Point-of-Care Technology: Glucose Meter's Role in Patient Care

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ABSTRACT

Glucose meters are a point-of-care device used in the management of blood glucose levels for hospitalized patients. Glucose meters provide results so quickly that, in some cases, health-care workers treat patients based on meter results before validating them. Events reported to the Pennsylvania Patient Safety Authority demonstrate unintended consequences that arose when patients were treated based solely on glucose meter results. Proper meter use, hospital policies and protocols, and a physical assessment coupled with effective communication are components of good patient care. The ability to think critically, balancing these components, can be the difference between the delivery of safe patient care and a serious or fatal adverse event. (Pa Patient Saf Advis 2011 Dec;8[4]:119-125.)

INTRODUCTION

Point-of-care (POC) glucose meters are an integral part of the typical approach to managing hospitalized patients' blood glucose levels[1,2] because they provide immediate results and are cost-effective. Used correctly, these devices are an invaluable aid; however, they are not infallible. Taking action solely on the basis of the glucose meter results without a patient assessment can lead to serious unintended consequences. The following event reported to the Pennsylvania Patient Safety Authority demonstrates this point:

> *A patient's [glucose meter result] read "RR HI." The patient was asymptomatic and previous [glucose meter results] were not running "HI." Insulin coverage was held until the result of the [laboratory] glucose [level] was obtained. The [laboratory] glucose result read 79. The patient was not given any insulin coverage and remained asymptomatic with low glucose [levels].*

The purpose of this review is to identify problems related to POC blood glucose testing in Pennsylvania hospitals and provide suggestions to prevent adverse events.

PROBLEMS WITH POC BLOOD GLUCOSE TESTING

A search of the Authority reporting system database, from June 28, 2004, through May 31, 2011, was conducted to identify glucose-meter-related event reports. The initial search, using the words "test strips," "glucose strips," and "accucheck," identified more than 3,200 event reports, which were refined to more than 1,300 reports by limiting the search to specific event types (e.g., procedure errors and complications, equipment use and device issues, miscellaneously identified glucose-meter-related reports). A review of the 1,300 reports identified 71 glucose meter near-miss and adverse event reports that composed the final data set. The detailed analysis identified four common themes, as follows:

- Equipment use
- Hospital policy and protocols
- Physical assessment of the patient
- Healthcare team communication

Seventy percent (n = 50) of the 71 reports document equipment use as the only issue, while the remaining 30% (n = 21) of the reports identified an equipment use issue in conjunction with 1 or more of the 3 other issues identified above, (e.g., equipment use and hospital policy; equipment use, hospital policy, and physical assessment). (See Table 1.)

Next, the analyst examined harm score event report categories.[3] Fifty-four percent (n = 38) of the reports were reported as harm scores A through C (an event did not reach the patient, or an event that reached the patient but did not cause harm or require increased monitoring). Forty-six percent (n = 33) of the reports were reported as harm scores D through I (the event reached the patient and required monitoring intervention or caused harm or death). Harm scores D through I were present whether there was only one issue (i.e., equipment use) or multiple issues reported.

Equipment Use

Results from blood glucose meters are not as accurate as lab-based blood glucose results.[4-6] The Authority data analysis identifies two types of glucose meter issues: questionable glucose meter results and test strip issues.

Standards set by the U.S. Food and Drug Administration (FDA) and the International Organization for Standardization require that 95% of glucose meter results vary no

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Table 1. Glucose-Meter-Related Events Reported to the Pennsylvania Patient Safety Authority, June 28, 2004, through May 31, 2011

EQUIPMENT USE	HOSPITAL POLICY AND PROTOCOL	PHYSICAL ASSESSMENT OF THE PATIENT	HEALTHCARE TEAM COMMUNICATION	TOTAL NUMBER OF REPORTS
✓				50
✓	✓			9
✓		✓		5
✓	✓		✓	3
✓	✓	✓		2
✓		✓	✓	1
✓	✓	✓	✓	1
				71

more than 20% (±20%) when glucose levels are greater than 75 mg/dl. This means that when a blood glucose level reads 100 mg/dl, 95 of 100 samples should read between 80 and 120 mg/dl.[4,5] The other 5% of results may fall just outside the 20% range or may be extreme outliers. The magnitude of this issue was presented at an FDA public meeting. A physician reported that at his hospital he had 600,000 glucose meter results per year; if 95% of the results fall within the 20% variability, the other 5% or 30,000 results fall outside the acceptable range.[5]

An analysis of the Authority data was conducted to determine the type of glucose meter variability within Pennsylvania hospitals. There are three types of variability: high-blood glucose results (72%, n = 51), unidentified questionable results (18%, n = 13), and low-blood glucose results (10%, n = 7). The analyst then evaluated whether the high-blood glucose results were validated, how they were validated, and where they occurred (see Table 2).

The following two Authority reports demonstrate the significance of high-blood glucose meter results:

> *The nightly [glucose meter] reading was 454. [Staff] obtained a stat blood glucose from the lab. The [lab result] was 152. A quality check was done to the machine and an out-of-order sign was placed on the machine.*

> *A patient's blood sugar was checked using a [glucose meter]. The lunchtime result was 517. A [blood glucose test] was [immediately] retaken to check for accuracy, and the result was greater than 600. A blood [laboratory] level check was conducted per protocol, and the [lab] glucose [result] was 136. The nurse used the serum glucose as the actual result and reported a malfunction in the machine to the lab and the [nurse manager]. The [nurse manager] was made aware of the situation and took the glucose meter out of use on the floor and notified the supervisor in the lab. The supervisor in lab removed the machine from service and replaced the machine with a new machine.*

Test strips are the second issue. Glucose meter test strips are layers of porous paper with enzyme reagents that react to substances, using whole blood to calculate a blood glucose result.[6,7] Test strips require careful handling because they can absorb and react to different types of nonblood substances (e.g., food, moisture, nonglucose sugars), leading to test strip contamination. Other commonly reported problems associated with test strips include improper use and patient physiologic conditions. The following is an Authority report example:

> *The nursing supervisor received a call from the community [outpatient] peritoneal dialysis [nurse] about a patient being directed to the ED. The peritoneal dialysis nurse called the ED nurse to report the patient was on extraneal/icodextran peritoneal dialysis solution, and that [certain] blood glucose machines cannot be used [on patients receiving certain types of peritoneal dialysis] or false readings will occur [because certain types of test strips cannot distinguish between glucose, maltose, galactose, and xylose]. The peritoneal dialysis nurse requested this information be placed on the patient chart and reported to the floor nurse. Only [lab] blood glucose [tests] can be performed on the patient. [Glucose meter results] were done [over a 24-hour period]. [On the second day,] ... [a glucose meter result] was done and results appeared normal. A serum blood was drawn ... and the [lab] blood glucose was 32. .... All unit managers involved were made aware. Orders were changed to reflect serum blood glucose [lab tests] only and a note was placed on the front of the chart.*

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Table 2. Validation Technique and Event Location (n = 51) of High Glucose Meter Result Events Reported to the Pennsylvania Patient Safety Authority, June 28, 2004, through May 31, 2011

AUTHORITY HIGH GLUCOSE METER RESULT REPORTS	NUMBER OF REPORTS	PERCENTAGE OF REPORTS
Validation Technique		
Compared to blood serum lab value	44	86.3%
Check result with same or different glucose meter	6	11.8
Not validated with glucose meter or serum lab	1	1.9
Location of Event		
Units other than intensive care units	36	70.6
Not specified	10	19.6
Intensive care units	5	9.8

Hospital Policy and Protocol Challenges

Hospital policies and procedures dictate how blood glucose meters are used. The Authority event descriptions that mention patient treatment delivered based on glucose meter results were a proxy for hospital policy and protocols. Twenty-one percent (n = 15) of the reports implicated hospital policy or protocols.

The following example demonstrates the impact of hospital policies on how blood glucose meters are used:

> *A [glucose meter] gave a reading of 468, and the physician was notified and ordered insulin, which was given. The morning [fasting blood sugar] from lab came back with result of 122. A [glucose meter test] was redone on a different machine with a reading of 135. [The second glucose meter] was calibrated [within normal limits] following the discrepancy. [The initial glucose meter] machine was taken out of service. The patient's [blood sugar] was checked [on the hour for six hours] and observed for hypoglycemia. No adverse outcome was observed.*

This report does not indicate whether the result was a new high glucose level or an existing condition. Before treating a patient's high glucose level, especially a new high glucose level, the result needs to be validated. Hospital policies and protocols can guide staff in the proper response to this situation.

Physical Assessment Symptoms

Hyperglycemia is more likely to occur when patients are experiencing a sympathetic response to physiologic stress. The challenge for healthcare workers is to distinguish actual hyperglycemic states from inaccurate meter results. When interpreting a high blood sugar reading, it is important to consider the clinical context. For example, has the patient been experiencing similar levels of hyperglycemia? Has he or she just eaten or taken sugar containing fluids? Has the patient just been started on steroids? Was a dose of insulin omitted? High glucose meter results accompanied with a physical assessment help validate the results and reduce the likelihood of patients developing hypoglycemia from inappropriate treatment. Nine of the 51 high glucose meter readings (13%) identified whether patients exhibited or were subsequently evaluated for symptoms of hypoglycemia. A separate analysis of high glucose meter results was conducted to determine the occurrence of insulin-induced hypoglycemia. Twenty-seven percent (n = 14 of 51) of patients with high meter results were administered insulin; four patients subsequently experienced hypoglycemic symptoms or were treated with dextrose 50%. See the following reported example:

> *Patient's glucose meter reading [prior to lunch] read "HI." Patient covered with 6 units Novolog insulin. A stat venous draw was done; [the result] was 62. The patient was lethargic at this time and was given orange juice with sugar. [Repeat glucose meter result] came up to 156.*

Healthcare Team Communication Delays

Miscommunications, lack of communication, or partial communication of information were reported in only 7% (n = 5 of 71) of the reports; see the following example:

> *A routine [glucose meter test] was performed with a result of 520. The lab was called to draw a blood glucose level. The patient was [treated] with 10 units of Novolog subcutaneous. The [blood glucose] result was 375. A [glucose meter test was performed] one hour later after administration of the insulin. The insulin coverage was given to the patient prior to lab verification, which could have been detrimental to the patient.*

This report demonstrates the importance of obtaining more detailed information, the lab glucose level, before any treatment decisions.

WAYS TO SAFELY INCORPORATE GLUCOSE METER USE INTO CLINICAL PRACTICE

Equipment Use

Questionable glucose meter results can occur because of meter variability, user variability (e.g., sample quality, timing),

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patient physiology, care of the meter, and test strips. The following measures (based on literature and analysis of reports) can reduce the chance of questionable glucose meter results:

- Perform quality checks at the beginning of every shift.
- Stay informed about the patient's blood glucose result history and activities.
- Use the same glucose meter for the same patient all day.[8]
- Place a clearly marked identification number on each glucose meter.
- Record the glucose meter identification number in the patient's chart to ensure that the same glucose meter is used on the same patient throughout the day.
- Perform a separate or additional glucose meter reading at the same time as the glucose serum blood draw each day to validate the blood glucose result with the serum lab value.
- If a glucose meter is dropped, check the manufacturer's protocol and run test strips with the appropriate control solution.[9]
- Clean meters at regular intervals and whenever visibly dirty, following the manufacturer's instructions and facility policy. Dirty optics and inappropriate cleaning products can produce invalid results.[9]
- Check the meter for check battery or replace battery messages.[9]
- Follow hospital policies for confirming questionable results.[9]
- Avoid squeezing the finger to obtain a drop of blood. Fluid from the surrounding tissue can mix with the blood sample and affect test results.[9]

Sources of test strip error come from the enzyme testing technology and the test strips. There are ways to avoid invalid glucose meter results that include knowing the limitations of certain types of enzyme testing glucose meters and ensuring the proper care and handling of test strips.

Glucose meters use enzymes (glucose oxidase, glucose hexokinase, or glucose dehydrogenase) and an indicator (pyrroloquinolinequinone or nicotine adenine dinucleotide) to calculate results.[10] Glucose meters that use the glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) enzyme testing method cannot distinguish between glucose, maltose, galactose, or xylose.[10] GDH-PQQ devices used in the wrong patient population can lead to fatal results.[11] Patients susceptible to GDH-PQQ enzyme indicator problems include those receiving peritoneal dialysis solutions containing icodextrin, certain types of immunoglobulin therapy, or other drugs containing maltose, galactose, or xylose.[7,10,12] (See "GDH-PQQ Test Strip Implementation Strategies" exclusively available on the Authority website.)

The following are other physiologic conditions that can invalidate glucose meter results:

- Hematocrit (low levels can falsely elevate results; high levels can falsely lower results)[12]
- Dehydration, hypotension, and hyperosmolar states
- Oxygen levels (both low and high oxygen levels can affect results)
- Perfusion rates (changes in perfusion rates, such as a shock state or post exercise, can influence results)[4,9]

Two types of therapies can invalidate glucose meter results, as follows:

- Uric acid and vitamin C can interfere with blood glucose meter measurement.[9]
- High levels of drugs such as acetaminophen or salicylate acid can affect results.[4]

The second problem with meters is the test strips. Special care is required to maintain their precision. Many different actions can invalidate test strip accuracy, including the following:

- Incorrect entry of the test strip lot or calibration code[4,7,12]
- Improper storage of the test strips (e.g., exposure to heat, moisture, light)[4,12,13]
- Improper handling of test strips (e.g., sugary foods such as bananas or fruit juice on hands can contaminate the strips)[4,7]
- Use of outdated strips[7,9,12]
- Improper blood sample collection[4]
- Inadequate blood sample size[4]

The following strategies can help maintain test strip validity:

- Follow the Centers for Disease Control and Prevention clinical laboratory improvement advisory rules and regulations for assuring meter/testing accuracy.[14,15]
- Consider the presence of physiologic conditions (listed above) when assessing the validity of an unexpected result.
- Perform quality checks on the machine and test strips at the beginning of every shift, especially if the meter is used on multiple patients each day.
- Check that test strip and control lot numbers have been correctly entered into the meter.[9]
- Read and follow manufacturer instructions on proper use and storage of test strips.[9]
- Ensure proper storage of test strips; do not expose to heat, light, or humidity.[4,13]
- Wear gloves to prevent contamination due to food or sugar residue on hands.
- Use all test strips in a bottle before opening a new bottle.
- Do not combine old test strips in a bottle of newly opened strips.
- Use a permanent marker to label bottles of test strips and control solution with the date and time opened.

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— Document the control solution expiration date after opening.
— Check test strip and control solution expiration dates.[4]

Hospital Policy and Protocol Refinement

Blood glucose meter use in the hospital setting is an accepted practice.[1,2] What hospitals may not be aware of is an FDA recommendation regarding inpatient hospital glucose meter use clearance. In 2009, FDA wrote a letter to the president of the American Association of Clinical Endocrinologists[16] in response to concerns about blood glucose testing meter performance. The letter addresses hospital uses of self-monitoring blood glucose (SMBG) devices, stating:

> FDA has cleared laboratory-based and bench-top point-of-care devices that provide accurate glucose test results with a fast turnaround time. Meters such as the HemoCue Glucose 201 RT system and the i-Stat system, which are not test strip based technologies, have accuracies approaching those of laboratory methods. Nevertheless, many hospitals continue to use SMBG [test strip based] devices, cleared only as aids in the management of diabetic patients, in these settings, even though they are not FDA cleared to diagnose disease or to maintain tight glycemic control of diabetic and non-diabetic patients in the hospital environment. This practice can be problematic.

This FDA concern is underscored in this event reported to the Authority:

> *[Glucose meter] read high on patient mentioned before. I obtained a stat blood glucose reading before covering my patient with the highest dose of coverage with Novolog. The blood glucose reading came back only 91. This could have been detrimental to the patient if policy was followed.*

Rather than follow hospital policy and treat the patient based on the glucose meter result, the individual withheld treatment until a lab result invalidated the result. This decision was beneficial since the patient's serum lab glucose result was normal.

Another report demonstrates the importance of hospital policies:

> *A [patient's] blood sugar was reported as 480 from the machine. Per policy, a venipuncture blood sugar was drawn for a new high. The patient was treated with [sliding scale] coverage as ordered. The blood sugar came back at 158. The machine was removed from service to be checked. All follow-up [glucose meter results were within normal limits] for the patient.*

Hospital policies and protocols that anticipate alternative scenarios, such as withholding insulin until lab results are received, guide staff when questionable situations arise. Hospital policies can be written in ways that empower staff to consider alternative actions, when necessary. (See "Hospital Policy Measures to Ensure Appropriate Use of Blood Glucose Meters.")

Physical Assessment Evaluation

Patient care is not to be based on POC glucose meter results alone. Quality bedside patient care includes a physical and mental assessment. The following report demonstrates the value of a physical assessment to validate glucose meter results.

> *The patient's evening [glucose meter result] read "hi." A [second glucose meter result] was rechecked and read "hi." A stat [laboratory] glucose was drawn. The result was 58. The [staff] spoke with the lab, which ran the [test] twice and [received] the same results. A third [glucose meter test] was done using a [different glucose meter and received] a reading of 112. The physician was made aware [of the results]. The patient was asymptomatic. An order was received to give an evening snack and to use the result of 112 as the patient's [glucose level].*

A physical and mental assessment can validate hyperglycemic or hypoglycemic glucose meter results. Hyperglycemic patients can experience polydipsia (increased thirst), polyuria (increased urination), and sugar in the urine. In cases of extremely high blood glucose levels (i.e., greater than 240 mg/dl), urine needs to be checked for ketones to determine whether the patient is in diabetic ketoacidosis. Symptoms of ketoacidosis include shortness of breath, breath that smells fruity, nausea and vomiting, and very dry mouth.[17]

Hypoglycemia is a condition that requires immediate attention because it can be fatal if left untreated. Hypoglycemic symptoms include hunger, shakiness, nervousness, sweatiness, sleepiness, irritability, light-headedness, fainting, unresponsiveness, coma, and death. Hypoglycemia can also cause symptoms when sleeping, including crying out or having nightmares, finding pajamas or sheets damp from perspiration, and feeling tired, irritable, or confused after waking up.[18] Not all patients are symptomatic. Careful and close monitoring is necessary to accurately identify the patient's condition and respond appropriately.

Effective Healthcare Team Communication

Effective communication provides appropriate situational information, including any pertinent background information, a physical assessment, and any test results upon which to base care.[19]

The following general actions can improve communication:

— State the situation succinctly, including pertinent background and physical assessment information.[19]

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HOSPITAL POLICY MEASURES TO ENSURE APPROPRIATE USE OF BLOOD GLUCOSE METERS

The following 10 measures are suggestions to add to current hospital blood glucose meter policies and protocols:

1. Consider facility-wide use of one type of blood glucose meter. It will decrease staff confusion and increase learning as staff shares experiences, problems, and potential solutions.[1]
2. Consider certification and recertification of healthcare personnel to use blood glucose meters, especially those performing routine quality control.
3. Provide routine education in the appropriate care and use of blood glucose meters and test strips.
4. Blood glucose meters are cleared only as aids in the management of diabetic patients in hospital settings and should be used as an aid. Blood glucose meters are not cleared by the U.S. Food and Drug Administration to diagnose disease or to maintain tight glycemic control of diabetic and non-diabetic patients in the hospital environment.[2]
5. Perform a separate or additional blood glucose meter test daily at the same time as a lab serum glucose draw to compare and validate blood glucose meter results with lab results.
6. Perform a quality-control check for each blood glucose meter at the beginning of each shift. Increased use increases the likelihood of inaccurate results (e.g., dirty optics, dropping or bumping the machine, issues with the test strips).
7. Place a hard stop (forced function) in the meter, if possible, to prevent use until a quality check is completed.
8. Consider a hospital policy that requires staff to wear gloves when touching the test strips.
9. Consider a hospital policy that requires staff to draw a serum lab value when questionable results arise (i.e., newly unexpected high blood glucose meter results) or when glucose meters are used in settings that increase the likelihood of invalid results (i.e., specific physiological conditions as identified in the main article). The policy can address withholding treatment of questionable blood glucose meter results until the serum lab value results are known.
10. Consider a hospital policy that requires stat glucose lab value results should be completed and available in a clinically reasonable time frame, preferably 30 minutes to no longer than 1 hour.
11. When questionable results arise, take the following actions:
    a. Check the last time a quality check was done.
    b. Check the meter for cleanliness.[3]
    c. Check the meter batteries and test strips.[3]
    d. Obtain a different meter to compare results.
    e. Draw a serum lab value and withhold treatment until results are available.
    f. Perform a patient physical assessment.
    g. Communicate the situation with physician. Provide a comprehensive summary of the patient's physical and mental status, the glucometer reading, and any other meter-related issues, serum lab value, and past medicine and diet history.
12. When blood glucose meter results are in doubt, remove the meter from patient care, and send it for servicing.

Notes

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— Inform appropriate individuals and all team members when plans change.[19]
— Speak clearly and simply, and repeat back information to decrease communication errors.[20]
— Use correct terminology, and provide explanations of ambiguous terms.[20]
— Request and provide clarifications as needed.[20]
— Ensure statements are direct and unambiguous.[20]
— Allow the receiver to review the information.[20]
— Allow opportunity for questions and clarifications.[20]

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CONCLUSION

Blood glucose management in hospitalized patients is a multifaceted process that requires critical thinking. Test results are one important measure of a patient's condition but should never be used as the sole basis for treatment. Treating a patient based on measurements alone can lead to serious and fatal patient events. Blood glucose meter results provide a starting point of inquiry about a patient's health status. A physical and mental assessment, along with an evaluation of the patient's previous history, are needed. As deviations arise, communication with the physician is essential before any actions are taken. The amount of time required considering all aspects of the patient's condition and the usual way to respond can be the difference between the delivery of safe patient care and serious or fatal patient events.

NOTES

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