April 2014

Dear (Editor):

Registered Dietitians (RD) play an integral role in patient care in the medical intensive care unit. RDs have increased knowledge in blood glucose control and reducing adverse events. Interdisciplinary teams drive innovation to solve problems in all areas including nutrition.

Technology is an emerging trend in patient care. Dietetic practitioners can be at the forefront of adaptability. Technologies such as the GlucoStablizer can empower interdisciplinary teams with better blood glucose control and less adverse events. Involvements in technological implementation prove RDs are valued members of coordinated care teams.

This study will establish the value and benefits of implementation of the IV insulin dosing software GlucoStabilizer in an acute care facility. This study will also promote and establish the value of services provided by the registered dietitian within the implementation of the software program GlucoStabilizer including carbohydrate coverage. Results of the study show positive relationships between regulation of blood glucose and reducing adverse events. Results also showed a positive relationship in provider confidence of carbohydrate coverage after coordination with the RD.

This study was conducted for fulfillment of requirements of the ARAMARK Distance Learning Dietetic Internship. The study was conducted under the supervision of an Endocrinologist and Clinical Pharmacist at St. Mary’s Hospital & Regional Center. The study was conducted with permission on behalf of the Research Compliance Oversight Pre-Review Subcommittee at St. Mary’s Hospital. The information provided from this study will help performance improvement measures for blood glucose control in the medical intensive care unit.

Thank you for your consideration of this manuscript.

Sincerely,

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Will implementation of the GlucoStabilizer software improve glucose control and lower the incidence of hyper and hypoglycemic events in the medical intensive care unit of an acute care hospital?

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Abstract

There are many indicators for continuous intravenous (IV) insulin infusion therapy for critically ill patients. To assure safe and accurate delivery, health care providers must use critical thinking skills. Registered dietitians (RDs) work as part of a multidisciplinary care team involved with blood glucose control and patient care before, during, and after delivery of insulin. RDs provide essential team support to implement technological advancement and standardized care for patients receiving IV insulin infusion. This study examined if implementation of the GlucoStabilizer software program improved blood glucose control and reduced the amount of adverse events in patients receiving IV insulin infusion. The study examined provider satisfaction with the use of the GlucoStabilizer compared to paper-protocols to determine infusion rate. The study also reported provider confidence in carbohydrate counting and coverage after a training session. Retrospective data of hyper and hypoglycemic events was gathered and compared to data gathered post implementation of the GlucoStabilizer. Results were grouped based on number of total patients receiving an insulin drip, hyperglycemic, and hypoglycemic events with the use of the paper-protocol algorithms. Results were then compared with the use of the computer based algorithm. Descriptive statistics were used to examine the relationship between adverse events and how the insulin infusion rate was determined. Implementation of the GlucoStabilizer eliminated the need for paper-protocols and the need to calculate doses for insulin infusion thereby reducing human error and the number of adverse events. Results showed that there was a positive relationship between implementation of the GlucoStabilizer and blood glucose control in the medical intensive care unit of an acute care hospital.
Will implementation of the GlucoStabilizer software improve glucose control and lower the incidence of hyper and hypoglycemic events in the medical intensive care unit of an acute care hospital?

**Introduction**

Management of blood glucose is an important piece of patient care. Continuous glucose management is a team effort. The health care team, including the Registered Dietitian (RD), must work together to implement monitoring to establish target blood glucose goals. The American Association of Clinical Endocrinologists and the American Diabetic Association now recommend tight glucose control in all critical care settings.¹² In critically ill adult patients, the RD should promote blood glucose control between 140 to 180mg per dL.³ These recommendations have led to adoption of tight glucose control in a variety of intensive care unit (ICU) settings. However, barriers of adoption include the increased risk of severe hypoglycemia and the difficulty of achieving target goals in critically ill patients.⁴

Current research has found that there are benefits and risks with tight blood glucose control in critically ill patients.⁴ Tight glucose control in adult intensive care patients is associated with an increased risk of hypoglycemia.⁴ It is now recognized that more moderate (140-180 mg/dL), rather than tight (80-110 mg/dL), control is associated with positive outcomes in critically ill patients.³ According to the Academy of Nutrition and Dietetics, tight blood glucose control (80 to 110mg per dL) does not improve hospital length of stay (LOS), infectious complications, cost of medical care, days on mechanical ventilation, and increases risk of hypoglycemia.⁵ Finter, S et al. found that patients with intensive glucose control compared to conventional control, had lower
blood glucose levels, received more insulin, and had more episodes of hypoglycemia.⁶ Findings however could not exclude the possibility that intensive glucose control may benefit some critically ill patients.

All critical care patients should be monitored for hyper and hypoglycemia. Insulin therapy should be initiated for treatment of persistent hyperglycemia starting at a threshold of no greater than 180 mg/dL.⁶ Once insulin therapy is started, a glucose range of 140-180 mg/dL is recommended for a majority of critically ill patients.¹ There are many indications for intravenous (IV) insulin infusion in an acute hospital setting. The most common indications include Diabetic Ketoacidosis (DKA), Hyperosmolar hyperglycemic state (HHS), very poorly controlled diabetes despite subcutaneous insulin, Total Parenteral Nutrition, any ICU patient with hyperglycemia, or suspected poor subcutaneous absorption of insulin.⁷ Due to recommended tight glucose control, more ICU patients require insulin IV drip administration.⁸ Currently many acute care settings rely on their health care staff to monitor and determine insulin infusion rates using a standard paper-protocol algorithm.⁹ Saur, N et al. determined that converting from a paper-based protocol to software-guided dosing method for intensive insulin therapy, resulted in superior control of hyperglycemia and marked decrements in the incidence of hypoglycemia.⁹

Implementation of independent, web-based computerized algorithm systems have been used to calculate the insulin drip infusion rate needed to facilitate hyperglycemia management. The system has also been used to maintain blood glucose levels within a prescribed target range. Research has shown the use of this software,
when compared to the standard paper-protocols, was associated with significant lower rate of severe hyperglycemia during insulin infusion. The mean time to reach a blood glucose target range was shorter with the computerized software and had a lower mean glucose value during insulin infusion. Once the target range was reached, the insulin dosing system produced lower mean blood glucose values than the current paper protocol.

The purpose of this research is to determine whether the implementation and use of computer-based software, GlucoStabilizer, will assist health care providers in managing tighter glucose control and reduce hypoglycemic events in the ICU. There is minimal research on the new FDA cleared IV insulin dosing software, GlucoStabilizer and research is needed in the clinical implementation within many intensive care unit settings.

Although research has determined that tighter protocols may increase the probability of hypoglycemic events, computer-based software has shown to reach tighter controls within less time than standard algorithms. Newton, et al. has also provided insight into long-term controls with the use of computer-guided software. The results of this research will incorporate the implementation of tighter blood glucose standards in an acute care setting and implementation of the GlucoStabilizer software. This study will test the hypothesis that although tighter blood glucose standards may increase hypoglycemic events, the software implemented in coordination will combat these risks.
This research is needed in many facilities that will consider implementing the approved new ICU protocol with tighter target ranges and close monitoring. St. Mary’s Hospital & Regional Center of Grand Junction, Colorado has recently implemented the GlucoStabilizer system to be used on any patient 18 years old and older requiring IV insulin drip administration. Research is needed to review effectiveness of implementation by the clinical team and determine the benefits of the GlucoStabilizer initiative. The study provides a retrospective look at blood glucose goals and hyper and hypoglycemic events using standard paper-protocols and compares the results found post-implementation of the web-based algorithm.

Implementation of a new blood glucose policy and insulin dosing system will require a team of health care providers. Registered Dietitians, Nurses, and Physicians will work together to facilitate glucose management within a target range. Results of this research present the role of a Registered Dietitian in the clinical implementation of a network based computerized algorithm software. Coordination with Registered Dietitians will help providers determine carbohydrate content of a consumed meal or snack as content varies. St. Mary’s Hospital & Regional Center has elected to enable the carbohydrate coverage feature of the GlucoStabilizer. The policy requires the nurse to provide a bolus of intravenous insulin for carbohydrate coverage based on the determined grams on carbohydrate consumed. The software has a default setting of 1 unit of regular insulin for every 10 grams of carbohydrate. Physician and RD consensus will determine the default carb ratio for a specific patient receiving nutrition support. When using the GlucoStabilizer to calculate intravenous insulin dosing, the amount of IV insulin administered can be calculated based on the insulin carbohydrate ratio.
Glucose management and software implementation is a team effort. RD’s, nurses, physicians, and other health care providers contribute their expertise to develop therapeutic regimens that help a patient achieve the best metabolic control possible. Implementation of a network based computerized algorithm system at St. Mary’s Hospital & Regional Center will facilitate hyperglycemia management and maintain blood glucose levels within a prescribed target range. Results of this research will determine if the GlucoStabilizer initiative will improve blood glucose control and lower the incidence of hypoglycemia in the medical intensive care unit of an acute care hospital.

Methodology

GlucoStabilizer will be used for any patient 18 years old and older requiring an intravenous insulin infusion. Exclusions will include pediatric patients younger than 18 years old as well as patients receiving subcutaneous insulin rather than IV drip administration and TPN. For this data collection subjects were recruited through the Vigilanz system. The VigiLanz Dynamic Monitoring Suite is a complete real-time decision support and care management solution used by the clinical pharmacy at St. Mary’s Hospital & Regional Center. The system simply collects designated numbers such as point of care glucose monitoring for that subject. The collection was strictly quantitative and did not include any patient identifiers.

A retrospective study was conducted to gather quantitative data of blood glucose control, hyperglycemic, and hypoglycemic events in the intensive care. With the help of lead clinical pharmacist, Rudy Bormann, collection of retrospective data from January
2013, was gathered on any patient $\geq$ 18 years old in the intensive care unit (ICU) and on an insulin drip. Outliers of hyper and hypoglycemic events were determined with a blood glucose of $>180$ mg/dL and $<70$ mg/dL. The GlucoStabilizer software is used for this population and post implementation comparable data was collected and analyzed from March 2014. The results determined blood glucose control and the amount of adverse events.

Qualitative data was collected via a survey to determine provider satisfaction of blood glucose control with the use of paper-protocol insulin infusion standards compared to the GlucoStabilizer. A panel study was conducted on providers in the caring for patients requiring IV insulin drip therapy. Nurses and Physicians in the ICU have been surveyed to determine satisfaction of glucose control and carbohydrate coverage pre and post implementation of GlucoStabilizer. The survey will evaluate the use of the GlucoStabilizer initiative at the current hospital.

This research will determine that the computer-based software system is a useful tool in managing blood glucose in patients receiving IV insulin infusion therapy. Results will improve glycemic control and lower the incidence of adverse events in critically ill patients in the ICU.

**Results**

**Quantitative Data: Vigilanz Results**

Retrospective data was collected during the month of January 2014 through the Vigilanz system. In January 2014, 29 adult patients in the ICU were placed on an insulin drip. 11 hyperglycemic events occurred resulting in 38% of the patients (Table 1, Figure 9)
1). 5 patients had a hypoglycemic event or 17% of the patients on an insulin drip (Table 4, Figure 5). Total adverse events in the ICU were 16 or 55% of the total population. Data also resulted in 5 patients whom had an adverse event having both a hyper and hypoglycemic event.

Data was later collected in March 2014 post implementation of the GlucoStabilizer software. During the month of March 2014, 21 adult patients in the ICU were placed on an insulin drip. Compared to January, only 3 hyperglycemic events occurred resulting in 14% of the patients (Table 2; Figure 2, 3 and 4). Only 1 patient had a hypoglycemic event or 5% of the patients however that 1 patient had both a hyper and hypoglycemic event. (Table 5, Figure 6 and 7). A total of 4 adverse events occurred in March compared January with a difference of 12 events. The use of the GlucoStablizer improved the number of adverse events occurring when compared to the use of a paper protocol algorithm (Figure 8).

The variance and standard deviation were low for the month of January however, compared to the results from the month of March results were much lower (Table 3 and 6). These results showed that with the use of the GlucoStabilizer software blood glucose was better controlled in the ICU with decreased amounts of adverse events. Comparing the two months is a small snap shot of the data; however the results provided a snap shot of better control. Compared to 16 adverse events with use of a paper-protocol, the use of the software algorithm only produced 3 adverse events, proving greater blood glucose control (Figure 8).
Qualitative Data: Survey Results

A total of 119 providers were surveyed during GlucoStabilizer training. 39 of the 119 participants worked in the intensive care unit. Results revealed increased confidence of providers when managing insulin infusion using the GlucoStabilizer over previous paper-protocols. 37 of the providers agreed the GlucoStabilizer made it easier to make adjustments in IV insulin infusions. 38 agreed the GlucoStabilizer provides quicker regulation of blood glucose. Results proved providers agree there is value in optimizing glycemic management for intensive care patients.

Post-Implementation survey results revealed that providers felt much more satisfied in the level of glycemic control. 35 providers reported increased confidence in counting estimated carbohydrate amounts when a patient consumed meals orally. All the providers reported understanding and accurately using the carbohydrate coverage feature of the GlucoStabilizer.

Discussion

When it comes to blood glucose control, RDs are an integral part of the multidisciplinary care team. RDs promote tight control in the critically ill patient in the intensive care unit. This study examined the role of the RD in the implementation of an IV insulin dosing software used to assist health care providers in managing blood glucose and reducing the number of adverse events. The results are consistent with findings that when compared to the use of paper protocol insulin dosing standards, a patient in the ICU in an insulin drip had less adverse events. The results of this study found an improved relationship between the number of adverse events and
implementation of the GlucoStabilizer. This data coincides with the data Saur, N et al. determined when converting from a paper-based protocol to software-guided dosing method for intensive insulin therapy. Data resulted in superior control of hyperglycemia and marked decrements in the incidence of hypoglycemia.

A limitation of this study is that it is over a short period of time. The study is simply a snap shot of blood glucose control in the ICU for one month with the use of a paper protocol algorithm, compared to one month with the use GlucoStabilizer. Recommendations for future studies on this topic should be done over a longer period of time to determine the long term effects of implementation of the GlucoStabilizer and blood glucose control in the ICU setting.

This study does not prove quicker regulation of blood glucose. This study does not take into account the amount of time it took to bring the patients' blood glucose into the targeted range once the insulin drip rate was determined. This data would be beneficial to this study to show that the GlucoStabilizer reduced the time to stabilize elevated blood glucose.

This survey study represents the first analysis of competencies for providers and implementation of the GlucoStabilizer in the intensive care unit at St. Mary’s Hospital & Regional Center. However, this study also does not take into consideration adverse events related to carbohydrate coverage. Although the qualitative data showed an increased confidence in counting carbohydrates and using the coverage feature, it did not report results of the blood glucose control with use of the software feature.
Recommendations for future studies on accuracy of carbohydrate counting and coverage for transferring subcutaneous insulin should be conducted.

**Conclusion**

Registered Dietitians play a key role in the multidisciplinary healthcare team when managing blood glucose. As a valued team member, RDs promote tight blood glucose control in critically ill patients, especially when the patient is able to consume carbohydrates. The results support the hypothesis that implementation of the computer based software GlucoStabilizer improved blood glucose control and decreased adverse events in patients in the ICU of an acute care hospital.
Appendix

Institutional Review Board: Claim of Exemption

March 6, 2014 a letter was presented to the request for an exemption determination for the given research project. The Research Compliance Oversight Pre-Review subcommittee reviewed the exemption criteria under 45 CFR 46.101b. The committee believed the research fit the exemption criteria. No data was recorded or received that would allow for identification of the participant, directly or through identifiers linked to the subjects.

Tables & Figures:

Table 1: Number of Hyperglycemic events in the ICU with the use of paper protocol algorithm to determine insulin drip rate from January 1-31st, 2014.

<table>
<thead>
<tr>
<th>Glucose Serum: POC</th>
<th>Total Patients on Insulin Drip N=29</th>
<th># of Hyperglycemic Events n=11</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 180-199 mg/dL</td>
<td>1 (3% of patients on drip)</td>
<td></td>
</tr>
<tr>
<td>&gt; 200-300 mg/dL</td>
<td>9 (43%)</td>
<td></td>
</tr>
<tr>
<td>&gt; 300-500 mg/dL</td>
<td>1 (3%)</td>
<td></td>
</tr>
<tr>
<td>&gt; 500 mg/dL</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>
**Figure 1:** Descriptive Data of Hyperglycemic Events in January 1-31\textsuperscript{st}, 2014.

**Table 2:** Number of Hyperglycemic events in the ICU after implementation of the GlucoStablizer to determine the insulin drip rate from March 1-31\textsuperscript{st}, 2014.

<table>
<thead>
<tr>
<th>Total Patients on an Insulin Drip</th>
<th># of Hyperglycemic Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>N= 21</td>
<td>N=3</td>
</tr>
<tr>
<td>Glucose Serum: POC</td>
<td>/= 180 mg/dL</td>
</tr>
<tr>
<td>&gt; 180-199 mg/dL</td>
<td>0</td>
</tr>
<tr>
<td>&gt; 200-300 mg/dL</td>
<td>2 (9% patients on drip)</td>
</tr>
<tr>
<td>&gt; 300-500 mg/dL</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>&gt; 500 mg/dL</td>
<td>0</td>
</tr>
</tbody>
</table>
Figure 2: Descriptive Data of Hyperglycemic events in March 2014.

Table 3: Comparison of hyperglycemic events in January 2014 with use of the paper protocols to March 2014 with use of the GlucoStabilizer software.

<table>
<thead>
<tr>
<th>Hyperglycemic Events ( \geq 180 \text{ mg/dL} )</th>
<th>January 1-31(^{st}) 2014: Paper-Protocol Algorithm</th>
<th>March 1-31(^{st}), 2014: GlucoStabilizer Algorithm</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Adverse Events</td>
<td>11</td>
<td>3</td>
</tr>
<tr>
<td>% total population (ICU patients on an insulin drip)</td>
<td>11/29 (38%)</td>
<td>3/ 21 (14%)</td>
</tr>
<tr>
<td>Maximum BG</td>
<td>309 mg/dL</td>
<td>337 mg/dL</td>
</tr>
<tr>
<td>Variance</td>
<td>1.82E-5</td>
<td>1.89E-14</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.0043</td>
<td>1.38E-7</td>
</tr>
</tbody>
</table>
**Figure 3:** Comparison of Hyperglycemic events in January 2014 and March 2014.

**Figure 4:** Comparison of Range of hyperglycemic Events in January 2014 and March 2014.
**Table 4:** Number of Hypoglycemic events in the ICU with the use of paper protocol algorithm to determine insulin drip rate from January 1-31<sup>st</sup>, 2014.

<table>
<thead>
<tr>
<th>Total # patients on an insulin drip</th>
<th>Total # Hypoglycemic Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>N= 29</td>
<td>n= 5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Glucose Serum: POC</th>
<th>&lt;= 70 MG/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 69-60 mg/dL</td>
<td>4 (14% patients on drip)</td>
</tr>
<tr>
<td>&lt; 50-59 mg/dL</td>
<td>0</td>
</tr>
<tr>
<td>&lt; 50 mg/dL</td>
<td>1 (3%)</td>
</tr>
</tbody>
</table>

**Figure 5:** Descriptive Data of Hypoglycemic Events in January 2014.
**Table 5:** Number of Hypoglycemic events in the ICU after implementation of the GlucoStablizer to determine the insulin drip rate from March 1-31\textsuperscript{st}, 2014.

<table>
<thead>
<tr>
<th>Total # patients on an insulin drip</th>
<th># of Hypoglycemic Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=21</td>
<td>N= 1</td>
</tr>
<tr>
<td>Glucose Serum: POC</td>
<td>&lt;= 70 mg/dL</td>
</tr>
<tr>
<td>&lt; 69-60 mg/dL</td>
<td>1</td>
</tr>
<tr>
<td>&lt; 50-59 mg/dL</td>
<td>0</td>
</tr>
<tr>
<td>&lt; 50 mg/dL</td>
<td>0</td>
</tr>
</tbody>
</table>

**Table 6:** Comparison of hypoglycemic events in January 2014 with use of the paper protocols to March 2014 with use of the GlucoStablizer software.

<table>
<thead>
<tr>
<th>Hypoglycemic Events</th>
<th>January 1-31\textsuperscript{st} 2014: Paper-Protocol Algorithm</th>
<th>March 1-31\textsuperscript{st}, 2014: GlucoStablizer Algorithm</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;= 70 mg/dL</td>
<td># Of Events</td>
<td># Of Events</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>% of total population (patients on an insulin drip in the ICU)</td>
<td>% of total population (patients on an insulin drip in the ICU)</td>
</tr>
<tr>
<td></td>
<td>Minimum</td>
<td>Minimum</td>
</tr>
<tr>
<td></td>
<td>42 mg/dL</td>
<td>61 mg/dL</td>
</tr>
<tr>
<td></td>
<td>Variance</td>
<td>Variance</td>
</tr>
<tr>
<td></td>
<td>1.42E-15</td>
<td>0, only one adverse event</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td></td>
<td>3.77E-8</td>
<td>0, only one adverse event</td>
</tr>
</tbody>
</table>
**Figure 6:** Comparison of Hypoglycemic events in January 2014 and March 2014.

**Figure 7:** Comparison of Range of hyperglycemic Events in January and March 2014.

**Figure 8:** Comparison of adverse events in January and March 2014.
References


