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REVIEW ARTICLE

Blood Glucose Testing in the Hospital: Error Sources and Risk Management

James H. Nichols, Ph.D., DABCC, FACB

Abstract

Glucose testing in the hospital with point-of-care devices presents multiple opportunities for error. Any device can fail under the right conditions. For glucose monitoring in the hospital, with thousands of operators, hundreds of devices, and dozens of locations involved, there is ample opportunity for errors that can impact the quality of test results. Errors can occur in any phase of the testing process: preanalytic, analytic, or postanalytic. Common sources of meter error include patient or methodology interferences, operator mistakes, environmental exposure, and device malfunction. Early models of glucose meters had few internal checks or capability to warn the operator of meter problems. The latest generation of glucose monitors has a number of internal checks and controls engineered into the testing process to prevent serious errors or warn the operator by suppressing test results. Some of these control processes are built into the software and data management system of the meters, others require the hospital to do something, such as regularly clean the meter or analyze control samples of known glucose concentration, to verify meter performance. Hospitals need to be aware of the potential for errors by understanding weaknesses in the testing process that could lead to erroneous results and take steps to prevent errors from occurring or to minimize the harm to patients when errors do occur. The reliability of a glucose result will depend on the balance of internal control features available from manufacturers in conjunction with the liquid control analysis and other control processes (operator training, device validation, and maintenance) utilized by the hospitals.

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Introduction

"No device is fool-proof, for a sufficiently talented fool." This quote from a distinguished colleague epitomizes the complexity of managing the quality of glucose monitoring in a hospital setting. All devices can fail under the right conditions. With hospital glucose monitoring, if an error can happen, it certainly will occur, given the number of glucose tests conducted among thousands of operators, hundreds of meters, and dozens of sites in an average size hospital.

Risk and Error Sources

Risk has two components: the probability of occurrence of harm and the consequences or severity of harm.[1,2] In order to minimize risk, a hospital can decrease the probability of an error occurring by (1) improving detection or (2) preventing the consequences of an undetected error from reaching the patient (i.e., minimizing harm). Historically, laboratories have utilized the analysis

Author Affiliations: Tufts University School of Medicine, Boston, Massachusetts; and Department of Pathology, Baystate Health, Springfield, Massachusetts

Abbreviations: (CLIA) Clinical Laboratory Improvement Amendments

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Corresponding Author: James H. Nichols, Ph.D., DABCC, FACB, Clinical Chemistry, Baystate Health, 759 Chestnut Street, Springfield, MA 01199; email address *james.nichols@baystatehealth.org*

of quality control, stabilized samples with a known amount of analyte that are analyzed like patient samples, to determine the stability and reliability of glucose testing systems (the device, the reagents, and the operator.) However, there is a residual risk of error even with the periodic analysis of control samples, particularly with point-of-care testing, where the test is conducted close to the site of patient care by so many operators, devices, and locations involved in the delivery of hospital glucose monitoring.

Thus, the quality and reliability of one glucose test is not necessarily equivalent to that of another glucose test. Different models of glucose meters are uniquely affected by patient, methodology, and environmental and operator effects.[3,4] **Table 1** contains a partial list of potential sources of error that could be encountered during the use of glucose meters. Drugs administered to a patient, physiologic conditions, and hematocrit can differentially affect glucose meters. Failure to replace the cap on test strip vials exposes strips to air, light, and humidity, with the risk of premature degradation (prior to manufacturer expiration). Operators can forget to check test strip expiration, leading to testing with expired strips, and operators can inadvertently change meter settings from mg/dl to standard international units, mmol/liter. Errors are possible when entering calibration codes or when operators forget to change the calibration with different lots of test strips. Analysis of samples by untrained operators or application of too little sample can compromise results. Failure to analyze quality control samples at a frequency recommended by the manufacturer or continuing to test patients when quality control results fail to recover the expected levels can also lead to errors. Use of devices outside recommended temperature ranges (in ambulances, in helicopters, and with visiting nurses) can affect results. Manual transcription mistakes, as well as inaccurate entry of patient identification, can lead to reporting errors to the patient's medical record. There are thus a variety of error sources to consider when conducting glucose monitoring, and test result quality and reliability should never be assumed without appropriate control processes in place to detect and prevent errors.

Control Processes to Reduce Risk

Newer devices have built-in electronic controls and other control processes engineered into the device by the manufacturer to reduce the possibility of certain errors. These control processes are internal software enhancements, checks, or other operational improvements

Table 1.
Glucose Meter Risk Management[a]

Potential sources of error	Control processes and risk mitigation strategies
Patient sources of error	
• Medications (i.e., maltose, xylose, galactose)	• Utilize alternate model of meter not subject to interference
• Hematocrit	• Education of acceptable hematocrit ranges • Use a meter that measures and corrects for hematocrit effects
• Disease contraindications (poor circulation, diabetic ketoacidosis, trauma)	• Education of meter limitations
Operator sources of error	
• Expired reagents	• Barcoded test strips that prevent use after expiration date
• Incorrect calibration	• Barcoded reagents that automatically calibrate meter with each test
• Reagent exposure from failure to recap bottles of test strips	• Use individually wrapped test strips
• Incorrect sample volume	• Use a meter that detects correct amount of blood or side-filling test strip
• Incorrect disinfection	• Match cleaning solution with manufacturer recommendations
• Inadvertent change of units from mg/dl to mmol/l	• Software administrative functions to prevent operator changing setting
• Untrained operator performing test	• Software operator ID[b] lockout, (checks operator against trained list)
• Failure to analyze controls or incorrectly interpret control pass/fail	• Software control lockout, (checks control performance passes at defined intervals)
• Wrong level control analyzed	• Use barcoded controls that automatically identify the level
• Incorrect patient identification	• Use meters with positive patient ID and barcoded patient wristbands
Environmental sources of error	
• Temperature extreme	• Internal meter checks that monitor temperature • Analyze controls to verify test strip performance

[a] A sample of error sources encountered during the use of glucose meters and potential control processes that can reduce risk of specific errors. (Note, this list is not intended to be comprehensive, and sources of error will vary depending on meter model, institution, and medical use of the test result.)
[b] (ID) identification

that provide additional quality assurance beyond the periodic analysis of control samples. While analysis of two levels of controls can detect certain systematic errors that affect the control samples in the same manner as patient samples, quality control does a poor job at detecting random errors, such as drugs, hematocrit, or patient identification mistakes, that affect individual samples. The combination of a hospital's quality control plan (the frequency of analyzing control samples) and the manufacturer control processes (engineered into the device) is required to minimize the variety of potential risks from hospital glucose monitoring.

Risk management starts by plotting the steps involved in the entire glucose meter testing process. Each step, from preanalytic ordering of the test through sample collection, analysis, and postanalytic reporting and interpretation of results, should be diagrammed so as to detect weak points in the testing process. Those weaknesses are places where there is a significant enough potential for error that the laboratory should intervene with a control process. These steps may be identified from problem logs, quality assurance reports, and physician complaints or through troubleshooting previous errors. Once identified, the hospital should look to recent glucose meter technologies that are now available that can address and minimize some of these common errors.

Patient Sources of Error

Patient and physiologic effects are one common source of error for certain meters. Maltose is a sugar that is found in certain intravenous medications (immune globulin) and used in dialysis. Maltose cross-reacts with glucose dehydrogenase methods using pyrroloquinolinequinone as the detection system.[5] Other sugars, including xylose and galactose, may also interfere with this technology, resulting in falsely elevated glucose meter levels. Physicians who have acted on these levels by administering insulin have sent patients into hypoglycemia, with several deaths reported.[6] Use of an alternative system, such as glucose dehydrogenase nicotinamide adenine dinucleotide or glycose dehydrogenase flavin adenine dinucleotide, is recommended because these systems are not affected by maltose or other sugars.

Glucose meters are affected by hematocrit. Glucose is measured in the liquid, plasma portion of blood through separation of the cells prior to chemical reaction in the whole blood sample applied to a test strip. High and low hematocrits generate variable biases depending on the meter technology because each model of meter utilizes slightly different separation and analytical method combinations that react uniquely to the differences in viscosity across the range of patient hematocrits. Clinicians should be aware of the operational hematocrit range and limit the use of glucose meters to patients within this range. However, most clinicians do not routinely determine a patient's hematocrit prior to interpreting glucose results, so a number of results may be inaccurate, particularly in those patient populations with extreme ranges of hematocrits (neonate, polycythemic, post-surgical, trauma, intensive care, and cancer patients). Meters that do not use separation technologies in their test strips (i.e., cuvette-based methods that lyse the sample) are not as affected by hematocrit. One manufacturer has recently released a meter that measures hematocrit simultaneously with each glucose test and offsets the result to minimize this effect.[7,8]

All meters are also affected by poor circulation, which can occur in shock, dehydration, diabetic ketoacidosis (particularly nonketotic hyperosmolar conditions), and trauma. In these situations the glucose meter can show markedly decreased values compared to laboratory plasma glucose results.[9] Clinicians should be aware of the potential for glucose meter biases in these conditions and utilize alternative methodologies such as blood gas or central laboratory analyzers.

Operator Sources of Error

Operator errors are frequent problems with glucose monitoring, given the number of operators and variety of educational levels of staff involved in the testing process. Staff who are involved with a patient may not take the time to carefully check the expiration date of test strips before use. While periodic control samples can detect gross errors from use of expired reagents, the possibility of reporting patient results before controls are analyzed poses a risk of error. Many manufacturers now offer barcoded vials and/or test strips that barcode the expiration dates and generate an error code on the meter when there is an attempt to use them past the expiration date. Calibration is also coded within the barcodes of test strips. This strategy eliminates the possibility of an operator utilizing expired test strips or forgetting to change the calibration with a new lot of test strips.

Failure to tightly cap vials of test strips can lead to exposure to air, light, and humidity, which degrades the performance of test strips. Periodic controls can detect degraded test strips, but some manufacturers

provide individually wrapped test strips. Each test strip is barcoded with calibration information and expiration dates, and the individual wrapping eliminates the risk of exposure to environmental conditions.

Operator technique is another source of error. Operators may apply too little or too much blood to the test strip. Some models of meters now offer automated sample detection that starts the test timing once sufficient sample is applied to the test strip. Some manufacturers allow reapplication of sample up to 15–30 seconds after initial application if the test strip is initially underfilled, while other manufacturers utilize side strip and off-meter application of sample to prevent overfilling, which could wet the meter and damage the electronics.

Disinfection of glucose meters also poses a risk of damaging a glucose meter, depending on the model of meter and disinfection solution utilized. The Centers for Disease Control and Prevention has recently recommended that glucose meters utilized on hospitalized inpatients should not be shared.[10] If they must be shared, the device should be cleaned and disinfected after each use. Certain cleaners, such as bleach, can leave salt residue that can contaminate electrodes on some meters and affect results. Other meters are susceptible to alcohol, which can fog and crack plastic screens, impairing result display functions. Operators must be mindful to follow manufacturer's recommendations for specific models of meters, as even different models from the same manufacturer can require different cleaning solutions.

Enhanced meter software provides significant reduction in errors compared with manual glucose monitoring systems. Software security only allows device settings to be changed by administrative level staff. This prevents an operator from inadvertently changing the reporting units from mg/dl to mmol/liter or altering calibration, lot number, date/time, or other critical device settings. Software operator lockout features check an operator identification number against a list of trained operators. If the operator is not on the active list of competent operators, the meter will not allow patient testing. Other meter enhancements require the analysis of control samples at defined time periods (which the hospital can customize). If controls are not analyzed as defined or if the control results are not within an acceptable range, the meter will lock and prevent patient testing until the operator troubleshoots the problem and achieves successful control performance. This feature prevents the possibility that patient samples will be tested when controls have not been performed as required and ensures documentation of compliance with local and regional regulations such as the Clinical Laboratory Improvement Amendments of 1988 (CLIA) in the United States. Despite quality control lockout, operators may not pay sufficient attention to analyze the correct level of control when required by the meter (i.e., a high control is analyzed when the meter is expecting a low control), which results in control failure and meter lockout. A newer generation of smarter meters barcodes the control lot and level on each vial, so that the operator can analyze any level of control in a random sequence, and the software will match the appropriate expected range to the level of control.

Smarter software is also assisting with result documentation and minimizing the risk of patient misidentification. Meter software allows the patient and control results to be stored in the meter and electronically transferred to the patient's medical record when meters are docked to the hospital intranet system (or through telephone modem). This software ensures accurate documentation of each test performed (whether control or patient test) on every meter, a task that was not always completed with manual recording of results because of the clinical pressures on staff in the hospital. In addition, the software links the test result to the operator performing the test, meter serial number, and lot of test strips in order to provide a documentation trail that meets CLIA quality requirements. Manual entry of patient identification with first generation data management meters leads to a number of mistakes where the test result gets stuck in the data management system (as an active patient record cannot be matched to send the result), or worse, is transferred to the wrong patient's medical record. Implementation of barcoded patient identification wristbands improves the accuracy of identification entry in the meter, but is not entirely accurate.[11] Barcode scanning errors (from the curvature of the wristband) lead operators to resort to manual entry with concurrent errors and incorrect selection of patient identification (outpatient accounts for inpatient stays), and identification bands from other hospitals continue to impede result transfer even with barcoded wristbands. [11] The latest generation of glucose meters now offers positive patient identification. Using the hospital admissions/discharge/transfer database, the patient's name is displayed when the patient's wristband is scanned. The operator must then accept the patient by entering a second patient identifier, such as birth date, to allow the patient testing to be completed. This operational

improvement lowers the risk of identification errors and mistaken transfer of results even more than the use of barcoded identifications alone.

Environmental Sources of Error

Device operation can present a risk of error when glucose meters are utilized outside of the well-controlled environment of the hospital. Ambulance, helicopter, and home-health care visiting nurses must transfer glucose meters and test strips in vehicles in the heat of summer and cold of winter. While all manufacturers have recommended operating conditions, staff may not remember those conditions when treating an urgent trauma case or monitor outside temperature conditions to ensure that the device is within recommended conditions. Newer glucose meters have internal checks that monitor temperature and humidity, displaying an error if the meter is operated outside recommended conditions. The meter must then be brought back within recommended ranges for several minutes before functionality is restored. These internal checks reduce the probability that a meter will be utilized outside recommended conditions that could lead to a result error. However, these checks do not monitor the reagent performance, so a temperature or environmental error code on the glucose meter should alert the operator to check the test strips using control samples to verify reagent performance prior to further patient testing.

Summary

In summary, risk management is the systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk.[1] There are a number of potential risks with glucose monitoring in the hospital including patient, environmental, device, and operator sources.[3,4] The quality of a glucose result will depend on the variety of control processes that hospitals employ in conjunction with those that the manufacturer has engineered into newer devices to minimize the probability of an error occurring, better detect errors, or reduce the harm to a patient if an error should occur. Automation is the best prevention for errors in glucose monitoring. Removing the human element, the need for operator action, judgment, or thought about the testing process, will minimize the risk of an erroneous result. While point-of-care testing provides a faster means of delivering laboratory testing, accuracy and quality should not be sacrificed. As Wyatt Earp once said, "Faster is fine, but accuracy is everything."

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