Chapter 11

Glucose control as a model for implementation of a clinical decision support system

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Glucose control in acute cardiac disease is difficult to achieve and may improve patient outcome. Because glucose levels were high at the Intensive Cardiac Care Unit, and adherence to a paper protocol was low, a web based decision support system for glucose control was developed. A board view of the currently admitted patients is provided; new glucose values are retrieved along with insulin infusion rates and patient data from the Patient Data Management System. For each new glucose value a pop-up is generated with the protocol advised action for insulin dosage and time for the next glucose measurement. Temporal trends in glucose and insulin values are displayed as an additional aid. An evaluation database is included in the design to provide feedback to the users on protocol compliance and glucose control. These data will also be used to improve the protocol.
INTRODUCTION

Glucose homeostasis in critical illness is altered due to changes in metabolism, release of hormones that counteract the normal action of insulin and an increase in hepatic glucose production; in addition the sensitivity of peripheral tissues to insulin may decrease (1). Hyperglycemia is also common in patients admitted with Acute Coronary Syndromes, and is associated with a more negative prognosis; possibly due to pro-inflammatory, pro-thrombotic and tissue damaging effects of glucose (2).

The importance of glucose control has lead to a large number of studies and published protocols. Use of automated glucose protocols has been associated with increased protocol compliance and better achievement of glucose target levels (3).

Designing applications for clinical decision support, such as automating existing protocols, is a complex task, requiring continuous evaluation and refining of the system (4). The aim of this project was to develop a Clinical Decision Support System (CDSS) for glucose control at the Intensive Cardiac Care Unit (ICCU) that can be easily adapted for other CDSS applications.

BASELINE EVALUATION

An evaluation of the existing situation at the ICCU was done: glucose levels and protocol compliance were analyzed for all admissions. Data was used from ChartAssist (Dräger Medical, Andover MA, USA), the Patient Data Management System (PDMS) (5).

Glucose level and protocol compliance
From January 1, 2007 thru July 28, 2008, 2398 ICCU admissions were identified. Of these, 1788 had at least one glucose measurement during admission and were included into the analysis. In total 16221 glucose measurements were used (Table 1).

Glucose level during admission was calculated using the Area Under the Curve (6) and Hyperglycemic Index (7). For the majority (60,5%) of the admissions the average glucose level was above protocol target range (4,5 to 7,0 mmol/dl). Thirty-nine percent were within the range and 0,5% was below. Measurements were performed within the protocol advised time in 37% (a 10% margin was included). Insulin was dosed according to the protocol in 50%, lower in 46% and higher in 4% of the cases.

In short: the majority of the admissions had average glucose levels higher than the target range, and compliance with the protocol was low.

Workplace analysis
Nurse and physician workflow patterns were observed and interviews were conducted. The 8-bed ICCU uses a web-based PDMS (5) that includes demographic data, laboratory
values and (IV) medications. The PDMS fully supports the nursing documentation; data from the PDMS are kept in a database which is replicated.

Laboratory measurements (including glucose) are performed using full blood samples (venous and arterial), which are determined at a nearby (approximately 25m) laboratory, where the sample is analyzed and the values are automatically entered into the Hospital Information System. There is an approximate delay of 20 minutes between sample acquisition and completed analysis; the nurse needs to check the PDMS regularly to see if the sample has been determined before taking action as advised by the paper protocol. The insulin infusion rate is adjusted, sometimes after consulting a physician, and the nurse manually enters the insulin dosage into the PDMS.

Table 1: Baseline glucose and protocol compliance

<table>
<thead>
<tr>
<th>Population characteristics</th>
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</thead>
<tbody>
<tr>
<td>Mean age (years)</td>
<td>64 ± 14</td>
</tr>
<tr>
<td>Male gender</td>
<td>71%</td>
</tr>
<tr>
<td>Pre-existent Diabetes</td>
<td>20%</td>
</tr>
<tr>
<td>Number of glucose measurements</td>
<td>3 (1 - 43)</td>
</tr>
<tr>
<td>Length of ICCU admission (days)</td>
<td>0.7 (0 - 10)</td>
</tr>
</tbody>
</table>

Glucose values

| Average glucose during admission (mmol/l) | 7.4 (5 - 12) |
|< 4.5 mmol/l | 0.5% |
|4.5 - 7.0 mmol/l | 39.0% |
|> 7.0 mmol/l | 60.5% |

Hyperglycemic index | 0.71 (0 - 4.9) |

Protocol compliance

| Glucose measurements on time | 37% |
| Insulin dosage according to protocol | 50% |
| Insulin dosage lower than protocol advice | 46% |
| Insulin dosage higher than protocol advice | 4% |

Values are displayed as mean±SD or median (5 - 95 percentile)

Table 2: Excerpt from glucose protocol

<table>
<thead>
<tr>
<th>Initial glucose value</th>
<th>Start Insulin Infusion at</th>
<th>remeasure</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 20 mmol/l</td>
<td>5 units/hour, notify physician</td>
<td>in 1 hour</td>
</tr>
<tr>
<td>17.1 - 20.0</td>
<td>4 units/hour</td>
<td>in 1 hour</td>
</tr>
<tr>
<td>14.1 - 17.0</td>
<td>3 units/hour</td>
<td>in 1 hour</td>
</tr>
<tr>
<td>11.1 - 14.0</td>
<td>2 units/hour</td>
<td>in 1 hour</td>
</tr>
<tr>
<td>7.1 - 11.0</td>
<td>1 units/hour</td>
<td>in 1 hour</td>
</tr>
<tr>
<td>&lt; 7.0</td>
<td>no insulin</td>
<td>in 4 hours</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Next glucose value</th>
<th>Insulin infusion</th>
<th>remeasure</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 11.0</td>
<td>ask physician about increase</td>
<td>in 2 hours</td>
</tr>
<tr>
<td>7.8 - 11.0</td>
<td>increase with 1 unit/hour</td>
<td>in 2 hours</td>
</tr>
<tr>
<td>7.1 - 7.8</td>
<td>increase with 0.5 unit/hour</td>
<td>in 2 hours</td>
</tr>
<tr>
<td>4.5 - 7.0</td>
<td>do not change</td>
<td>in 4 hours</td>
</tr>
</tbody>
</table>
The existing paper protocol (Table 2) is available at several locations on the ICCU, but not at bedside. It is a simple, rule-based protocol; rate of change in glucose value, nutritional status, medications, diurnal variation and history of diabetes are not taken into account.

Requirements for the glucose CDSS
Based on analysis of the current workflow, protocol limitations and technical possibilities, the following requirements were defined for the glucose CDSS:
- Notification of new glucose values with advice regarding insulin dosage and time of next measurement.
- Display of temporal trends in glucose values and insulin infusion rates.
- No manual data entry, straightforward and ‘nurse-proof’ interface.
- Use of PDMS data without compromising its speed, stability or manufacturer warranty.

DESIGN OF THE GLUCOSE CDSS
A board view display was developed (Figure 1), showing all eight ICCU beds. In each square colored bars represent glucose values; red indicating a value outside of target range, and green a value within. Insulin infusion rate is represented by a black line. Bars are displayed for measurements over the last 15 hours.

**Figure 1:** Eight ICCU beds are displayed; five admitted patients are shown, four with glucose values. The pop-up indicates a new value (1). Bars represent the preceding values; touching a bar will display the respective values (2). Insulin dosage is displayed by the black marks (3).
When a new glucose value is reported by the lab, a popup is displayed with the value and the protocol advised course of action: the adjustment in insulin infusion rate and the time when next glucose is to be determined. The popup can be closed with a finger press. Additionally the last popup can be recalled by touching the patient name. The glucose value and insulin infusion rate at a given time can be recalled by touching the respective bar. A 15-inch touch screen integrated PC was used, and mounted behind the nurses desk, easily accessible and clearly visible to all nurses.

**Front-end design**

The current design is a web 2.0 application, incorporating Simple Object Access Protocol, Asynchronous JavaScript and XML, and C#. The front end requests all available glucose values and insulin infusion rates of all (currently) admitted patients on the ICCU from the web service (see section on data acquisition and web service). The values are requested at a 10 second interval, followed by redrawing parts of the screen and generating pop-ups for new glucose values. This combination of web service and JavaScript allows for a quick screen redraw without using a ‘hard page refresh’.

A web-based interface was chosen for the front-end design of the DSP screen. This was done for several reasons: it is lightweight, enables access to the screen from multiple locations, and enables a design that in future it can easily be switched from a ‘nurse desk board view’ to a ‘single patient bedside’ view.

**Data acquisition and web service**

The data required for the CDSS is stored at different locations on the different hospital based systems (figure 2). The glucose values are received from the Hospital Information System by a buffer and then sent to the PDMS. Replicated data from the commercial PDMS database is used; running the CDSS on the primary database could slow or lock the database, and would void the warranty. The glucose values and PDMS data are also stored in an evaluation database.

The CDSS is a web service consisting of three different components. First is a cache, which stores all glucose values, insulin infusion rates and patient information of the patients currently admitted to the ICCU. The cache is renewed every minute, reducing the strain on the PDMS database server for each request from the glucose screens. Second is a simple (based on the paper glucose protocol) rule engine which uses the insulin infusion rates and glucose levels obtained from the PDMS database and laboratory buffer respectively, to generate a patient specific advice, which is also stored in the cache. Last is a web service function which queries the cache and sends the data from the cache in XML to the requesting glucose screens.
IMPLEMENTATION AND EVALUATION

A team consisting of a research physician, cardiologist and nurse was formed to help with the development and testing of the application. On July 28 the project was presented and demonstrated to the nursing staff.

During a 4-week pilot starting on August 11, technical and user aspects of the application were evaluated at the end of each shift. Nurses were instructed to enter the reason for deviation from protocol as a note into the PDMS. These notes are, along with insulin infusion rates, glucose values, and touch-screen utilization, collected in an evaluation database (Figure 2). A query and calculations are done to determine protocol compliance, reasons for deviation and glucose control data. These data are evaluated with the team on a monthly basis and used to improve the application and protocol. Additional data, including disease and mortality information will be collected on a regular basis to investigate the relation between glucose control and patient outcomes.

**Figure 2:** Overview of dataflow: 1. glucose values, 2. patient demographics and insulin infusion rates, reason for deviating from advice, 3. glucose protocol advice, 4. reaction times to advice, 5. feedback to users on use of system.

DISCUSSION

Analysis of existing ICCU data showed that glucose control could be improved, and that compliance with the existing paper protocol was low.

Workflow evaluation revealed the following obstacles to protocol compliance: the absence of notification of new lab results, low availability of paper protocol and belief that adherence to protocol would lead to increased hypoglycaemic episodes.

A multidisciplinary approach using these findings as a starting point led to the current CDSS for glucose control.
Encountered challenges

As with any electronic system, the quality of the entered data determines the quality of the output: laboratory times are the times of blood sampling, as written on the lab form by the nurse, and may differ significantly from the actual time of blood sampling. Insulin dosage is also entered manually into the PDMS, thus incorrect entry may lead to incorrect perceived dosage by the CDSS and an incorrect advice.

Flaws in protocols or guidelines are more apparent in electronic than in paper form. Inadequate advice from a paper version can easily go unnoticed, whereas electronic versions are designed to actively confront the user. For this reason the users are asked to provide the reason for deviating from the protocol advice: this will help identify and resolve potential flaws in the protocol.

During the initial pilot the following additional reasons for deviating from the protocol were identified: method of feeding (normal, enteric tube or parenteral), specific medications (e.g. steroids), time of day and quickly declining glucose levels.

The next step of incorporating these factors into the CDSS without additional data entry may be challenging: some of these factors are not entered into the PDMS, and may not always require deviation from the protocol.

Lastly, the clinical problem remains a difficult and controversial one; glucose control in critically ill patients has many research questions, including the range in which levels should be kept, as well as which patients benefit most from a tight glucose control (8).

Future directions

The CDSS display is currently not available at the patient bedside; initial results from the pilot suggest that a display at a central location as well as the bedside would increase protocol compliance; the nurse would then be able to see the advice and at the same time adjust the insulin dosage accordingly. Ideally the CDSS would be integrated into the PDMS, thus eliminating the need for an extra patient bedside monitor.

CDSS in general, and the current system specifically, have enormous potential to collect data for protocol and guideline improvement. In the current setting data acquisition and validation is a time-consuming process. Use of a data warehouse where PDMS data is stored may facilitate the data retrieval in a form that is suitable for further analysis.

The current design is suited for many different types of protocols in the critical care environment; such as sedation, heparin, nutrition, ventilation, and others where the information needed is available in electronic format. The interface for multiple CDSS running at the same time will be challenging; assigning a level of importance to the CDSS notification may be useful to prevent ‘alert fatigue’.

The current CDSS can be adapted to other units. With only minor adjustments it may be used on other intensive cares, as these have the highest level of electronic charting, but with additional changes it could also be used on the medium care wards.
CONCLUSION

A thorough investigation led to a system that fits into the workflow, requires no additional data input and prospectively collects data for evaluation.

Using a flexible web based platform a clinical decision support system for glucose control was developed.

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REFERENCES
