Adoption of New Technology for Bedside Glucose Testing

The first major metropolitan hospital to adopt a new technology specifically developed to improve analytical performance at the bedside shares its experience.

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Technology for bedside glucose testing has been somewhat untapped. The measurement technology was originally developed for self-testing of diabetics without considering the increased acuity of hospitalized patients.

Challenges are associated with bedside glucose technology on hospitalized patients, including hematocrit errors, interferences, biases and poor correlation with central laboratory reference methods. This is compounded by new protocols citing that better control of glucose levels in hospitalized patients results in significantly improved outcomes.

Given these new protocols, specialists at Saint Vincent Hospital, Worcester, MA, questioned the ability of technology to meet the analytical requirements necessary to manage patient glucose levels within the narrower ranges and set a course for new system selection.

Background

After Saint Vincent Hospital moved from Vernon Hill, MA, to a new 348-bed acute care hospital in downtown Worcester, one of our primary goals was to address our bedside glucose program toward enhancing analytical performance, building confidence of the nurses and laboratory in the test results, and improving operator compliance and laboratory control of the entire process.

Our bedside glucose program encompasses virtually every department in the hospital, including all 33 nursing locations, a 10-bed labor and delivery unit, a 22-bed intensive care unit, an active 38-bed emergency department receiving approximately 70,000 patients per year (and rising), same-day surgery and the post-operative unit. In total, we have 55 glucose meters in use with nearly 1,000 operators handling the meters over three shifts performing approximately 180,000 glucose tests per year.

The meters and strips formerly in use throughout the hospital offered a performance range consistent with accepted technology at the time. However, the potential for errors due to abnormal hematocrit levels and other interferences by bedside meters had been widely recognized and was a cause for concern. This concern was heightened by a recent FDA announcement that glucose test strips based on the dehydrogenase method could lead to adverse medical incidents due to glucose interference by maltose. While maltose is not widely used at Saint Vincent, a large outpatient and Emergency Department population introduces a risk potential we were not anxious to test. Adding to these concerns was an inherent 10-15 percent bias between our meters and the laboratory reference analyzer.

Lastly, numerous studies substantiating the benefits of close management of inpatient hyperglycemia led to a decision to implement better glycemic management in our hospital. Other studies highlighted fear of causing hypoglycemia or other maladies as barriers to glycemic

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management and questioned the ability of bedside glucose meters to meet analytical demands. Since insulin is considered by the Joint Commission to be one of the five highest risk therapeutic agents in the inpatient setting, and because glucose results from our bedside testing would often be used to adjust insulin dosing, the analytical limitations of our former technology were no longer acceptable.

**Evaluation Process**

In early 2006, we learned of a new technology for bedside glucose testing (StatStrip™ Glucose Monitoring System, Nova Biomedical, Waltham, MA) that professed to eliminate interferences from hematocrit, maltose, oxygen and other electrochemical substances using a patented multi-well glucose strip. (See related box for additional bedside glucose testing technologies.) Undaunted by the fact that the technology was new to the market and no other hospital had yet adopted it, we proceeded with a laboratory evaluation consisting of side-by-side bench studies between the Nova StatStrip and the legacy meter. The evaluation included comparative studies at low, mid and high levels of glucose and hematocrit; maltose interference studies; precision studies at low, mid and high glucose levels; and correlation studies versus our laboratory analyzer. The results of our bench studies confirmed the manufacturer's claims regarding measurement accuracy and precision throughout the entire glucose range (10 to 600 mg/dL) and hematocrit range (20 to 65 percent), and at maltose levels up to 200 mg/dL, as well as correlation to our laboratory reference method (R2 = 0.996; average percent bias = 0.07).

Based on these results, we moved forward with an in-depth internal evaluation involving the Nova StatStrip encompassing four nursing units, including patient care assistants, who perform about 95 percent of our fingerstick glucose tests, and 10-20 ICU nurses. The color touch screen, speed of test results and small sample volume were cited as their top features. Significantly, our medical director commented that the measurement accuracy throughout the hematocrit range would be a major benefit to their tight glycemic control program.

**Implementation**

At the outset, the company worked closely with our nurse educators to devise a training schedule that included day, evening, night and weekend training sessions. Six hundred operators were trained before the "go live" date. Comprehensive meter validation included linearity studies on 100 percent of the meters, precision studies on 10 percent of the meters, and correlation studies versus the reference method on 10 percent of the meters. For the first few days following installation, application specialists were present on the floors for impromptu troubleshooting as necessary, to answer any operator questions and to train additional operators.

For the connectivity portion of the implementation, a facility site plan was generated in which docking station sites were identified. Our IT department was then contacted, and suitable network access drops were identified and activated. The Data Manager Server was then installed and networked. Utilizing the AegisPOC Information Management System (Laboratory Data Systems, Tampa, FL), meter configurations, operator lists and reagent lists were built and assigned for each docking station site.

Before meters were placed into service, each docking station was configured with the appropriate network communication settings and tested to ensure connection to the server. Each meter was uploaded with the specific configuration for its location, including valid operators, QC mode and frequency, normal and critical ranges, pre-set comments, patient and operator ID requirements, mandatory fields and docking requirements. Each meter was then tested to ensure the configuration had been applied. Uploading the configuration of all meters from the AegisPOC workstation eliminated the need to manually configure the meters.
Process Improvements

We went live with StatStrip meters and test strips throughout the hospital in December 2006. Since StatStrip will not provide a result unless the dosing is correct, one immediate benefit has been the elimination of dosing errors due to the unique multi-well design. In addition, the new technology is able to accurately measure over broader glucose (10-600 mg/dL) and hematocrit (20-65 percent) range with excellent agreement to our central laboratory ($R^2 = 0.996$; average % bias = 0.07%). The technology has a much improved glucose measurement range and is free from interferences, which eliminates the need to perform repeat testing on the critical samples except at the physician's discretion.

Additionally, our caregivers are no longer able to enter a random operator ID number to use the meter, as the new technology provides an optional fail-safe "scan only" system that requires scanning of the operator's barcode. Patient identification is established by entering the number of digits once. Barcode entry of the patient ID number, to be added in the near future, will significantly improve our ability to enter patient ID numbers correctly.

Tight glycemic control was implemented in our ICU within the past year. With this regimen came more frequent glucose testing—once every 30 minutes. The new technology reduces testing time from 40 seconds to six seconds.

Moving Forward With Connectivity

At implementation, all of the meters were connected through our LAN into the information management system. The meters are stored in the nurses' docking stations when not in use, facilitating utilization of the patient data. In the months ahead, we plan to install an admission discharge transfer system to be configured to our new LIS that will allow patient ID tracking throughout the hospital as well as billing of the bedside glucose testing.

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