

In Brief

Point-of-care (POC) glucose meters are an essential part of diabetes care, but if their results are inaccurate, patients can be harmed. This review discusses pitfalls in the use and analysis of results from POC glucose meters. It also offers guidance on when these devices should not be used.

Glycemic Variability in the Use of Point-of-Care Glucose Meters

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Blood glucose testing by point-of-care (POC) meters has revolutionized the care of diabetes in the modern era by providing relatively accurate estimates of the true blood glucose of patients in real time. Since the invention of the first device, the Dextrostix, in 1963,¹ followed 7 years later by the Ames Reflectance Meter, the devices and strips used have improved in sophistication, ease of use, precision, and accuracy. More than 44 million tests are performed daily worldwide, at a global cost of > \$8.8 billion per year.²

Yet, despite great improvements in the nearly 50 years of use of self-monitoring of blood glucose (SMBG), significant problems remain. For example, the difference in glucose values provided by different meters may be as much as 50–70 mg/dl.³

Manufacturers of glucose meters and strips tout the excellent precision and accuracy of their products. The International Organization for Standardization (ISO) 15197 clinical standard states that $\geq 95\%$ of the values obtained with a meter should be within $\pm 20\%$ of a blood glucose reference standard when the glucose level is ≥ 75 mg/dl and within ± 15 mg/dl of the blood glucose reference standard when glucose is < 75 mg/dl. However, in 2010, Freckmann et al.⁴ reviewed 27 meters that had been approved in Europe from 18 companies. Although each manufacturer claimed that it adhered to the ISO 15197 standard, careful analytic testing showed that 41% of the meters did not conform to even these basic minimal standards,

and many of the meters were not equally accurate or precise during the expected usable glucose range, especially within the hypoglycemic range when accuracy is most crucial.

In another study, Kristensen et al.⁵ in 2009 tested nine meters for the accuracy of their strips within certain hematocrit ranges and found that, contrary to claims of five manufacturing companies, their strips showed relatively large variations within those ranges.

In addition, Cembroski et al., investigators in the Normoglycaemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation (NICE-SUGAR) study, found that, in contrast to manufacturers' claims, the specific lots of the glucose meter strips used in NICE-SUGAR varied considerably in their susceptibility to loss of accuracy because of variation in hematocrit. They hypothesized that some of true blood glucose levels that were in the hypoglycemic range might have been missed because of falsely elevated POC glucose meter readings.⁶

Clinicians are interested in whether POC glucose meter readings are close to the true blood glucose level. And, in the absence of a unified central international standard for whole blood glucose (there is one for plasma and serum glucose), they will accept that the whole blood glucose of a POC glucose meter correlates closely with a standard central laboratory method, provided that it is tied to an international standard.¹ Unfortunately, there is no agreement about which central

laboratory technique is the preferred standard for comparison. One consequence of this failure is the lack of correlation between supposedly equally accurate POC glucose meters.

Additionally, from the clinicians' point of view, it is not just the total analytic error of the meter that is important, but the total error, which is the sum of its total analytic error plus user error. User error includes pre-analytic errors such as omitting hand washing, as well as normal biological variation and post-analytic errors, which can be caused by either the user or the instrument.⁷ An example of an instrument error would be the instrument failing to correctly display the result or giving no result at all.

At present, the total allowable analytic error is the U.S. Food and Drug Administration (FDA) standard requiring a meter's performance to be within $\pm 20\%$ of a blood glucose reference standard for 95% of the glucose values ≥ 100 mg/dl and an allowable error ≤ 12 mg/dl for 95% of the glucose values < 100 mg/dl. Following this standard, the total error will almost certainly be significantly larger.

In 2001, Boyd and Bruns⁸ carefully analyzed the effect of total analytic error on clinical decision-making using a computer simulation. They showed that a total analytic error of 5% led to an 8–23% error rate in choosing insulin doses from an insulin algorithm based on glucose level. A total analytic error of 10% led to an error rate of 16–45%. However, their data indicate that error rates of 20%, even in the absence of interfering substances or conditions, will lead to unacceptably large errors in clinical decision-making.

Moreover, in many clinical situations, POC glucose meters may give values called "outliers," which are so far removed from patients' true blood glucose level that they could cause medical errors by patients, their family members, or their care providers, with potentially catastrophic consequences.⁷ Unfortunately, with the present standards, the ISO and FDA allow up to 5% of values obtained by a POC meter to be outliers of any degree of magnitude. Yet, whether outliers are falsely low or falsely high, they are highly likely to mislead clinicians or patients and lead to serious errors in care. This is one of the key reasons many experts are urging these regulatory bodies to tighten the POC

glucose meter standards for precision and accuracy and limit outliers to rare events.^{7,9}

The remainder of this review focuses on the factors that lead to problems with glucose variability in the use of POC glucose meters and that clinicians need to be aware of to ensure that people with diabetes receive safe and effective therapy for glycemic control. There are many potential sources of error involved in POC glucose testing with current instruments, and several case studies illustrate the types of issues involved.

Case Study 1

A 24-year-old woman with a 15-year history of type 1 diabetes calls her care provider with complaints of abdominal pain and two episodes of vomiting. She is having a menstrual period with a heavy flow, and she has a history of migraines. She uses 30 units of insulin daily in four divided doses with pre-meal short-acting insulin and basal insulin at bedtime. She reports that her blood glucose by her POC glucose meter is 248 mg/dl. Her care provider examines her and obtains a glucose sample using a POC glucose meter; the result is 256 mg/dl.

The patient is given an anti-nausea medicine, but she is anxious to leave the clinic to pick up her son from daycare. The care provider is faced with a dilemma of whether to allow the patient to leave after being given supplemental insulin or to send her to a hospital for a work-up of the abdominal pain (both of which may be reasonable if the POC glucose determinations are accurate) or to verify the POC glucose meter result with a rush order for a central laboratory glucose determination.

The provider chose to verify the POC glucose result and discovered that the laboratory glucose level was 548 mg/dl with moderate serum ketones. It was now clear that the patient had diabetic ketoacidosis (DKA). Her abdominal pain proved to be secondary to DKA and cleared with appropriate treatment with intravenous insulin, fluids, and electrolyte repletion.

This case is typical and provides an example in which the POC glucose reading was an outlier (i.e., so different from the true glucose level that it could lead both the care provider and the patient to make a judgment error). In the presence of DKA, it is common

for POC glucose meters to underestimate the true glucose level by as much as 300 mg/dl or more.¹⁰ In contrast, central laboratory glucose levels in hospitals and large clinics are usually performed on instruments using precise and accurate methods that are tied to an international standard and are unaffected by many of the factors that commonly degrade the accuracy and precision of POC glucose meters.^{1,3} Nearly all POC glucose meters today give falsely low glucose levels in the presence of DKA, as well as in the presence of poor tissue perfusion or hyperosmolar states.^{1,3} Again, this can result in outliers that delay the recognition of potentially life-threatening hyperglycemia.

This is but one example of the many pathological conditions that can influence and degrade the accuracy and precision of POC glucose meter results. Other examples can be found in Table 1.

POC Meters in Critical Care

Many experts recommend that POC glucose meters, with the exception of a very few, not be used in a hospital critical care unit and that POC blood-gas analyzers be used instead.⁹ POC blood-gas glucose analyzers, in contrast to the vast majority of POC glucose meters, use a wet chemistry method similar to many central laboratory glucose methods, which is much less susceptible to interference by clinical conditions and interfering substances and has much greater accuracy and precision than POC glucose meters. Although Van den Berghe et al. in 2006¹¹ did use a POC glucose meter when an arterial line was not available, the POC meter they used corrected well for variation in hematocrit, something only a few POC meters do well. A 2009 report by Scott et al.⁹ reviewed the data that support this perspective.

POC Meters in the Operating Room

Two recent reviews by Rice et al.¹² and Pitkin and Rice¹³ discuss issues in the operating room, where changes in blood pressure, hematocrit, acid-base balance, and regional blood flows may be very rapid and may render finger-stick glucose measurements unreliable. These authors do not recommend the use of current POC glucose meters during perioperative clinical trials.

Table 1. Effects of Various Physical Conditions on Glucose Measurement

Condition	Type of Meter	
	Glucose Oxidase	Glucose Dehydrogenase
Anemia	↑ nearly all	↑ nearly all
Polycythemia	↓ nearly all	↓ nearly all
Increased altitude or hypoxia	↑	none
Ambient temperature ≥ 39.2° C (102.2° F)	↓	↓
Ambient temperature ≤ 10° C (50° F)	↑	↑
Postprandial state (< 2.5 hours)	↑	↑
Hypotension	↑	↑ or ↓
Diabetic ketoacidosis	↓	↓
Severe acidosis (pH < 6.95)	↓	↓

POC Meters in Non-Intensive Care Hospital Settings

The enormous advantage of having glucose data in real time has been evident in inpatient noncritical care settings.¹⁴ Hospitals should choose POC meters carefully, using those with valid hematocrit corrections and corrections for multiple interferences and having not just minimal standards of accuracy and precision, but rather total analytic error ratings in the 4–5% range,^{15–18} as are currently attained by a few newer meters.¹⁵ Hospital clinical laboratories and nursing staff are well advised to develop a robust quality improvement and monitoring program to ensure proper training of personnel who use and interpret POC glucose results and to be sure that meter calibration and data analysis are done using a continuous quality improvement method. With such a plan, POC meters can be used successfully in most areas of a hospital and add great value to patient care, given that achieving near-normoglycemia has been shown to reduce morbidity and mortality in both surgical and nonsurgical hospital settings.^{19,20}

Case Study 2

A 74-year-old man who has a 28-year history of diabetes is receiving peritoneal dialysis. During the dialysis, the POC glucose reading is 256 mg/dl, and supplemental insulin is given. Three

hours later, the POC glucose reading is 284 mg/dl, and the supplemental insulin is doubled. One hour later, the patient becomes comatose and begins having uncontrolled seizures.

What is the problem here?

The central laboratory, which used a hexokinase glucose measurement method that is not susceptible to interference from non-glucose sugars, showed a venous glucose of 19 mg/dl at the same time the POC glucose reading rose to 284 mg/dl. This outlier result, a falsely elevated glucose, was the result of an interfering substance, in this case, sugar maltose.

Icodextrin, which is commonly infused in peritoneal dialysis, is converted by the body into maltose. POC glucose meters that use glucose dehydrogenase pyrroloquinoline quinone (GD-PQQ) technology to detect glucose cannot distinguish between maltose and glucose and were the cause of this error. The FDA reported in 2009 on 13 patients who died as a result of this error, a falsely elevated glucose. All were on peritoneal dialysis and using POC meters that used GD-PQQ technology.²¹

These glucose meters, including some in common use today, should never be used with patients on peritoneal dialysis. Even patients who recently were on peritoneal dialysis are at risk because the maltose slowly clears from the blood.

Other solutions used in patient care contain maltose, including some intravenous gamma globulin solutions such as Octagam 5%, Gammimune 5%, and drugs such as Orencia (abatacept).²¹ In general, glucose meters that use the enzymatic method involving glucose dehydrogenase are more prone to being influenced by interfering substances, but meters that use the enzyme glucose oxidase technology are also vulnerable to interfering substances, as seen in Table 2.

Case Study 3

A 16-year-old girl presents with an A1C of 10.4% and a carefully handwritten log of glucose levels checked four times daily, with an average glucose of 136 mg/dl. After counseling, education, and pump training, she is placed on an external insulin pump with instructions to use a glucose meter that is downloadable to a computer in the provider's office. The levels show an average of 184 mg/dl, but the simultaneous A1C is 10.6%. The adolescent is referred to a clinical psychologist, who makes the diagnosis of depression.

What is the likely cause of the discrepancies between the A1C and SMBG readings?

There is a relationship between high depression scores in children and adolescents and false or inadequate reporting of glucose levels.²² The deception may be carried out, as in this case, by patients writing down false values instead of the reported results from their glucose meter,²³ or by fabricating results not performed at all, or in more subtle ways such as avoiding performing SMBG at times when they know their glucose levels are either too high or too low.

In a study by Wilson and Endres,²⁴ 40% of the children ages 12–18 years fabricated test results, and 18% failed to record test results. In addition, although it is commonly recognized that patients with longstanding diabetes, those with autonomic neuropathy, and those in the geriatric population frequently cannot recognize serious hypoglycemia, children and their parents also do poorly in recognizing hypoglycemia. In a recent study²² of children ages 6–11 years and their parents, both parents and children frequently did not recognize hypoglycemia. The parents failed to note low glucose levels of < 54 mg/dl in their children > 50% of the time, and the

children failed to note such low glucose levels in themselves > 40% of the time.

In addition to the common problem of deceptive recording of glucose results, poor technique in obtaining glucose readings is a common and serious problem. A study by Perwien et al.²⁵ at a diabetes camp found that children ages 7–14 years made crucial errors in their glucose monitoring technique.

The most serious was failure to wash their hands before measuring their glucose, leaving interfering substances (usually traces of food) on their fingers that often led to falsely high results, often by > 30%. Only 19.1% of the children washed their hands before checking their glucose. Only 14.6% allowed their hands to dry, an error that can result in dilution of the blood specimen and a falsely low glucose reading.

The children also did not always put the cap securely back on the meter strip container; only 70.6% did so. This error leads to excessive exposure to humidity, heat, and other environmental factors that degrade the strips, which are sensitive to environmental influences. Unfortunately, these types of operator errors are common and not limited to children. Table 3 provides a list of pre-analytic errors and their likely effects on blood glucose measurement.

Another common error is the failure to properly calibrate the glucose meter. Many, but not all, glucose meters provide calibration solutions and require users to recalibrate the meter against each new container of glucose testing strips and at least monthly in any case. Errors resulting from a failure to calibrate a meter that requires regular calibration can be large. Both adult patients and providers are often unaware of the importance of proper technique to achieving optimal results from a POC glucose meter and can commit significant operator errors that diminish the accuracy of the glucose measurement.

Excellent technique and training in the use of POC glucose meters and their strips is clearly undervalued at present and often taken for granted, although not often attained. Excellent technique is difficult to achieve but well worth the effort. In a study from Norway²⁶ that compared the results of glucose meter use between experienced laboratory technicians and

adult patients, although the training was most helpful to the patients, they still, at the end of the study, could not achieve the precision and accuracy of the laboratory technicians. In another randomized, controlled study,²⁷ which evaluated the effect of a comprehensive education program for SMBG, the patients who received this intervention not only improved their SMBG technique, but also experienced a small measurable improvement in A1C. Unfortunately, the result was not statistically significant.

Clearly, teaching methods must be tailored to the needs and capabilities of the patients. Children, for example,

learn best when the teaching method is appropriate to their age, education level, and culture and includes follow-up supervision and re-education. Shared responsibility often works best.²⁸ Innovative recent approaches have tried to include active, relevant games with the procedure of glucose measurement, but these are not yet firmly established.²⁹

In contrast to teaching methods that are tailored to youth, those for older patients must address very different educational needs. Such patients tend to learn poorly from manuals alone, faring better with a visual edu-

Table 2. Effects of Interfering Substances on Glucose Measurement

Interfering Substance	Type of Meter	
	Glucose Oxidase	Glucose Dehydrogenase
Maltose	none	↑ ↑ (GD-PQQ type only)
Xylose or galactose (health foods, etc.)	none	↑ ↑ (GD-PQQ type only)
Ascorbic acid	small	↑
Acetaminophen	↓	↑
Dopamine	none	↓
Mannitol	↑	none

Table 3. Effects of Pre-Analytic Errors on Glucose Measurement

Pre-Analytic Error	Type of Meter	
	Glucose Oxidase	Glucose Dehydrogenase
Exposure of strips to elevated temperature*	↓	↓
Exposure of strips to decreased temperature*	↑	↑
Exposure of strips to humidity, vibration, or dirt*	↑ or ↓	↑ or ↓
Out-of-date strips*	↑ or ↓	↑ or ↓
Failure to calibrate strips	↑ or ↓	↑ or ↓
Failure to wash hands	↑↑	↑↑
Failure to dry hands	↓	↓
Inadequate drop size	↓	↓

*May destroy strip

cation format that includes re-testing in 2 weeks.³⁰

Success in teaching SMBG technique requires assessment of patients' language skills, reading ability, vision, and dexterity, as well as their cognitive abilities and emotional state. Teaching SMBG technique, for example, to a patient who is just recovering from DKA or a severe illness or emotional crisis may lead to poorer retention and understanding of the information because the patient may be distracted, less focused, and less able to learn at that moment. A follow-up visit to review the initial education may well be necessary to help the patient learn the necessary skills.

Economic Issues

The expense of POC glucose meter strips has increased by > 400% in the past 25 years and is now a significant barrier to the use of SMBG. As patients and insurers scramble to deal with the increased costs of SMBG, there have been many attempts to get around the high cost of strips. Apart from the error of using outdated strips, which can lead to large errors in accuracy, there is also the problem that arises from people purchasing strips from less reliable sources and thus increasing the chance that the strips are either counterfeit or made improperly and will be less accurate.

Part of the issue is that, under current FDA rules, the entrance of a new POC glucose meter into the market is not necessarily accompanied by either an inspection of the factories in which the meters and strips are made or a post-approval review of the performance of the meters and strips.³¹ Improper manufacturing, handling, storage, or transport at any point in the chain from manufacturer to warehouse to clinic or patients' homes can have an adverse effect on the accuracy and precision of the meter or strips.³²

Payors are also under pressure to prefer POC meters that are cheaper, and they usually do not independently check manufacturers' accuracy claims, a mistake that can lead to selection of lesser-quality meters. Also, patients who have learned how to use one meter may not do as well with a different one that they did not choose and

which may not be as easy for them to operate.

Conclusion

POC glucose meters and strips are an invaluable part of the armamentarium of diabetic patients and their care providers. Although they have been greatly improved since their inception, these devices remain in need of improvement in terms of their accuracy and precision. In addition, patients who use these meters often use them suboptimally. This problem requires robust educational programs; however, such programs are undervalued by payors. Adequate education for providers is equally important and, too often, also lacking.

There are a number of settings, including critical care units and operating rooms, and selected clinical conditions for which the use of POC meters can lead to large errors in care. This is often because of variation between the meter-measured glucose and patients' true blood glucose.

The solutions to these problems will come through continued technological innovation. We are beginning to see new meters that are designed to better deal with interfering substances, hematocrit variation, and other clinical conditions than most of the currently available meters. Some newer meters have data management functions that allow better graphic display, allowing patients and providers to analyze their results in more detail.

Some glucose meters with superior download capabilities can also aid in more detailed analysis. However, such downloads are not possible if the time and date set in the meter are absent or inaccurate. Furthermore, the major meter manufacturers have resisted agreeing on a universal download protocol that would make it possible for more providers to download information from all types of meters instead of only from those for which they have the manufacturers' proprietary software.

Also sorely needed is a marked change in the policies of regulatory bodies regarding the accuracy and precision of POC glucose meters, both in the United States and internationally.⁷ Clearly, the lower standards for meter accuracy and precision and the frequency of outliers currently allowed have played a role in the wide variations that often occur in POC blood

glucose measurements. This excessive variation should not be allowed.

Yet, on balance, SMBG remains an invaluable tool, and POC glucose meters are far better now than only a decade ago. With more focus on ensuring that glucose values derived from POC meters more closely reflect patients' true glucose levels, the value of monitoring in both inpatient and outpatient settings will continue to increase, to the benefit of patients.

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