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USE OF A COMPUTER-GUIDED GLUCOSE MANAGEMENT SYSTEM TO IMPROVE GLYCEMIC CONTROL AND ADDRESS NATIONAL QUALITY MEASURES: A 7-YEAR RETROSPECTIVE OBSERVATIONAL STUDY AT A TERTIARY CARE TEACHING HOSPITAL

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Running title: eGMS Inpatient Glucose Control

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** Monarch Medical Technologies markets the EndoTool® System*

Abstract

Objectives

Inpatient hyperglycemia, hypoglycemia, and glucose variability are associated with increased mortality. The use of electronic Glucose Management Systems (eGMS) to guide intravenous (IV) insulin infusion have been found to significantly improve blood glucose (BG) control. This retrospective observational study evaluated the 7-year (1/2009-12/2015) impact of the EndoTool® eGMS in intensive and intermediate units at Vidant Medical Center, a 900-bed tertiary teaching hospital.

Methods

Patients assigned to eGMS had indications for IV insulin infusion, including uncontrolled diabetes, stress hyperglycemia, and/or post-operative BG levels >140 mg/dL. This study evaluated time required to achieve BG control (<180 mg/dL; <140 mg/dL for cardiovascular

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surgery patients); hypoglycemia incidence (<70 and <40 mg/dL); glucose variability (assessed by SD and coefficient of variation percentage [CV%]) and excursions (BG levels >180 mg/dL after control attained); and the impact of eGMS on Hospital Acquired Condition (HAC)-8 rates.

Results

Data were available for all treated patients (492,078 BG readings from 16,850 patients). With eGMS, BG levels were brought to target within 1.5-2.3 hours (4.5-4.8 hours for cardiovascular patients). Minimal hypoglycemia was observed (BG values <70 mg/dL, 0.93%; <40 mg/dL, 0.03%), and ANOVA of BG values <70 mg/dL showed significant reductions over time in hypoglycemia frequency, from 1.04% in 2009 to 0.46% in 2015 (P<0.0001). The CV% per patient visit was 26.5 (±12.9)% and 4% of patients experienced glucose excursions. HAC-8 rates were reduced from 0.083/1000 patients (2008) to 0.032/1000 (2011).

Conclusions

The use of eGMS resulted in rapid, effective control of inpatient BG levels, including significantly reduced hypoglycemia rates.

Key Words

Electronic glycemic management systems, blood glucose, hypoglycemia, hyperglycemia, insulin, computer-assisted therapy

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Abbreviations:

eGMS = electronic Glucose Management Systems**; (HAC)** = Hospital Acquired Condition**; ANOVA** = Analysis of variance**; CV** = coefficient of variation; **CV%** = coefficient of variation percentage; **SD** = standard variation; **BG** = blood glucose; **GV** = glycemic variability; **LOS** = length of stay; **ICU** = intensive care unit; **NICE-SUGAR** = The Normoglycemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation; **IV** = intravenous; **ACE** = American College of Endocrinology; **ADA** = American Diabetes Association; **CMS** = Centers for Medicare and Medicaid Services; **HITECH** = Health Information Technology for Economic and Clinical Health (Act); **VMC** = Vidant Medical Center.

Introduction

A disproportionate number of hospitalized patients experience hyperglycemia. (1,2) Substantial risk is associated with inpatient hyper- and hypoglycemia due to diabetes and stress hyperglycemia. This has led to ongoing efforts to maintain glucose control in hospitalized patients. (1,3) Three typical hyperglycemic patterns exist in hospitalized patients: diabetes that is known/previously diagnosed; undiagnosed diabetes identified during hospitalization; and hospital-related hyperglycemia (also known as stress hyperglycemia). Stress hyperglycemia presents during hospitalization, but often reverts to normoglycemia following discharge. (4) Hypoglycemia during hospitalization is also associated with increased mortality, longer length of stay (LOS), and an elevated risk of intensive care unit (ICU) admission in both insulin-treated and non-insulin-treated patients. (5,6) Research indicates that approximately 8% of admitted patients will experience at least 1 hypoglycemic event. (7) Additionally, inpatient glycemic

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variability (GV), defined as the overall distribution of glucose values around the mean, is an emergent risk factor that has been independently associated with increased mortality. (8)

In-hospital hyperglycemia is an independent predictor of morbidity and mortality, and its appropriate management improves patient outcomes. (2,9-11) In a 2002 study, Umpierrez and colleagues found patients with hyperglycemia (on admission or in-hospital diagnosis) and no history of known diabetes were 29% more likely to be admitted to the intensive care unit (ICU), and experienced a 16% mortality rate. (2) In 2001, Van Den Berghe and colleagues found that critically ill patients treated to target BG levels 80 to 110 mg/dL had a 32% mortality reduction compared to those with BG maintained at 180 to 200 mg/dL ($P<0.04$). (9) Subsequent to this initial research, our understanding of ideal in-hospital glucose targets has been further refined. The Normoglycemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation (NICE-SUGAR), a randomized controlled trial of more than 6,000 patients, found that lowering BG to <108 mg/dL in the ICU resulted in increased mortality (27.5%) over the control group, in which intermediate BG control (140 to 180 mg/dL) was maintained (24.9%; $P=0.02$). (10,11) Likewise, during and after cardiac surgery, maintaining BG control <180 mg/dL reduces mortality, morbidity, reduces length of stay (LOS), and improves long-term survival. (12) In a study of patients undergoing open-heart surgery, elevated BG levels were independent predictors of mortality ($P<0.0001$), LOS ($P<0.002$), and post-operative sternal infections ($P=0.017$). (13) These data suggest that the association between BG and hospital mortality forms a J-curve, with euglycemia having the lowest mortality rate vs. both hyperglycemia and hypoglycemia. (10)

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Substantial evidence indicates that blood glucose (BG) management using protocol-driven insulin administration leads to improved patient outcomes. (13-15) Typically, intravenous (IV) insulin infusion is the preferred management strategy, especially for critically ill patients, (1,16) and several published protocols are available to guide IV insulin infusion administration. (13,17,18) In a study comparing cardiac surgery patients with BG controlled via subcutaneous injection vs. a protocol-based continuous infusion, use of the IV protocol led to a 2.5-fold decrease in post-operative complications such as sternal infection (P=0.011). (14) IV insulin protocol use has also been associated with substantial per-patient cost savings. (19) In 2006, the American College of Endocrinology (ACE) and the American Diabetes Association (ADA) recommended that insulin protocols, algorithms, and/or order sets be used to manage hyperglycemia and hypoglycemia in the hospital setting. (1)

Until recently, hospitals were limited to paper-based IV insulin infusion protocol management. In the last decade, however, computerized approaches, known as electronic glycemic management systems (eGMS), have become available. This has led to a growing literature base evaluating computerized insulin delivery mechanisms in the hospital setting. The past decade has seen substantial research to describe the performance of computer-programmed protocols (20,21) and a series of controlled studies have found significantly improved BG control with eGMS vs. paper-based protocols. (22-29) This retrospective observational study was designed to evaluate the 7-year impact of an eGMS on patient hyperglycemia and hypoglycemia at Vidant Medical Center (VMC).

DOI:10.4158/EP161402.OR

Methods

Study Setting / Intervention

VMC (formerly Pitt County Memorial Hospital) is a 900-bed tertiary care teaching hospital affiliated with the Brody School at East Carolina University in Greenville, NC. VMC provides acute, intermediate, rehabilitation, and outpatient health services to more than 1.4 million people in 29 counties, treating about 33,000 inpatients per year. In December 2008 to improve patient glucose control, VMC implemented the EndoTool® eGMS (now marketed by Monarch Medical Technologies) in select ICUs. Over subsequent years, eGMS use was expanded to include VMC's intermediate units (IUs).

EndoTool integrates with hospital information systems to manage IV insulin delivery. Using mathematical modeling and feedback controls, this eGMS analyzes BG reading trends to develop patient-specific physiologic insulin dosing curves based on patient weight, age, diabetes type, and glomerular filtration rate (**Figure 1**). Clinician-inputted, patient-specific information is used to calculate the optimal timing of both fingerstick BG checks and appropriate IV insulin dosing, both of which are performed manually by nursing staff. Using patent-pending Model Predictive Control algorithms, the eGMS makes automatic, non-linear adjustments to dose recommendations in order to minimize and help prevent episodes of hypoglycemia and hyperglycemia. (26)

[Figure 1. Comparison of Linear Protocol and EndoTool's Non-linear Physiologic Dosing on Insulin Administration and Blood Glucose Control]

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Prior to implementing eGMS, VMC initiated a multistep assessment process that included: interdisciplinary review of failed cases; identification of a standardized IV continuous infusion protocol; selection of an appropriate computerized management tool; and action step generation.

Patients and Outcomes Evaluated

This retrospective observational study evaluated the 7-year impact (1/2009 to 12/2015) of the EndoTool eGMS in VMC's ICUs and IUs. During this period, VMC patients were assigned to BG management with eGMS if they had an indication for IV insulin infusion due to hyperglycemic emergency, severely uncontrolled diabetes, stress hyperglycemia, and/or post-operative glucose levels >140 mg/dL. Evaluated outcomes included: (a) average time to BG target following eGMS implementation, both overall (target <180 mg/dL) and for cardiovascular surgery patients (target <140 mg/dL); b) overall incidence of hypoglycemia and severe hypoglycemia (BG <70 mg/dL and <40 mg/dL, respectively) and rate of hypoglycemic events per patient visit; and, (d) glucose variability and glucose excursions, with variability calculated as coefficient of variation [CV] and excursions defined as BG levels >180 mg/dL after prior glucose control was attained. Finally, the impact of eGMS on VMC's rates of Hospital Acquired Condition (HAC)-8 was assessed.

The evaluated hyperglycemia targets of <180 mg/dL and <140 mg/dL were based on threshold levels recommended by ACE and the ADA. (1) The hypoglycemia cut-offs were based on recommendations from the International Hypoglycemia Study Group to treat BG levels ≤70

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mg/dL to avoid progression to clinical iatrogenic hypoglycemia, (30) and prior research which has set a threshold for severe hypoglycemia at <40 mg/dL. (25,29,31) Glucose variability was assessed by calculating the percentage CV, defined as the ratio of the standard deviation [SD] to mean BG data for each patient visit. (8) HACs were established in 2008 by the U.S. Centers for Medicare and Medicaid Services (CMS) and are defined as conditions that: (a) are high-cost, high-volume; or both; (b) result in the assignment of a case to a diagnosis-related group with a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines. This study's relevant measure is HAC-8, "manifestations of poor glycemic control," with criteria outlined in **Table 2**. (32) HAC-8 data were evaluated for all VMC patients and compared with national average data (2008 to 2011 only; as of 2012, CMS is no longer reporting national data for individual HAC outcomes). (33)

Implementation

As shown in **Table 1**, the eGMS was introduced in a staggered process starting with VMC's surgical, medical, and cardiothoracic ICUs in December 2008. The system was subsequently extended to all ICUs and multiple IUs and step-down units, for a total of 18 units. To be evaluable, patients were required to have: (a) at least 6 BG measurements obtained during their stay; (b) a first BG measurement >70 mg/dL; and, (c) a series of BG measurements with time gaps ≤4 hours (240 minutes). The >4-hour time gap between BG measurements was imposed to identify patients with multiple hospital admissions as well as those taken off eGMS management

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for a substantial time period during a particular admission. Consequently, a given patient could have multiple visits, each representing a unique eGMS measurement series.

Patients' BG testing frequency was recommended by eGMS, and occurred every 30, 60, or 120 minutes, depending on patient status and BG level. As shown in **Figure 2**, with EndoTool, nurses are alerted to: a) review patient BG levels; select individual patients and manually enter BG values that move patients towards their target range, and; b) confirm the data entered, as well as any recommended dosing changes. Following this, EndoTool makes appropriate insulin adjustments. EndoTool demonstrates optimal performance when BG readings are entered within 15 minutes of an alert. The alert comprises 3 consecutive rings per minute until the past-due BG is entered. Past-due alerts cannot be manually disabled from the bedside, a feature developed to promote compliance with patient BG management requirements. If a patient is being moved or transferred, users can temporarily discontinue a patient to avoid unintentional past-due alerts.

[Figure 2. EndoTool Screen View: Nurse Management of Patient Blood Glucose Levels]

Analytics

Individual patient data were generated by the eGMS's analytic function. Year-by-year comparisons of patient data samples were analyzed using one-way analysis of variance (ANOVA). Glucose variability was assessed using mean BG data to identify the SD of BG measurements for each patient visit, followed by CV calculation, expressed as a percentage.

DOI:10.4158/EP161402.OR

Cumulative data were analyzed using descriptive statistics only. VMC HAC-8 data were compared with national data obtained from CMS.

Results

Data were available for 100% of treated patients. Over 7 years, 492,078 BG readings were obtained from 16,850 patients, for an average of 29 readings per patient. As shown in **Table 3**, between 2009 and 2015, the eGMS was able to bring hyperglycemic patients to glucose levels <180 mg/dL within 1.5 to 2.3 hours. Among evaluable patient records, only 4% showed glucose excursions (>180 mg/dL) after prior glucose control was achieved; the average duration of a glucose excursion was 1.91 hours. In terms of GV, the mean BG ± SD was 143 ± 39.9 mg/dL on average per patient visit, with an average CV per patient visit of 26.5 (±12.9)%.

Data from VMC cardiovascular surgery units are shown in **Table 4**: approximately 4.5 to 4.8 hours was required for these patients to achieve a BG target of 140 mg/dL; ~98% of patients achieved this target. Likewise, the majority of cardiovascular ICU and IU patients reached an assigned BG target of 120 mg/dL (88.7% and 93.7%, respectively) while about one-half of patients with a lower target BG range (90 mg/dL) achieved this level. The average amount of time spent in glucose excursions per visit was 1.7 hours for the cardiovascular surgery intensive care unit and 1.5 hours for the cardiovascular surgery intermediate unit (data not shown).

Table 5 shows the number and percent of hypoglycemic values (<40mg/dL to <70 mg/dL) obtained between 2009 and 2015. Overall, minimal hypoglycemia was observed at VMC, with

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only 0.93% of BG values <70 mg/dL and 0.03% <40mg/dL. Over all medical units, on average only 1.01% of BG measurements per patient visit were <70 mg/dL and 0.03% were <40 mg/dL. Additionally, reductions in individual patient hypoglycemic blood glucose levels showed a year-on-year decrease (**Figure 3**). ANOVA analysis of the percentage of glucose values <70 mg/dL obtained at VMC between 2009 to 2015 showed a statistically significant reduction in this measure of hypoglycemia frequency from 1.04% in 2009 to 0.46% in 2015 (P<0.0001).

[Figure 3. Percentage of VMC Patient Glucose Values <70 mg/dL Following Introduction of Electronic Glycemic Management System: 2009 To 2015]

Last, overall improvements in glycemic control for all evaluated patients led to immediate and sustained reductions in HAC-8 measures, with rates showing consistent improvement over the evaluable period (**Figure 4**), from 0.083/1000 patients in 2008 to 0.032/1000 in 2011, the last year national data were available for this measure. (33) As of 2011, the national average for HAC-8 was 0.050 per 1,000 discharges. (34,35)

[Figure 4. Hospital Acquired Conditions-8 (HAC-8) Rate per 1,000 Patients: 2008-2011 Vidant Medical Center vs. U.S. National Average: 2008 To 2011]

Discussion

DOI:10.4158/EP161402.OR

The progressive roll-out of the EndoTool eGMS by VMC to administer IV insulin in its ICUs and IUs resulted in a marked improvement in patient quality of care. Over the 7-year study period, the appropriate use of eGMS led to only 0.03% of BG readings (157 out of 492,078) consistent with severe hypoglycemia (<40 mg/dL), while the proportion of readings with hypoglycemic BG values <70 mg/dL was 0.93%. These results for successful hypoglycemia management are similar to or better than those reported in prior retrospective studies evaluating other computerized glucose management systems. (21,22,31) Other notable results included a significant reduction in year-upon-year hypoglycemia incidence (<70 mg/dL), from 1.04% in 2009 to 0.05% in 2015. This was the case even as patient volume more than doubled (from 1,280 patients treated with eGMS in 2009 to 2,890 in 2015).

VMC patients also experienced a relatively rapid time to BG control <180 mg/dL (1.5 to 2.3 hours) and a very low rate (0.4%) of glucose excursions (defined as BG levels >180 mg/dL once control was attained). Additionally, the overall rate of GV (calculated as CV%) was 26.5% (±12.9). To put this finding in context, in 2011 Rodbard identified CV% levels <33.5% as "excellent." (36) Additionally, the CV% observed in this multi-site study were substantially lower than hospital-level mean CV% analyzed in a similar fashion by two recent single-site epidemiologic analyses (31.9% [±13.4] and 34.2% [±11.1]). (8,37)

Post-surgical cardiovascular patients, who had more stringent BG targets, were able to achieve goal within 4.5 to 5.0 hours (patients with BG target <140 mg/dL) or 6.1 to 8.2 hours (target <120 mg/dL). Thus, EndoTool is effective at achieving and maintaining cardiovascular patients at the higher end of the 90 to 140 mg/dL target range. Last, 2011 HAC-8 glycemic outcomes for

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VMC were 0.032/1000 compared to a national average of 0.050/1000. (34) These results placed VMC in the top 10% of all U.S. hospitals for HAC-8 compliance. (38)

Research has documented the improved performance of eGMS systems compared with paper algorithms. (23-25,27-29,31,39) However, it has been difficult to determine what factors are responsible for this superiority. Recent evidence indicates that, compared with paper-based protocols, software-driven IV insulin administration more effectively manages the 3 pivotal domains of glucose control (hyperglycemia, hypoglycemia, and GV). (23,27,39) These 3 BG parameters are all independently associated with higher in-hospital mortality rates and length of stay, (2,7,8) and have all been shown to improve with eGMS compared with paper-based protocols, both in previous studies (23,25,26,28,39) and the current analysis.

VMC's success mirrors other sites' experience with the EndoTool eGMS. Two prior randomized studies and a retrospective analysis have found that, in eGMS-managed surgical ICU patients, the number of BG measurements falling within target range significantly improved and BG excursions significantly decreased compared with paper protocol management. (23,28,39) Likewise, the use of this eGMS to manage BG levels in critically ill surgical ICU patients has been associated with a decreased frequency of serious hypo- and hyperglycemia. (26) Another study reported that the mean time free from severe hypoglycemia following cardiovascular ICU discharge was 7.0 days for patients treated with eGMS and 1.1 days for paper protocol-treated patients. (25)

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The EndoTool eGMS uses an algorithm comprising clinician-inputted, patient-specific information to calculate the optimal timing of both fingerstick BG checks and appropriate insulin infusion dosing. Each BG reading and insulin dose is entered into the system, allowing the algorithm to re-calculate as needed. The resulting individualized insulin dosage curve helps to minimize hyperglycemia, hypoglycemia, and glucose excursions. Furthermore, this system can typically be integrated into electronic health record systems and/or order entry menus, eliminating the need for paper or printed protocols. EndoTool is a U.S. Food and Drug Administration-approved eGMS that uses patented modeling with individualized feedback to maintain glycemic control. (40) To evaluate performance, the system provides patient- and unit-specific reporting capabilities and post-use analytics. (39)

Limitations

This study is one of the largest and longest retrospective analyses of eGMS data conducted to date; it also reflects a range of patients with varying characteristics on admission. The primary limitation of this study is that it was a retrospective, single center analysis. Based on this, it is difficult to know whether other variables or heterogeneity between the multiple units analyzed influenced outcomes. Ideally, future studies will evaluate patient outcomes both prior to and following eGMS implementation. However, the observed improved glucose outcomes, and the similarity of these results with prior research findings, argue in favor of a positive relationship between eGMS use and improved BG control.

DOI:10.4158/EP161402.OR

It is also feasible that other factors contributed to the year-upon-year improvements observed in this study. For example, increased staff familiarity with eGMS technology procedures and subsequent improved response could drive ongoing performance efficiency. It should also be noted that, in late 2015, VMC upgraded to a web-based version of EndoTool that included several upgrades (staged goals for diabetic ketoacidosis [DKA] and hyperglycemic hyperosmolar syndrome, as well improved dextrose supplementation recommendations at certain BG thresholds).

Last, some paradoxical year-on-year data were observed in terms of time required for VMC patients to achieve glucose control <180 mg/dL. Between 2009 and 2011, patients achieved BG control in 1.5 hours; however, this increased to 1.9 hours by 2014 and 2.3 hours by 2015. This change may be explained in part by a VMC procedural adjustment made in May 2014. In an effort to reduce hypoglycemia and to prevent rapid drops in fasting BG, all eGMS patients were assigned to receive a maximum insulin bolus of 10 units (instead of 20 or 50 units as previously established). This likely affected patient time to target.

With the passage of the HITECH (Health Information Technology for Economic and Clinical Health) Act and other incentives, in-hospital use of eGMS is on the rise. (41) Therefore, it is worth noting that the results of this study suggest potential future research directions. To date, very few randomized controlled trials (RCTs) of eGMS have been published. (29) A RCT evaluating clinical outcomes associated with eGMS-managed moderate vs. strict BG control would provide hospitals and clinicians with valuable, practicable information. Similarly,

DOI:10.4158/EP161402.OR

controlled research examining the relationship between time to BG target and patient outcomes will help clinicians to even further refine in-hospital hyperglycemia management. Last, the impact of BG management with eGMS in specific high-risk patient groups should be evaluated (for example, following coronary artery bypass grafting or in patients with diabetic ketoacidosis).

Conclusion

The use of an eGMS to manage glucose levels in hospitalized patients with diabetes may lead to improved glycemic control, and therefore better patient outcomes. VMC's use of the eGMS to administer IV insulin in the ICUs and IUs in the setting of a large tertiary care hospital resulted in significant improvements in overall glucose control, assessed as hyperglycemia, hypoglycemia, and glucose excursions. It is likely that other facilities could achieve similar improvements in BG control and patient outcomes using the EndoTool eGMS.

DOI:10.4158/EP161402.OR

Table 1. Vidant Medical Center EndoTool Implementation and Blood Glucose Targets: 2008-2015

Dates	Units	Target BG Range
December 2008	NSICU	110 mg/dL to 150 mg/dL
January 2009	LD MICU	70 mg/dL to 110 mg/dL 100 mg/dL to 150 mg/dL
February 2009	CICU, CIU, CVICU, CVIU, SICU	90 mg/dL to 140 mg/dL
May 2009	MICU	130 mg/dL to 160mg/dL
November 2009	SIU, SICU, NSU	100 mg/dL to 150 mg/dL
December 2012	MIU	90 mg/dL to 140 mg/dL
July 2013	1SO, BGSU, CICU, CIU, MICU, SICU*, SIU , MIU	140 mg/dL to 180 mg/dL
August 2013	3EAS	140 mg/dL to 180 mg/dL
September 2013	ORTHO	140 mg/dL to 180 mg/dL
October 2013	1EAS, 3WEST	140 mg/dL to 180 mg/dL
January 2014	HDU	140 mg/dL to 180 mg/dL

* An optional SICU glucose target of 110 mg/dL to 150 mg/dL was introduced 12/2013 for brain surgery patients.

Key: 1EAS=East intermediate surgery unit; 1SO=South intermediate surgery unit; 3EAS=East intermediate medicine unit; 3WEST=West intermediate oncology unit; BGSU=bariatric-general surgery unit (intermediate); BG=blood glucose; CICU=cardiac care intensive unit; CIU=cardiac intermediate unit;

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CVICU=cardiovascular intensive care unit; CVIU=cardiovascular intermediate unit; HDU=hemodialysis unit; LD=Labor & Delivery; MICU=medical intensive care unit; MICU=medical intensive care unit; MIU=medical intermediate unit; NSICU=neurosurgical intensive care unit; NSU=neurosurgical intermediate unit; ORTHO=Orthopedics unit; SICU=surgical intensive care unit; SIU=surgical intermediate unit

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Table 2. Hospital Acquired Conditions-8 (HAC-8): Manifestation of Poor Glycemic Control (34)

Hospital Acquired Conditions-8 (HAC-8): Manifestations of Poor Glycemic Control	ICD-9-CM Codes
Diabetic ketoacidosis	250.10-250.13.9 (MCC)
Nonketotic hyperosmolar coma	250.20-250.23 (MCC)
Hypoglycemic coma	251.0 (CC)
Secondary diabetes with ketoacidosis	249.10-249.1 (MCC)
Secondary diabetes with hyperosmolarity	249.20-249.21 (MCC)

CC=complicating or comorbid condition; MCC=major complicating or comorbid condition

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Table 3. Time To Achieve Blood Glucose <180 mg/dL with EndoTool, All Vidant Medical Center Patients: 2009-2015

Year	Evaluable Patient Visits	Average Time to Target (<180 mg/dL), hours
2009	1,275	1.5
2010	2,051	1.5
2011	1,993	1.5
2012	2,268	1.7
2013	2,995	1.9
2014	3,327	1.9
2015	2,862	2.3

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Table 4. Vidant Medical Center, Cumulative Blood Glucose Data (2009-2015) for Cardiovascular Post-operative Patients

BG Target (mg/dL)	Number of Evaluable Patient Visits	Percent of Patient Visits that Achieved BG Control	Average Time (hours) To BG Target
CVICU			
90	1,011	56.2	20.0
120	1,687	93.7	8.2
140	1,762	97.9	4.8
CVIU			
90	218	48.3	11.2
120	400	88.7	6.1
140	440	97.6	4.5

Key: BG=blood glucose; CVICU=cardiovascular intensive care unit; CVIU=cardiovascular intermediate unit

DOI:10.4158/EP161402.OR

Table 5. Vidant Medical Center Hypoglycemia Summary Data for All Patients (2009-2015 and Overall) and Per-Patient Visit (Overall)

Summary Data, All Patients										
Year	**# Patient Visits**	**# BG Records**	**# BG Values (mg/dL)**				**Percent of BG Values (mg/dL, %)**			
			<40	**<50**	**<60**	**<70**	**<40**	**<50**	**<60**	**<70**
2009	1,280	41,666	16	50	145	433	0.04	0.12	0.35	1.04
2010	2,055	61,507	24	71	274	796	0.04	0.12	0.45	1.29
2011	1,998	58,354	22	55	184	646	0.04	0.09	0.32	1.11
2012	2,274	64,906	15	63	234	715	0.02	0.10	0.36	1.10
2013	3,004	84,163	35	114	319	898	0.04	0.14	0.38	1.07
2014	3,349	94,550	26	89	262	665	0.03	0.09	0.28	0.70
2015	2,890	86,932	19	51	157	403	0.02	0.06	0.18	0.46
Overall	16,850	492,078	157	493	1575	4556	0.03*	0.10*	0.32*	0.93*
Per-Patient Visit Data, All Patients										
# Patient Visits		**Average # BG Records Per Patient Visit**	**Average # BG Records Per Patient Visit (mg/dL)**				**Average Hypoglycemia Rate Per Patient Visit (mg/dL, %)**			
			<40	**<50**	**<60**	**<70**	**<40**	**<50**	**<60**	**<70**
Overall	16,850	29.21	0.01	0.03	0.09	0.27	0.04	0.12	0.37	1.02

BG, blood glucose. *Mean: 2009 to 2015 data

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Figure 1a-b. Comparison of Linear Protocol and EndoTool's Non-linear Physiologic Dosing on Insulin Administration and Blood Glucose Control

Figure 2a-b. EndoTool Screen View: Nurse Management of Patient Blood Glucose Levels

Figure 3. Percentage of VMC Patient Glucose Values <70 mg/dL With EndoTool: 2009 To 2015

Figure 4. Hospital Acquired Conditions-8 (HAC-8) Rate per 1,000 Patients: 2008-2011 Vidant Medical Center vs. U.S. National Average: 2008 To 2011*

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Figure 1. Comparison of Linear (Paper) Protocol and EndoTool's Non-linear Physiologic Dosing on Insulin Administration and Blood Glucose Control

A: Linear (paper) Protocol

Linear protocols dose insulin based on an initial blood glucose reading. As readings continue, insulin continues to be administered without accounting for previously administered insulin. If/when a patient reaches a blood glucose target range, the patient is at risk for a hypoglycemia event as a result of residual and active insulin.

B: EndoTool

EndoTool initiates the first insulin dose based on multiple patient variables (including the blood glucose reading). EndoTool then develops a trend to model and predict the patient response in order to reduce the amount of insulin administered, thus bringing the patient safely to control.

Figure 2a-b. EndoTool Screen View: Nurse Management of Patient Blood Glucose Levels

2a. The EndoTool Dashboard shows a list of active patients and alerts the nurse when blood glucose (BG) checks are due. In this image, the nurse selects patient with a previous BG value of 155 mg/dL. The nurse enters a new BG level (133 mg/dL), which will be used by the system to adjust the patient's insulin drip and move the patient safely towards goal range (90 mg/dL to 120 mg/dL). When appropriate, the nurse indicates if the patient has eaten a meal or snack (so the system may adjust for additional carbohydrates).

2b. The nurse confirms the recommended insulin drip rate that coincides with the BG entered. EndoTool will use the inputted BG value and patient's physiologic data to make a new insulin dosing recommendation and set the frequency for the next BG Check.

Figure 3. Percentage of VMC Patient Glucose Values <70 mg/dL With EndoTool: 2009 To 2015

N=number of patient visits

*EndoTool was rolled out progressively at VMC sites as follows: 2008/2009: CICU, CIU, CVICU, CVIU, LD, MICU, NSICU, SICU; 2010: NSU, SIU; 2012: MIU; 2013: 1EAS, 1SO, 3EAS, 3WEST, BGSU, ORTHO; 2014: HDU.

Key: 1EAS=East intermediate surgery unit; 1SO=South intermediate surgery unit; 3EAS=East intermediate medicine unit; 3WEST=West intermediate oncology unit; BGSU=bariatric-general surgery unit (intermediate); BG=blood glucose; CICU=cardiac care intensive unit; CIU=cardiac intermediate unit; CVICU=cardiovascular intensive care unit; CVIU=cardiovascular

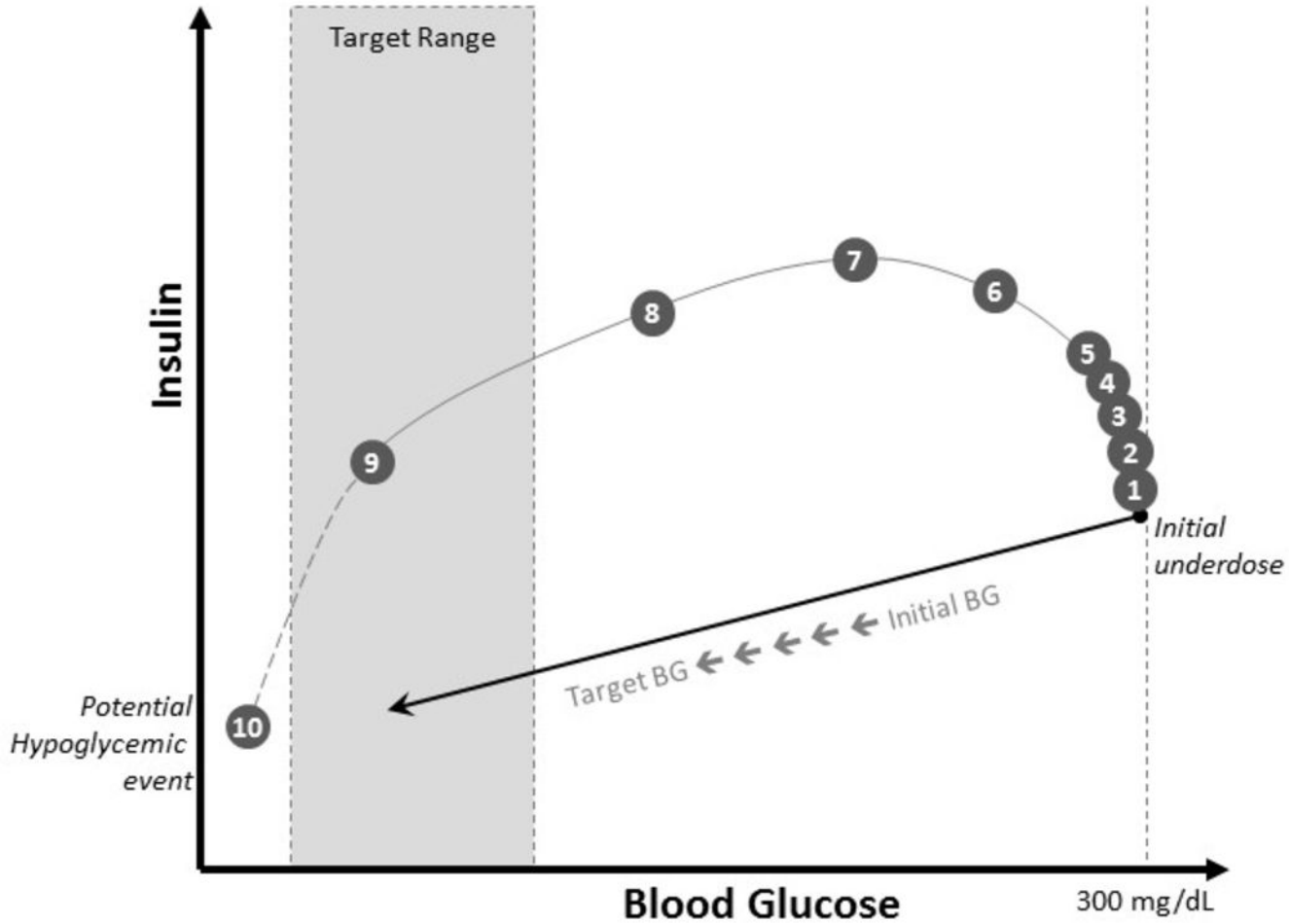
intermediate unit; HDU= hemodialysis unit; LD=Labor & Delivery; MICU=medical intensive care unit; MIU=medical intermediate unit; NSICU=neurosurgical intensive care unit; NSU=neurosurgical intermediate unit; ORTHO=Orthopedics unit; SICU=surgical intensive care unit; SIU=surgical intermediate unit.

Figure 4. Hospital Acquired Conditions-8 (HAC-8) Rate per 1,000 Patients: 2008-2011 Vidant Medical Center vs. U.S. National Average: 2008 To 2011* (38,40)

HAC = hospital acquired conditions; VMC = Vidant Medical Center

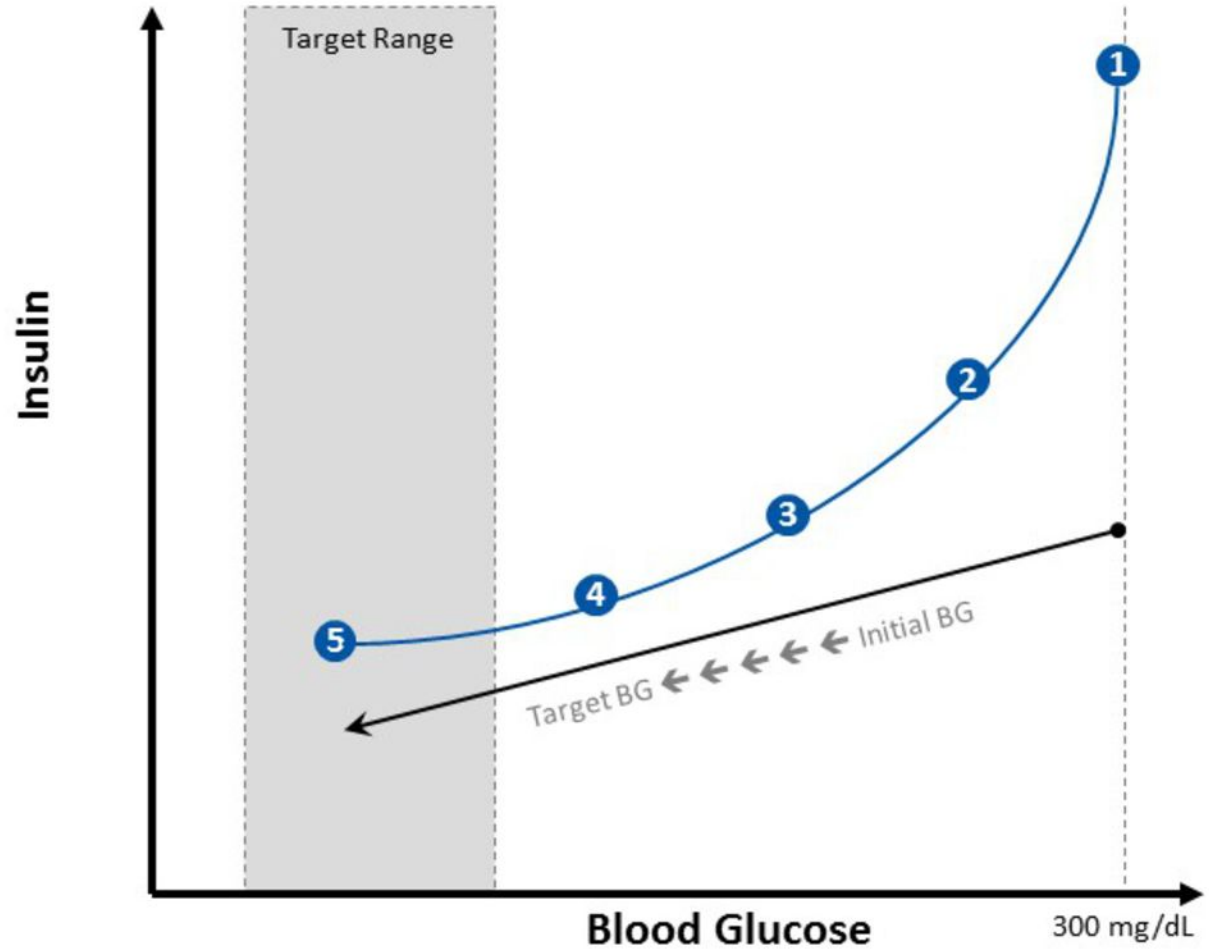
* Data Reported only through 2011; after this year, individual mean HAC measures were no longer reported by the Centers for Medicare and Medicaid Services.

Linear Protocol



NOTE: Many protocols dose insulin based on an initial blood glucose reading. As readings continue, insulin continues to be administered without accounting for previously administered insulin. If/when a patient reaches a blood glucose target range, the patient is at risk for a hypoglycemia event as a result of residual and active insulin.

EndoTool



NOTE: EndoTool initiates the first insulin dose based on multiple patient variables (including the blood glucose reading). EndoTool then develops a trend to model and predict the patient response in order to reduce the amount of insulin administered, thus bringing the patient safely to control.


ENDOTOOL IV
General Hospital
CCU
Medical Director
2
Smith, James
Medical Record : 78787
GLUCOSE / EXTRA CALORIES
PREVIOUS GLUCOSE: 155 mg/dL GOAL RANGE: 90-120 mg/dL
Glucose:
133
mg/dL
Sample Time:
07:01
Sample Date:
08-25-2015
Extra calories:
Simple Calorie
Meal Eaten
Meal Timer
Calculate
Cancel

3

Smith, James
Medical Record : 78787

DOSING RECOMMENDATION

BLOOD GLUCOSE: 133 mg/dL GOAL RANGE: 90-120 mg/dL

Insulin-Regular Infusion

3

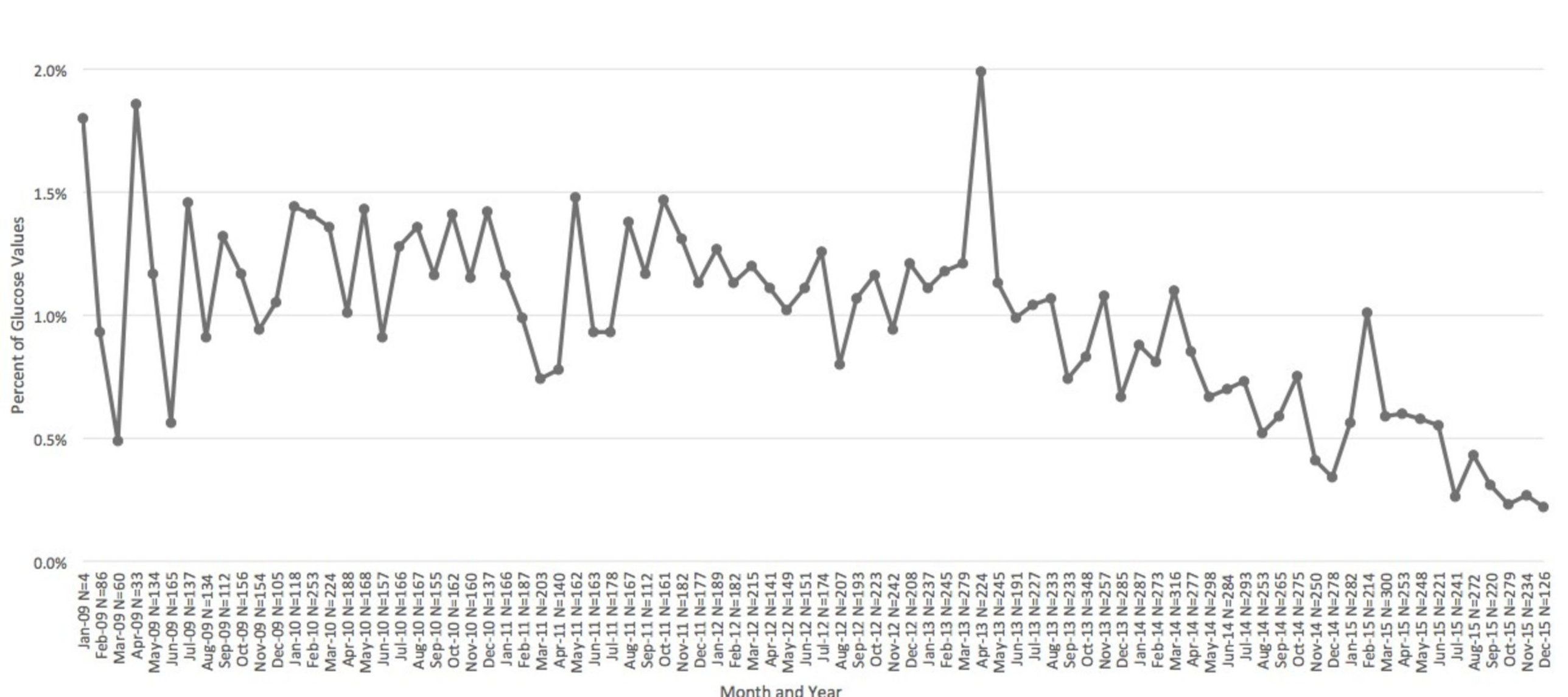
units / hour

Next Glucose Check

30 MIN

09:33

Back to Dashboard | Continue to Patient History


2.0%
1.5%
1.0%
0.5%
0.0%
Percent of Glucose Values
Jan-09 N=4
Feb-09 N=86
Mar-09 N=60
Apr-09 N=33
May-09 N=134
Jun-09 N=165
Jul-09 N=137
Aug-09 N=134
Sep-09 N=112
Oct-09 N=156
Nov-09 N=154
Dec-09 N=105
Jan-10 N=118
Feb-10 N=253
Mar-10 N=224
Apr-10 N=188
May-10 N=168
Jun-10 N=157
Jul-10 N=166
Aug-10 N=167
Sep-10 N=155
Oct-10 N=162
Nov-10 N=160
Dec-10 N=137
Jan-11 N=166
Feb-11 N=187
Mar-11 N=203
Apr-11 N=140
May-11 N=162
Jun-11 N=163
Jul-11 N=178
Aug-11 N=167
Sep-11 N=112
Oct-11 N=161
Nov-11 N=182
Dec-11 N=177
Jan-12 N=189
Feb-12 N=182
Mar-12 N=215
Apr-12 N=141
May-12 N=149
Jun-12 N=151
Jul-12 N=174
Aug-12 N=207
Sep-12 N=193
Oct-12 N=223
Nov-12 N=242
Dec-12 N=208
Jan-13 N=237
Feb-13 N=245
Mar-13 N=279
Apr-13 N=224
May-13 N=245
Jun-13 N=191
Jul-13 N=227
Aug-13 N=233
Sep-13 N=233
Oct-13 N=348
Nov-13 N=257
Dec-13 N=285
Jan-14 N=287
Feb-14 N=273
Mar-14 N=316
Apr-14 N=277
May-14 N=298
Jun-14 N=284
Jul-14 N=293
Aug-14 N=253
Sep-14 N=265
Oct-14 N=275
Nov-14 N=250
Dec-14 N=278
Jan-15 N=282
Feb-15 N=214
Mar-15 N=300
Apr-15 N=253
May-15 N=248
Jun-15 N=221
Jul-15 N=241
Aug-15 N=272
Sep-15 N=220
Oct-15 N=279
Nov-15 N=234
Dec-15 N=126
Month and Year

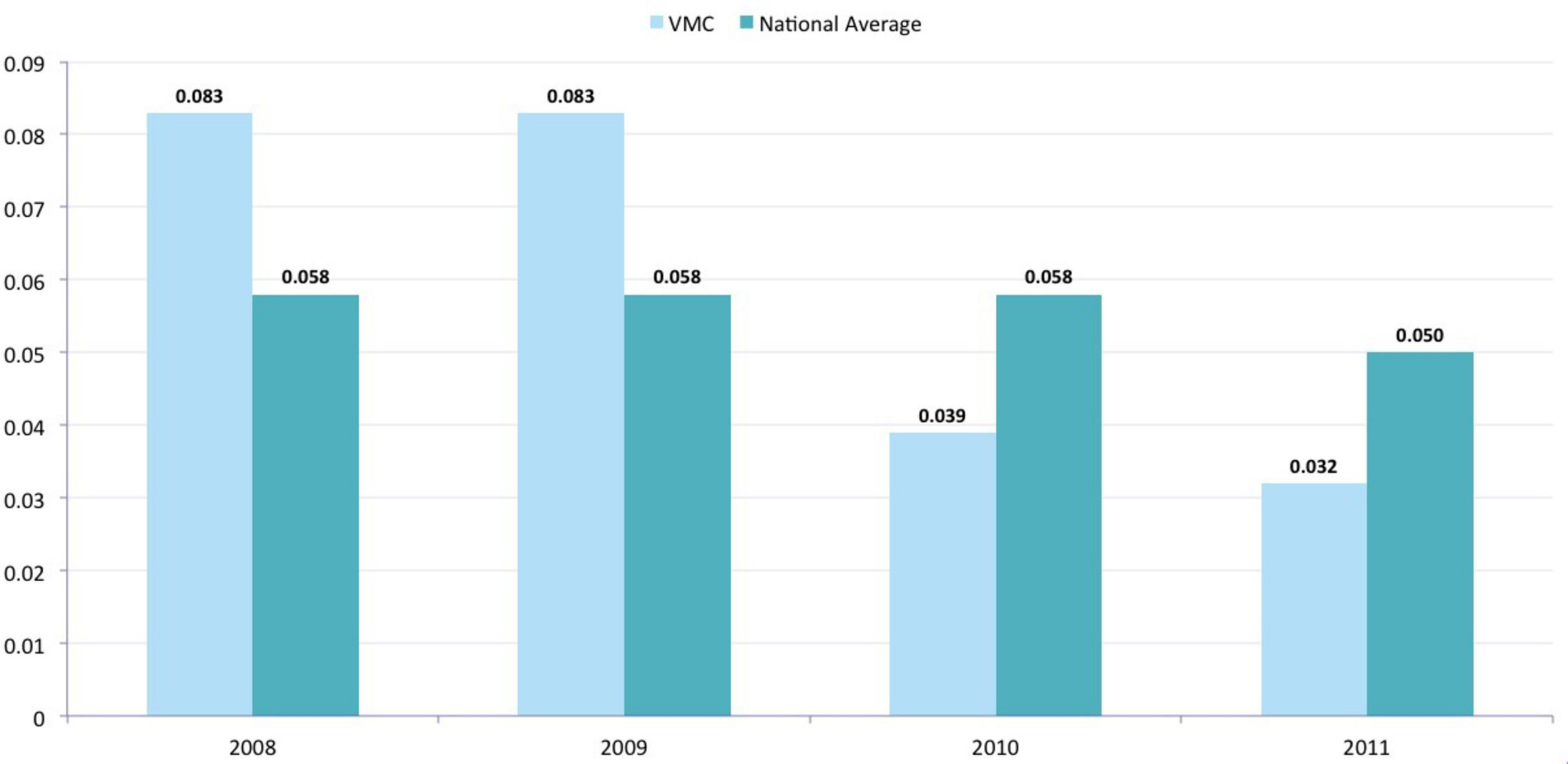

VMC
National Average
0.09
0.08
0.07
0.06
0.05
0.04
0.03
0.02
0.01
0
0.083
0.058
0.083
0.058
0.039
0.058
0.032
0.050
2008
2009
2010
2011

Table 1. Vidant Medical Center EndoTool Implementation and Blood Glucose Targets: 2008-2015

Dates	Units	Target BG Range
December 2008	NSICU	110 mg/dL to 150 mg/dL
January 2009	LD MICU	70 mg/dL to 110 mg/dL 100 mg/dL to 150 mg/dL
February 2009	CICU, CIU, CVICU, CVIU, SICU	90 mg/dL to 140 mg/dL
May 2009	MICU	130 mg/dL to 160mg/dL
November 2009	SIU, SICU, NSU	100 mg/dL to 150 mg/dL
December 2012	MIU	90 mg/dL to 140 mg/dL
July 2013	1SO, BGSU, CICU, CIU, MICU, SICU*, SIU, , MIU	140 mg/dL to 180 mg/dL
August 2013	3EAS	140 mg/dL to 180 mg/dL
September 2013	ORTHO	140 mg/dL to 180 mg/dL
October 2013	1EAS, 3WEST	140 mg/dL to 180 mg/dL
January 2014	HDU	140 mg/dL to 180 mg/dL

* An optional SICU glucose target of 110 mg/dL to 150 mg/dL was introduced 12/2013 for neurosurgery patients.

Key: 1EAS=East intermediate surgery unit; 1SO=South intermediate surgery unit; 3EAS=East intermediate medicine unit; 3WEST=West intermediate oncology unit; BGSU=bariatric-general surgery unit (intermediate); BG=blood glucose; CICU=cardiac care intensive unit; CIU=cardiac intermediate unit; CVICU=cardiovascular intensive care unit; CVIU=cardiovascular intermediate unit; HDU=hemodialysis unit; LD=Labor & Delivery; MICU=medical intensive care unit; MICU=medical intensive care unit; MIU=medical intermediate unit; NSICU=neurosurgical intensive care unit; NSU=neurosurgical intermediate unit; ORTHO=Orthopedics unit; SICU=surgical intensive care unit; SIU=surgical intermediate unit

Table 2. Hospital Acquired Conditions-8 (HAC-8): Manifestation of Poor Glycemic Control (34)

Hospital Acquired Conditions-8 (HAC-8): Manifestations of Poor Glycemic Control	ICD-9-CM Codes
Diabetic Ketoacidosis	250.10-250.13.9 (MCC)
Nonketotic Hyperosmolar coma	250.20-250.23 (MCC)
Hypoglycemic coma	251.0 (CC)
Secondary diabetes with ketoacidosis	249.10-249.1 (MCC)
Secondary diabetes with hyperosmolarity	249.20-249.21 (MCC)

CC=complicating or comorbid condition; MCC=major complicating or comorbid condition

Table 3. Time To Achieve Blood Glucose <180 mg/dL with EndoTool, All Vidant Medical Center Patients: 2009-2015

Year	Evaluable Patient Visits	Average Time to Target (hours)
2009	1,275	1.5
2010	2,051	1.5
2011	1,993	1.5
2012	2,268	1.7
2013	2,995	1.9
2014	3,327	1.9
2015	2,862	2.3

Table 4. Vidant Medical Center, Cumulative Blood Glucose Data (2009-2015) for Cardiovascular Post-operative Patients

BG Target (mg/dL)	Number of Evaluable Patient Visits	Percent of Patient Visits that Achieved BG Control	Average Time (hours) To BG Target
CVICU			
90	1,011	56.2	20.0
120	1,687	93.7	8.2
140	1,762	97.9	4.8
CVIU			
90	218	48.3	11.2
120	400	88.7	6.1
140	440	97.6	4.5

Key: BG=blood glucose; CVICU=cardiovascular intensive care unit; CVIU=cardiovascular intermediate unit

Table 5. Vidant Medical Center Blood Glucose Summary Data for All Patients: 2009-2015

Year	Number of Patient Visits	Number of Glucose Records	Number of Glucose Values (mg/dL)				Percent of Glucose Values (mg/dL, %)			
			<40	<50	<60	<70	<40	<50	<60	<70
2009	1,280	41,666	16	50	145	433	0.04	0.12	0.35	1.04
2010	2,055	61,507	24	71	274	796	0.04	0.12	0.45	1.29
2011	1,998	58,354	22	55	184	646	0.04	0.09	0.32	1.11
2012	2,274	64,906	15	63	234	715	0.02	0.10	0.36	1.10
2013	3,004	84,163	35	114	319	898	0.04	0.14	0.38	1.07
2014	3,349	94,550	26	89	262	665	0.03	0.09	0.28	0.70
2015	2,890	86,932	19	51	157	403	0.02	0.06	0.18	0.46
Overall	16,850	492,078	157	493	1575	4556	0.03*	0.10*	0.32*	0.93*

*Mean: 2009 to 2015 data