0%)
Myocardial infarction			
Insulin regimen during hospitalization (n, %)			
Supplemental insulin only*	47 (54.7%)	106 (74.6%)	153 (67.1%)
Basal, prandial, and supplemental insulin	20 (23.3%)	23 (16.2%)	43 (18.9%)
Basal insulin only$^{\perp}$	8 (9.3%)	27 (19%)	35 (15.4%)
No insulin	7 (8.1%)	8 (5.6%)	15 (6.6%)
Prandial only*	11 (12.8%)	1 (0.7%)	12 (5.3%)
Basal and prandial insulin	1 (1.2%)	2 (1.4%)	3 (1.3%)
Hypoglycemic agents in hospital (n, %)			
Apidra*	76 (88.4%)	92 (64.8%)	168 (73.7%)
Lantus	22 (25.6%)	36 (25.4%)	58 (25.4%)
Humalog*	1 (1.2%)	28 (19.7%)	29 (12.7%)
Tresiba	7 (8.1%)	13 (9.2%)	20 (8.8%)
Humalin R*	1 (1.2%)	11 (7.7%)	12 (5.3%)
Insulin degludec-insulin aspar (70-30)	0 (0)	3 (2.1%)	3 (1.3%)
Humalin N	1 (1.2%)	0 (0)	1 (0.4%)
Trajenta PO	0 (0)	1 (0.7%)	1 (0.4%)
Novonorm	0 (0)	1 (0.7%)	1 (0.4%)
Number of oral hypoglycemic agents taken at home (Mean ± SD)	2.02±1.35	1.89±1.20	1.94 ±1.25
Glucocorticoid treatment (n, %)	24 (27.9%)	27 (19%)	51 (22.4%)

Legend: SD = standard deviation; ⊥: 0.05 < p value <0.1; * p < 0.05

A. Glucometrics Indicators

Table 2 illustrates the glucometrics of the three models for the whole sample which includes mean, median, and the percent of BG in range, hypoglycemia (<70 mg/dL), and hyperglycemia (≥180) and severe hyperglycemia >299 mg/dL).

The overall fingerstick dataset contained 4579 samples from 228 patients, yielding an average of 20.09 BG results per patient. There were 1,196 days during which an individual patient had at least one BG measurement (patient days), for an average of 3.83 BG results per patient day.

The means and median BG levels of the three models were different. The patient day mean BG was the highest at 175.51 mg/dL ± 45.13 median = 168.48 mg/dL; after that, the patient stay mean BG was 175.03 mg/dL ± 44.65 median = 166.45 mg/dL, and the patient sample mean BG was 173.87 mg/dL ± 66.56 median = 158.00 mg/dL. Furthermore, the patient day had the lowest percent of BG values within the range 70-149 mg/dL, which was 36.75%, versus 44.29% for the patient stay; and 45.2%, which is slightly higher in the patient sample. Hypoglycemia events less than 70 mg/dL were roughly comparable in both the patient sample and the patient stay models (0.7% vs. 0.62%), but it was higher in the patient day at 3.07%. Furthermore, the numbers were nearly identical in hyperglycemia (BG ≥ 180 mg/dL) (39.5 vs. 40.25%, 40% across models). Finally, severe hyperglycemic events >299 mg/dL were highest in the patient day model (9.05%) and lowest in the patient stay (0.44%), with the patient sample accounting for 5.4%.

Such disparities in the findings by unit of analysis were to be expected, as the frequency of such dichotomous occurrences is highly dependent on the size of the

denominator. When using the patient/patient stay as the unit of analysis, for example, a single hyperglycemic episode classifies a patient's whole hospital stay as "hyperglycemic," even if that patient had normal BG levels for the duration of his or her hospital stay.

Table 3 Glucometrics for the whole sample using the 3 levels of analysis

Measure Model	Patient sample (4,579 samples)	Patients stay (228 patients)	Patient day (1,196 days)
Number of BG samples	4,579	20.09	3.83
Mean ± SD BG (mg/dL)	173.87±66.56	175.03 ± 44.65	175.51 ± 45.13
Median BG (mg/dL)	158.00	166.45	168.48
% BG in range (70-149 mg/dL)	45.2	44.29	36.75
%Hypoglycemic events (BG < 70 mg/dL)	0.7	0.62	3.07
% Hyperglycemic events (BG ≥ 180 mg/dL)	39.2	40.25	40.00
% Severe hyperglycemic events (BG >299 mg/dL)	5.4	0.44	9.05

Comparison of glucometrics pre and post protocol for the BG samples.

Table 3 outlines the difference in glucometrics between pre- and post-protocol groups. The number of post-protocol patient days (735), the patient stays (142), and the patient sample (2837) were all greater than the number of pre-protocol patient days (461), the patient stays (86), and patient sample (1742).

The mean of BG samples has significantly decreased from 182.93 mg/dL ± 71.21 pre-protocol to 168.31 mg/dL ± 62.90 post-protocol ($p < 0.001$). Moreover, the BG within range in the sample has considerably increased from 42.5% to 46.9% ($p =$

0.002). Hypoglycemia < 70 mg/dL was more common in post-protocol, (0.9% vs. 0.3%; p = 0.016). Nevertheless, hyperglycemia ≥ 180 mg/dL and > 299 mg/dL both significantly dropped from 43.4% to 36.6%, and from 7.9% to 3.8%, respectively.

The mean BG within range per stay was also increased, but not significantly, from 42.40 mg/dL ± 29.77 to 45.43 mg/dL ± 31.60 (p=0.475). In addition, the BG < 70 mg/dL per stay was not significantly higher in the post-protocol analysis, from 0.29 mg/dL ± 2.01 to 0.82 mg/dL ±3.37 (p= 0.132). In the same manner, the BG ≥ 180 mg/dL per stay has decreased in post-protocol (44.16 mg/dL ±28.10 vs. 37.88 mg/dL ±30.20; p=0.124) but is not significant. On the other hand, the BG > 299 mg/dL per stay was significantly lower in post-protocol than pre-protocol (0.67 mg/ dL ±1.36 vs. 0.30 mg/dL ±0.83 0.83; p = 0.027).

The patient-day weighed BG mean dropped significantly from 183.48mg/dL ±47.57 to 170.68 mg/dL ±42.76 (p = 0.038). The BG within range per day was higher in the post-protocol group (39.65±39.94 vs. 31.96±36.30; P=0.147) but was not statistically significant. Similarly, BG < 70 mg/dL per day was not significantly higher in the post-protocol than the pre-protocol (3.07 mg/dL ±12.36 vs. 3.07 mg/dL ±12.36; P = 0.139). Furthermore, hyperglycemic BG ≥ 180 mg/dL per day has dramatically dropped from 67.14 mg/dL ±36.58 to 62.10 mg/dL ±38.32 (p= 0.324). Finally, hyperglycemic BG > 299 mg/dL per day was significantly lower in the post-protocol (18.47 ±28.68 vs. 9.05 ± 19.38; p = 0.07).

Table 4 Difference between the pre-protocol and post-protocol groups in glucometrics by sample

Measures	**Pre protocol group Mean ± SD Or %**	**Post protocol group Mean ± SD Or %**	**95% confidence interval of the Mean difference**	**P value**

Patient days	461	735		
Patient stays	86	142		
Patient samples Sample BG	1,742 182.93 ±71.21	2,837 168.31 ±62.90	10.56, 18.70	< 0.001
BG samples within range (%)	42.5%	46.9%	1.06. 1.34	0.002
BG < 70 mg/dL (%)	0.3%	0.9%	1.10, 6.52	0.016
BG ≥ 180 mg/dL (%)	43.4%	36.6%	0.67, 0.85	<0.001
BG > 299 mg/dL (%)	7.9%	3.8%	0.35, 0.59	<0.001
Patients stay level Any BG within range per stay	42.40±29.77	45.43±31.60	-11.35, 5.30	0.475
Any BG < 70 mg/dL per stay (%)	0.29 ± 2.01	0.82 ±3.37	-1.24, 0.16	0.132
Any BG ≥ 180 mg/dL per stay (%)	44.16 ±28.10	37.88 ±30.20	-1.73, 14.29	0.124
Any BG > 299 mg/dL per stay (%)	0.67 ±1.36	0.30 ±0.83	0.04, 0.68	0.027
Patient day level Patient-day weighed BG mean	183.48±47.57	170.68±42.76	0.73, 24.86	0.038
Any BG within range 70-149 mg/dL per day (%)	31.96±36.30	39.65±39.94	-18.08, 2.71	0.147
Any BG < 70 mg/dL per day (%)	1.12 ±7.50	3.07 ±12.36	-4.55, 0.64	0.139
Any day with at least one hyperglycemic BG ≥ 180 mg/dL per day (%)	67.14 ±36.58	62.10 ±38.32	-5.00, 15.08	0.324

Any day with at least one hyperglycemic BG > 299 mg/dL per day (%)	18.47 ±28.68	9.05 ± 19.38	2.56, 16.27	0.007

B. Comparison of post protocol glucometrics with the benchmark

Table 4 compares the AUBMC post-protocol glucometrics data to the USA benchmark. In order to compare the results with those reported by Maynard and colleagues (2014), the following parameters were compared in addition to the patient-day-weighed mean glucose: 1) percent stays with BG means ≥ 180 mg/dL, 2) percent patients days with any BG ≥ 180 mg/dL, 3) percent patients days with any BG < 70 mg/dL, and 4) percent patient day with any BG means per day > 299 mg/dL. The post-protocol mean of 169.66 mg/dL was slightly higher than the benchmark's mean of 162 mg/dL ($p = 0.033$), but it was within the range of the benchmark of 128.4 to 187.5 mg/dL. Furthermore, with a p value < 0.001, the patient's stays with BG means ≥ 180 mg/dL were higher by 10.37% than the benchmark, yet within the range of 6.8-43.3%. Moreover, patient days post-protocol with any BG per day ≥ 180 mg/dL were 62.09%, which was double the benchmark of 30.5% and higher than the range 12-45.8% ($p < 0.001$). On the other hand, there was no significant difference between the AUBMC data and the benchmark in the percent patient days with any BG mean > 299 mg/dL. Finally, the mean patient day with any BG less than 70 mg/dL was lower than the benchmark (3.07% vs 5%), approaching statistical significance ($p = 0.065$).

Table 5 Comparison of post protocol glucometrics with the benchmark

Variable	**Post protocol sample**			**Benchmark**			**t**	**P value**
	Mean	**Median**	**Range**	**Mean**	**Median**	**Range**		
Patient-day Weighed	169.66	163.10	96.27-294.75	162	164.4	128.4-187.5	2.16	0.033

mean glucose								
Stays with BG mean ≥ 180 mg/dL (%)	37.87	33.33	0-100	27.5	28.4	6.8-43.3	4.10	<0.001
Patient day with any BG ≥ 180 mg/dL (%)	62.09	75.0	0-100	29.5	30.5	12-45.8	10.14	<0.001
Patient day with any BG > 299 mg/dL (%)	9.05	0.00	0-100	10.5	10.9	2.7-21.5	-0.89	0.375
Patient day with any BG < 70 mg/dL (%)	3.07	0.00	0-100	5.0	4.9	1.7-13.1	-1.86	0.065

CHAPTER V

DISCUSSION

This quality improvement project was done to compare the glucometrics at AUBMC before and after implementation of adult subcutaneous insulin clinical order sets and a hypoglycemia management protocol, and to compare glucometrics after the protocol's implementation with the SHM benchmark values. The analysis was done at three levels (population, patient, and patient day).

When examining practice at AUBMC, a number of observations can be made based on the sample data. There was no difference in the descriptive variables between the two groups, pre- and post-protocol. During the study, endocrinologists were only consulted when there were patients with severe, uncontrolled BG, particularly those who were scheduled for surgery. There was a minimal increase post-protocol in endocrinology consultations of 1.6%. When considered with the increase in use of supplemental insulin only from 54.7% to 74.6%, these findings suggest lack of compliance with ADA recommendations by ordering an insulin supplemental scale exclusively. Thus, the endocrinology team should be consulted to adjust the patients' regimens and to guide the medical team on the proper use of the AUBMC protocols.

In addition, supplemental insulin only was the most common order among insulin regimens during hospitalization, and it showed a significant increase in post-protocol with 74.6% compared to 54.7% in pre-protocol. However, the ADA strongly advises against using supplemental insulin based on sliding scales exclusively in managing BG in patients with T2DM (ADA professional practice committee, 2022). The ADA recommends the basal, prandial, and supplemental scales combined as the regimen of preference; yet in this study, such combination regimen accounted for only

18.9% of the insulin regimens used, with the pre-protocol at 23.3% as compared to the post-protocol (16.2%). These data suggest the need for greater rates of compliance in diabetes management with the ADA guidelines in order to improve glucose control. It is worth noting that those cases seen by the endocrinologist were more likely to be treated according to the guidelines.

Apidra was by far the most often utilized kind of insulin; it was considerably more frequently administered as short-acting insulin (86.4%) prior to protocol. Apidra usage fell to 64.8% when Humalog and Humulin R were added to the post-protocol. This change was due to the unavailability of Apidra as a short-acting insulin.

The comparison of pre- and post-protocol data revealed significantly lower sample BG values, lower hyperglycemia, and less severe hyperglycemia, with somewhat higher hypoglycemia in the post-protocol data compared to the pre-protocol data, as shown in Table 3. There was a significant reduction in the sample mean BG level from 182.93 mg/dL in the pre-protocol period to 168.31 mg/dL in the post-protocol period. The post-protocol sample patient day weighed mean BG (169.91 mg/dL) was lower than the 178 mg/dL reported by Kyi et al. (2019) in the non-critical care units.

Furthermore, in the study that was done by Goldberg et al. (2006), the percent of hypoglycemic events was 1.5%, and another study done by Kyi et al. (2019) showed a hypoglycemic event rate of 1.9%, which was higher than the two protocol groups at AUBMC: 0.29% for the pre-protocol group and 0.82% for the post-protocol group. Therefore, AUBMC has a low percentage of hypoglycemia (BG less than 70 mg/dL) compared to the findings by Goldberg et al. (2006) and Kyi et al. (2019).

The percent of hyperglycemia (BG ≥ 180 mg/dL) in the patient-sample decreased from 43.4% in the pre-protocol period to 36.6% in the post protocol period. However, Kyi et al. (2019) reported 40% hyperglycemia in their sample. In addition, in Goldberg et al.'s (2006) study, the prevalence of severe hyperglycemia (BG > 299 mg/dL) was 12.8%, whereas AUBMC percentage with severe hyperglycemia for patient-samples have decreased from 7.9% in the pre-protocol to 3.8% in the post-protocol. So, both the pre- and post-protocols at AUBMC have a lower percentage of patient samples with severe hyperglycemia than the Goldberg study sample.

The percentage of BG samples in the range (70-149 mg/dL) increased from 42.50% in the pre-protocol period to 46.9% in the post-protocol period. Goldberg et al. (2006), 33.9% of their samples were in range, which is lower than AUBMC protocols, but their range was narrower than ours: 80 to 139 mg/dL versus 70 to 149 mg/dL. Therefore, comparison of pre and post protocol data revealed significantly lower sample BG values, lower hyperglycemia, and less severe hyperglycemia, with somewhat higher hypoglycemia in post-protocol data compared to pre-protocol data. So, there seems to be better glycemic control after implementation of the protocol.

The weighed patient-day mean BG has significantly dropped from 183.48 mg/dL in the pre-protocol to 170.68 mg/dL in the post-protocol period, which is lower than the one reported by Kyi et al. (2019) of 172 mg/dL. Besides, the percentage of days with any BG per day ≥180 mg/dL, which was 67.14% in the pre-protocol, has deflated to 62.10% post-protocol, which is slightly higher than that reported by Kyi et al. (2019) at 57%. Nevertheless, the percentage of BG per day within range (between 70 and 149 mg/d) has increased from 31.96% to 39.65%, which shows an improvement in

the patients within range and shows that there is still room for improvement. On the other hand, the percent patient days in which at least one hypoglycemic event occurred in this study at AUBMC was much lower than in that of Bersoux et al (2014), at 3.07% vs 6.1%, whereas the percent patient days with at least one BG $\geq$ 180 mg/dL was higher (62.09 vs 32.3%).

Goldberg et al. (2006) noted that the analysis at the level of the population is more biased towards showing significant difference, by virtue of the large number of samples, as opposed to using patient-days or patient stays as the unit of analysis, as shown in this study. Each model has its strengths and limitations, so a combination of ways of analyzing data is recommended. The improvement in glucometrics was statistically significant mostly at the samples' level of analysis. This may be due to the small sample (228 patient stays). Significantly lower severe hyperglycemia (BG > 299 mg/dL) was found post protocol at all levels of analyses (samples, patient stay and patient day). The protocols were effective in reducing severe hyperglycemia but there is room for improvement for this protocol.

Optimal glycemic management requires a balance between minimizing hyperglycemia and avoiding hypoglycemia, and a full glucometrics study evaluates and reports both parameters concurrently. We followed the SHM benchmark numbers to identify hyperglycemia, severe hyperglycemia, hypoglycemia, and severe hypoglycemia, but other investigators had different thresholds to glycemic alterations. Goldberg et al. (2006), for example, determined hypoglycemia to be BG less than 60 mg/dL, hyperglycemia to be BG greater than 300 mg/dL, and the normal range to be 80–139 mg/dL. The results in Table 4 that compare the post protocol data at AUBMC to

the benchmark, showed that all BG values post protocol at AUBMC were all within the range of the benchmark, except for the patient day with any BG $\geq$ 180 mg/dL, which was 62.09% vs. 29.5% for the benchmark and also higher than the upper limit of the benchmark's range of 12% to 45.8%, which shows that there is room for improvement for this protocol. It is worth noting that in a later study Maynard and colleagues (2017) examined glycemic control from non-ICU units in 9 US hospitals and reported only the patient day-weighed mean BG of 161 mg/dL (median 160); percent patient-days with any BG > 299 mg/dL of 1.2% (median 10.5%) and percent patient-days with any BG < 70 mg/dL of 5.1% (median 4.7%). These benchmarks do not differ significantly from the ones used earlier by Maynard et al. (2014) for the non-ICU units of 76 hospitals in the USA.

A. Limitations

Differences in patient selection and hospital processes may restrict comparisons to the SHM standard. Because the SHM benchmark lacked information about patient-level clinical data, we could not determine if the AUBMC and SHM samples were similar. It is worth noting that only diabetic patients were included in this study, whereas the SHM benchmark study (Maynard et al., 2014) included all patients with hyperglycemia who are monitored, including diabetic and non-diabetic patients. This could explain the higher hyperglycemia. Also, the AUBMC population was small, and 17 patients were readmitted during the period of this study on different dates, but we included all these admissions as we considered the admission to be the case, not the particular patient, which may affect the results. Furthermore, there were different frequencies in the number of BG samples per day for the same patient, where some of the patients had less than 4 BG readings either because the patient was out of the nursing unit, or he/she

refused to have a BG fingerstick test. Nevertheless, AUBMC has recently introduced standardized protocols, which made it possible to analyze glucometrics and compare them with the SHM benchmark. Another limitation may be the different treatments for T2DM to control hyperglycemia and hypoglycemia used in our study compared to others, especially since the investigators in the literature did not describe their treatment protocols. Also, the benchmark used for this study (Maynard et al., 2014) was the most cited one that was available in the literature. Maynard et al. published a benchmark based on nine hospitals in 2017, but the results did not vary from those of 2014. In addition, there were limited studies about glucometrics and benchmarking, which were covered in only a few articles. The literature was heterogeneous in its definition of hypoglycemia, which limited the comparisons. Finally, the mean time to resolution of hypoglycemia could not be evaluated/compared to the benchmark because of inaccurate documentation.

B. Conclusion

This project provided preliminary data to evaluate the effectiveness of the newly introduced protocols for BG control. To evaluate the accuracy of the various methods and levels of analysis of the data, investigators recommend using user-friendly tool that hospitals may use to expedite quality measure computation for the management of inpatients with diabetes like the one mentioned in Chen et al. (2021) to allow such concurrent analyses, using machine learning. It is worth mentioning that in this study, the results did not differ a lot by the method of analysis used. Other investigators still used different ways of analyzing the data. It is recommended to use multiple ways of analysis since no one method is considered superior. The findings show promise, but

there is room for improvement, including more compliance with the guidelines and better documentation.

APPENDIX I

Glucometrics	**Mean**	**Median**	**Range**	**Top 25th percentile**
Patient-day weighed mean POC BG (mg/dL)	162	164.4	128.4 – 187.5	≤ 157.0
Patient-day POC BG means ≥180 mg/dL (%)	29.5	30.5	12.0 – 45.8	≤ 21
Stays with POC BG mean (day-weighed) ≥ 180 mg/dL (%)	27.5	28.4	6.8 – 43.3	≤ 24
Patient-days with any POC BG > 299 mg/dL (%)	10.5	10.9	2.7 – 21.5	≤ 6.9
Patient-days with any POC BG < 0.570 mg/dL (%)	5.0	4.9	1.7 – 13.1	≤ 3.3
Patient-days with any POC BG < 40 mg/dL (%)	0.6	0.5	0.1 – 1.6	≤ 0.3
Hypoglycemic patients with recurrence (%)	32.4	33.2	7.0-52.7	≤ 27.3
Mean time to resolution of hypoglycemia (minutes)	127	120	39 - 245	≤ 78

Benchmarking for Select Glucometrics from 76 Hospitals: Non-ICU Adult Units

NB: Reproduced from Maynard et al. (2014). Based on data from 476 non-ICU units representing 265,337 patient-stays and 956,424 patient-days.

APPENDIX II

AUBMC AMERICAN UNIVERSITY of BEIRUT MEDICAL CENTER **Adult Subcutaneous Insulin Clinical Order Sets**	Identification label
Last Name: _____ **First & Middle Name:** _____ **Patient Number:** _____ **Date of Birth:** _____ **Age:** _____ **Gender: ☐ Male ☐ Female** **Admission Date:** _____ **Admitting Physician:** _____	**Unit:** _____ **Weight:** _____ **Height:** _____ **Expanded Precautions:** ☐ None ☐ Airborne ☐ Droplet ☐ Contact ☐Contact Plus **Other Precautions:** _____ **Allergy (specify reaction):**

The following abbreviations may not be used to document patient care: U IU QD QOD .X mg X.0 mg MS MSO_4 $MgSO_4$ CC µg mcg

☑Check the Applicable Order

	Nurse's Name & Signature	**Time Noted**
☐ HbA1C level (if none obtained in past 90 days) ☑ Activate hypoglycemia protocol		
Take finger stick blood glucose ☐ Before meals and at bedtime (if patient is tolerating diet or bolus tube feeds) (7:30 a.m., 11:30 a.m, 5pm, 9 p.m) ☐ Every 4 Hours (if patient is NPO, on continuous tube feeding, or receiving Total Parenteral Nutrition or Peripheral Parenteral Nutrition) ☐ Every 6 Hours (6am, 12am, 6 pm, 12 am) ☐ Before meals and at bedtime and 1 a.m. when there is a concern about night time hypoglycemia ((7:30 a.m., 11:30 a.m, 5pm, 9 p.m, 1a.m.)		
Information for MD ✓ **Consider Discontinuing Oral anti-hyperglycemic agents during hospitalization and perform discharge reconciliation** ✓ **Most patients should receive scheduled and supplemental/correction insulin** • If patient is on insulin pre-hospitalization, initial dose should be adjusted according to usual home insulin requirements. • If Oral hypoglycemic agents discontinued, and patients new to insulin, the following are suggestions for Total Daily Dose (TDD), however clinical judgment should always be used: – 0.3 units / kg / day if age greater than 70 years or hemodialysis or Chronic Kidney Disease – 0.4 units / kg / day if random blood glucose (BG) less than or equal to 180 mg/dL – 0.5 units / kg / day if random BG greater than 180 mg/dL or BMI greater than 27 kg/m2 or patient on glucocorticoid – 40-50% of total insulin dose is given as basal; balance as prandial / pre-meal bolus (divided by 3) ✓ **Re-evaluate & adjust the TDD daily based on the glycemic control of the previous 24h** in case of hypo- or hyperglycemia(**Use a new order set)** • If overall glucose consistently > 180-200, increase Total Daily Dose by 20% • If any episodes hypoglycemia (less than 70 mg/dl) adjust the corresponding insulin dose ✓**Re-evaluate & adjust the TDD daily based on a change in diet order (initiation of TPN, enteral feed) or nutritional status (e.g. vomiting, decrease in food intake) to assess the need for a new order** ✓ **Re-evaluate & adjust if patient is requiring more than 10 units of supplemental/correction insulin per 24 hours , or more than 3 results are greater than 200 mg/dL** ✓**Suggested Scale** Scale 1: For Insulin-sensitive < 40 units / day of scheduled insulin Scale 2: Standard dosing 40-80 units/day of scheduled insulin Scale 3: Insulin-resistant dosing > 80 units / day of scheduled insulin		

<table>
<tr><td colspan="4">Scheduled Insulin</td><td></td><td></td></tr>
<tr><td>Basal (Choose one)
☐ Lantus®
☐ Levemir®
☐ Tresiba® once daily
☐ Humulin® N</td><td>am
_____ units subcutaneously</td><td>NA</td><td>p.m.
_____ units subcutaneously</td><td></td><td></td></tr>
<tr><td>Prandial for Patients on oral diet

☐ Apidra ® (glulisine) 0-15 minutes before meals
☐ Humalog® (Lispro)
0-15 minutes before meals
☐ Regular R (short acting) 30 minutes before eating)</td><td>Breakfast
_____ units subcutaneously</td><td>Lunch
_____ units subcutaneously</td><td>Dinner
_____ units subcutaneously</td><td></td><td></td></tr>
<tr><td>Bolus tube feeding
☐ Apidra ® (glulisine) 0-15 minutes before meals
☐ Humalog® (Lispro)
0-15 minutes before meals
☐ Regular R (short acting) 30 minutes before eating)</td><td colspan="3">_____ units subcutaneously with each feeding bolus
every (circle one)
☐ 4 hours
☐ 6 hours
☐ 8 hours</td><td></td><td></td></tr>
<tr><td>Patient on continuous parenteral or tube feeding
☐ Apidra (glulisine)
☐ Humalog (Lispro)
☐ Regular</td><td colspan="3">_____ units subcutaneously every (circle one)
☐ 4 hours
☐ 6 hours</td><td></td><td></td></tr>
<tr><td colspan="4">Supplemental/ Correction Insulin (Should be the same type/brand as prandial insulin)
☐ Apidra® ☐ Humalog® ☐ Humulin® R

<table>
<tr><th>Blood Glucose mg/dl</th><th>☐ Scale 1</th><th>☐ Scale 2</th><th>☐ Scale 3</th></tr>
<tr><td>150 to 200 mg per dL</td><td>1</td><td>2</td><td>2</td></tr>
<tr><td>201 to 250 mg per dL</td><td>2</td><td>3</td><td>4</td></tr>
<tr><td>251to 300 mg per dL</td><td>3</td><td>5</td><td>7</td></tr>
<tr><td>301 to 350 mg per dL</td><td>4</td><td>7</td><td>10</td></tr>
<tr><td>Greater than 350 mg per dL</td><td>5+ Inform Physician</td><td>8+ Inform Physician</td><td>12+ Inform Physician</td></tr>
</table></td><td></td><td></td></tr>
<tr><td colspan="4">Administration Instruction
☑If glucose result is greater than 200 mg/dl at bedtime (or at 1 am if BG was checked) give 50% of the short acting insulin sliding scale dose rounded down (e.g. 2.5 rounded to 2)
☑ Skip the due scheduled short acting insulin when sources of feeding are discontinued (PN, Enteral or meals)
☑ Skip the due scheduled short acting insulin when blood glucose reading is less than 70mg/dl
☑ Administer Supplemental/ Correction AND Basal Insulin even if the patient is NPO</td><td></td><td></td></tr>
<tr><td colspan="4">☑ Inform physician in case of change in in diet order (initiation of Parenteral Nutrition, enteral feed) or nutritional status (e.g. vomiting, decrease in food intake) to assess the need for a new order
☑Inform physician if more than 3 results are greater than 200 mg/dL</td><td></td><td></td></tr>
</table>

MD Name: _____ **Signature:** _____

Date: _____**Time:** _____ **Pager Number:** _____

Original: Medical Record **~~ FAX OR SCAN TO PHARMACY ~~**

Copy: Pharmacy

APPENDIX III

AUBMC AMERICAN UNIVERSITY of BEIRUT MEDICAL CENTER	ID Label
Adult Hypoglycemia Management Protocol Order SET	
Last Name…… **First & Middle Name……..** **Patient Number……..** **Date of birth……** **Age…….....Gender……** **Admission Date ……** **Admitting Physician……**	**Unit:** **Weight:** **Height:** **Expanded Precautions:** ☐ None ☐ Airborne ☐ Droplet ☐ Contact ☐ Contact Plus **Other Precautions:** **Allergy (specify reaction):**

The following abbreviations may not be used to document patient care: U IU QD QOD .X mg X.0 mg MS MSO_4 $MgSO_4$

Adult Hypoglycemia Management Protocol Orders	RN name and sign remains under ature	Time
Diagnosis: Condition: Activity:		
☑ Activate adult hypoglycemia management protocol STAT if blood glucose reading less than **70 mg/dl and inform the physician**		
☑ Skip any due short acting insulin dose		
PRN Medications If patient has an IV line Give D30W 40 ml IV push STAT PRN every 20 minutes if Blood Glucose (BG) reading is less than 70 mg/dl If patient does not have an IV line and can tolerate oral intake or with an enteral tube Give 15 grams of glucose Orally STAT if glucose test reading is between 50-70 mg/dl 30 grams of glucose Orally STAT if glucose test reading is less than 50mg/dl And secure physician order for Dextrose 5 % IV drip at a rate of 30 ml/hour If patient cannot take PO, has no IV access or no enteral tube Give Glucagon 1 mg Intramuscular STAT and secure physician order for Dextrose 5% IV drip at a rate of 30 ml/hour		
☑ Repeat blood glucose test every 20 minutes until BG reading is greater than or equal 70 mg/dl ☑ If blood glucose reading is more than or equal to **70 mg/dl**, repeat blood glucose test every 1 hour until 2 consecutive blood glucose values are greater than 100mg/dl		
If patient is NPO., make blood glucose test every 4 hours for 24 hours after any hypoglycemic event If patient is on oral diet Make blood glucose test 5 times : preameals, bed time, and 1 am		
Consult endocrinology		

~~ FAX TO PHARMACY ~~

Revision Dates: Draft 10/05/2011

Form Control #:

MD Signature: _____ **Date:** _____ **Time:** _____

Print Name: _____ Pager Number _____

APPENDIX IV

Demographic and clinical variables	**Results**
Age	
BG levels with date & time	
Gender:	
Male Female	
HbA1c	
eGFR:	
≤ 30 31–59 60–89 ≥ 90	
Length of stay	
endocrinology team consultations:	
Yes or No	
Insulin treatment during hospital admission:	
No insulin Basal insulin only Basal & Prandial insulin Supplemental insulin only Basal, Prandial and Supplemental insulins	
Comorbidities:	
Coronary artery disease Myocardial infarction Atrial fibrillation Arterial hypertension Heart failure Malignancy Chronic renal failure Stroke Hyperlipidemia/dyslipidemia Thyroid diseases Peripheral vascular disease	
Insulin type	
Number of hypoglycemic agents maintained at home	
glucocorticoid treatment:	
Yes or No	

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