

Evaluating the Accuracy of Modern Glucose Meters

Richard M. Bergenstal, MD

Executive Director, International Diabetes Center at Park Nicollet, Minneapolis, Minnesota

ABSTRACT

Background: Self-monitoring of blood glucose (SMBG) is important for all patients with diabetes, as it provides valuable feedback on the effects of diet, exercise, and medications. To maximize the potential benefits of SMBG, clinicians must have confidence in the accuracy of their patients' glucose meters.

Objective: The aim of this article is to review several issues related to glucose meter accuracy and ways that accuracy can be enhanced.

Methods: A MEDLINE search of English-language articles using the terms *SMBG*, *glucose meter*, and *accuracy* as an initial screen was performed. After articles describing the use of outdated technologies or vague methodologies were excluded, appropriate articles that analyzed various aspects regarding meter accuracy were selected.

Results: Glucose meter accuracy studies are complicated by issues related to the reference method, the sample being assayed, and the way in which accuracy is reported. Error grid analysis gives clinicians a means to evaluate the clinical importance of meter error. Modern glucose meters have many technological improvements and enhanced clinical accuracy; however, the accuracy of readings depends not only on the instrument but also on patient technique and other aspects of the overall testing process.

Conclusions: SMBG has proven to be a valuable tool for the management of diabetes whether it is used to guide insulin dosing, provide feedback on the effect of meals, or detect hypoglycemia. Accuracy of SMBG can be optimized by patient education and continued improvements in meter technology. (*Insulin*. 2008;3:5–14) © 2008 Excerpta Medica Inc.

Key words: glucose meter, accuracy, SMBG, diabetes, error grid analysis, ISO.

INTRODUCTION

Monitoring of blood glucose has evolved over the past 2 decades from a clinical laboratory test to a cornerstone of blood glucose management that patients can perform at any time in their own homes.¹ The American Academy of Family Physicians (AAFP), the American Diabetes Association (ADA), and other experts in diabetes care recommend self-monitoring of blood glucose (SMBG) for patients with diabetes as part of their overall disease management program to provide valuable feedback on the effects of diet, exercise, and medications and to improve safety for insulin-treated patients through detection of hypoglycemia.^{2–6}

Achieving maximum benefit from SMBG ultimately requires that either patients or their health care providers act on the data that have been collected.⁷ This process, in turn, requires that providers have confidence that SMBG results are reasonably accurate. Unfortunately, evaluating glucose meter accuracy can be a daunting task for the clinician. Accuracy depends on the user, the instrument, and other aspects of the evaluation, including how accuracy is defined.⁸ The current International Organization for Standardization (ISO) criteria used by glucose meter manufacturers to gain regulatory approval require that 95% of the glucose values

measured by the meter fall within 15 mg/dL (0.83 mmol/L) of the manufacturer's reference method for glucose concentrations <75 mg/dL (<4.2 mmol/L) or within 20% for glucose concentrations ≥75 mg/dL (≥4.2 mmol/L).⁹ Studies have shown, however, that most meters cannot yet achieve the more stringent ADA goal of a total analytical error <5%.^{1,10–14} But more important to the clinician is that *clinical accuracy*, defined as glucose concentrations obtained from different methods that lead to the same clinical management decision or patient outcome,¹⁵ has generally been very high,^{1,16} and SMBG has a proven track record in helping patients and their providers manage blood glucose levels.

Glucose meter accuracy depends on the user, the instrument, and other aspects of the evaluation, including how accuracy is defined.

In landmark clinical studies of patients with type 1 or type 2 diabetes mellitus (DM), intensive insulin therapy with

dosages adjusted according to SMBG performed ≥ 4 times per day was shown to reduce the risk of diabetes complications.^{17,18} Conclusive data regarding the benefits of SMBG for patients not treated with insulin have been slower to emerge; however, 2 recent meta-analyses, a review, and a long-term epidemiologic study have shown that SMBG was associated with improved glycemic control and a lower rate of fatal and nonfatal microvascular and macrovascular events.^{19–22} In part because of its ability to complement glycosylated hemoglobin by providing real-time feedback on glucose levels, SMBG has been considered one of the most significant breakthroughs in diabetes management since the discovery of insulin.⁸

In part because of its ability to complement glycosylated hemoglobin by providing real-time feedback on glucose levels, SMBG has been considered one of the most significant breakthroughs in diabetes management since the discovery of insulin.

MATERIALS AND METHODS

Because of the importance of SMBG to patient care, the confusion regarding blood glucose meter accuracy, and the technical nature of the subject, we saw the need for a user-friendly review of issues surrounding glucose meter accuracy. We have therefore performed a MEDLINE search of English-language articles using the terms *SMBG*, *glucose meter*, and *accuracy* as an initial screen. After excluding articles describing the use of outdated technologies or vague methodologies, we selected appropriate articles, and references therein, that analyzed various aspects regarding meter accuracy.

EVALUATING GLUCOSE METER ACCURACY

To have confidence in the accuracy of a patient's blood glucose values, the practicing physician should be armed with a basic understanding of how glucose meter accuracy is commonly assessed and where some types of errors may arise. The discussion can be broken down into issues related to the reference method, the sample itself, patient factors, or how accuracy results are reported.

The Reference Method

Instrument accuracy is generally evaluated by testing the device against a known standard. In the case of an unstable entity like glucose in whole blood, the development of a whole blood glucose standard has been elusive.¹⁵ Consequently, the results from a patient's glucose meter are usually compared with one of several different reference methods, usually the main clinical laboratory methodology. Ideally, the same capillary blood specimen obtained by the patient would be tested by both the patient's glucose meter

and the laboratory reference instrument⁸; however, only a few laboratory reference instruments can accept the small sample volumes obtained by finger prick. As a result, most laboratory methods require a plasma/serum sample, and comparison with the whole blood sample measured by the patient may require a conversion factor that assumes a normal hematocrit.²³ The Yellow Springs Instrument (YSI, Inc. [formerly Yellow Springs Instruments Company], Yellow Springs, Ohio) biochemistry analyzer is a highly accurate reference instrument that can accept whole blood or plasma/serum samples, but it is not widely available.^{8,15} Additionally, the reference instruments used in most clinical laboratories may not maintain precise calibration,⁸ and this error can cause discrepancies between the glucose meter being tested and the clinical laboratory instrument.²⁴ Although accuracy is assumed, the error rate for individual measurements by central laboratory methods may be as high as 10%.¹

The Blood Sample

In addition to issues related to the reference instrument, factors related to the blood sample being analyzed can introduce discrepancies between glucose meter readings and readings of the reference instrument. Fasting glucose concentrations in capillary whole blood are 10% to 15% lower than those in venous plasma (most modern glucose meters are plasma calibrated, meaning they display measured concentrations in plasma) and show even greater variation if the patient is not fasting.^{24–26} Differences of up to 32% have been reported between capillary and venous plasma values in the nonfasting state²⁴; therefore, only fasting specimens should be used for comparison of capillary and venous glucose.⁸ Blood cells continue to metabolize glucose after the specimen has been obtained. In whole blood, glycolysis decreases glucose concentrations at a rate of ~5% to 7% per hour.^{26–28} Therefore, a delay in either transporting the specimen to the laboratory or separating serum/plasma from whole blood cells can lead to lower glucose levels.²⁸ Inhibitors of glycolysis such as sodium fluoride slow but do not completely prevent glycolysis^{26,29} and may interfere with the determination of glucose concentration by some reference methods.²⁸ Thus, SMBG and laboratory determinations that use similar enzymatic methods would be similarly affected by interfering substances. In addition, between-lot variability of glucose strips may have a negative impact on glucose meter accuracy.^{30,31}

Patient Factors

Individual patient factors can affect meter accuracy as well. An abnormal hematocrit can result in erroneous SMBG results, with low hematocrit levels leading to increased glucose values and high hematocrit levels leading to decreased glucose values.^{32–34} Other patient factors that may affect the comparison of SMBG results to a reference method include hypotension, hypoxia, oxygen therapy, marked hypertriglyceridemia or hyperuricemia, the presence of high concentrations of reducing agents (eg, glutathione, vitamin C,

cysteine), treatment with high-dose tolbutamide, aspirin or paracetamol, and hemolysis.^{25,35}

How Accuracy Results Are Reported

A final issue related to meter accuracy is the way in which accuracy results are reported. In addition to a lack of consensus among various organizations regarding meter performance standards (Table I),^{9,10,28,36} several methods for reporting accuracy data exist. Statistical methods, such as correlation coefficients, linear regression, percent deviation, and mean differences, are frequently used to evaluate meter accuracy.³⁷ Although these methods have their place, each has specific problems. For example, a good correlation coefficient can result from a constant, yet significant, deviation from the reference method.²⁵ Similarly, an evaluation based on a fixed percent deviation from a reference value may yield a clinically meaningless error at higher glucose concentrations but may result in an inappropriate treatment decision at lower concentrations.²⁵ Most important, statistical methods do not evaluate the clinical significance of analytical errors.^{16,25,38} Clarke et al³⁷ developed the error grid analysis method to take into account both the differences between the reference and SMBG values and the clinical significance of the treatment decision resulting from the SMBG value. As shown in Figure 1,³⁷ the grid has 5 accuracy zones. Glucose measurements that fall within zones A and B are deemed clinically acceptable, whereas those that fall within zones C, D, and E are considered clinically significant errors.

Although widely used since its introduction in the late 1980s, the Clarke Error Grid has been criticized for several discontinuities between risk zones where small changes in blood glucose levels cause the risk category to skip a level.³⁸ Based on a consensus conference of 100 diabetes experts, Parkes et al³⁸ created a modified error grid (the Consensus Error Grid) that avoids these discontinuities. A representative Consensus Error Grid is shown in Figure 2.^{38–42} A recent paper by Mahoney and Ellison⁴³ reviews the literature on approaches to evaluating glucose meter accuracy and proposes a checklist to facilitate

the incorporation of international consensus standards and quality guidelines into the meter evaluation process.

CLINICAL ACCURACY OF MODERN METERS

There have been rapid advances in glucose meter technology in the last 20 years, resulting in newer-generation glucose meters that are easier to use, require a smaller blood sample, and incorporate many additional features, such as advanced data management.^{16,44,45} Technological improvements in modern glucose meters have also resulted in greater accuracy, as demonstrated by a comprehensive study of 4 older-generation and 4 newer-generation glucose meters.¹⁶ As a result of these improvements, some older accuracy studies may be outdated, whereas others have omitted any analysis of the clinical significance of reported errors. An informal review of studies evaluating the clinical accuracy of glucose meters published within the last 5 years shows that although there is still room for improvement in precision and accuracy, the percentage of results deemed clinically acceptable by error grid analysis often approaches 100%.

A recent Diabetes Research in Children Network (DirecNet) study⁴⁵ evaluated 2 commonly used glucose meters, the FreeStyle Flash[®] (Abbott Diabetes Care, Alameda, California) and the OneTouch[®] Ultra[®] (LifeScan, Inc., Milpitas, California), using venous blood samples from 50 children with type 1 DM. The study found that both meters had similar accuracy results, with 98% to 99% of measurements meeting the ISO criteria and 81% of values being within 10% of the reference method for both meters. A previous DirecNet study⁴³ of a single meter showed that >99% of measurements were within zones A and B of the Consensus Error Grid (Table II) and that accuracy was comparable to laboratory-quality glucose analyzers during an insulin-induced hypoglycemia test—a glucose range where accuracy is critical but often variable.²⁶

A study of 5 glucose meters currently available in Australia⁴⁶ examined capillary blood samples from 49 patients. Error grid analysis showed that 94% to 100% of readings

Table I. Criteria for meter accuracy suggested by various organizations.

Organization	Criteria
International Organization for Standardization ⁹ and National Committee for Clinical Laboratory Standards ²⁸	Compared with the manufacturer's reference method, glucose values should fall within 15 mg/dL (0.83 mmol/L) for: 95% of values at glucose concentrations <75 mg/dL (<4.2 mmol/L) OR 20% of values at glucose concentrations ≥75 mg/dL (≥4.2 mmol/L)
US Food and Drug Administration ³⁶	Total analytical error <5%
American Diabetes Association ¹⁰	Current systems: Within 15% of reference measurements Future systems: 100% of results achieve a variability (system plus user) of 10% at glucose concentrations of 30 to 400 mg/dL (1.7–22.2 mmol/L)

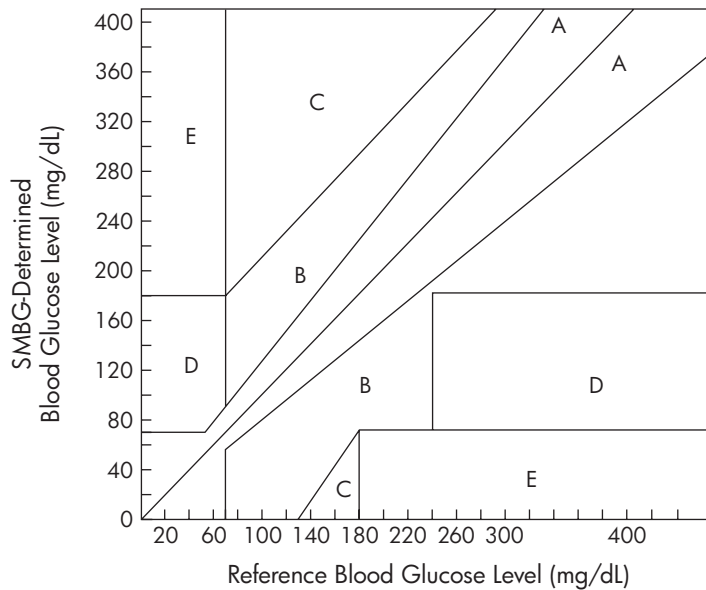


Figure 1. Clarke Error Grid analysis for evaluation of clinical implications of self-monitoring of blood glucose (SMBG) accuracy. SMBG values in zone A are clinically accurate and should lead to clinically correct treatment decisions. Values in zone B deviate by >20% from the reference but would lead to benign or no treatment. Values in zone C would lead to overcorrection of acceptable blood glucose levels. Those in zone D are considered “dangerous failure to detect and treat” errors, and zone E is considered an “erroneous treatment” zone in which SMBG values are the opposite of reference values. To convert mg/dL values to mmol/L, multiply by 0.0555. Copyright © 1987 American Diabetes Association. From *Diabetes Care*[®] Vol 10, 1987. Reprinted with permission.³⁷

were clinically accurate (zone A) and none of the readings would lead to clinical errors; however, only 1 meter satisfied the ADA goal of <5% bias. A study of a single, highly affordable glucose meter designed for use in developing countries⁴⁷ showed that even a meter limited to the most essential features can be highly accurate. Whereas 99% to 100% of results from this meter fell within zone A of the Consensus (Parkes) Error Grid when performed by clinical staff, it is noteworthy that 97% of results also fell within zone A when patients performed the test. Finally, a study by Chen et al¹ of 4 glucose meters showed that the meters had good precision, with <4% coefficient of variation across a wide range of glucose concentrations and >99% of results in zones A or B by Clarke Error Grid analysis (Table III). Thus, clinicians can have confidence that many modern glucose meters achieve a high level of accuracy as it relates to decisions regarding diabetes management. Continuing technological improvements can be expected to further improve precision

and accuracy in the same manner that newer-generation meters have surpassed previous-generation devices.

CONSIDERATIONS FOR IMPROVING METER ACCURACY

Steps to improve glucose meter accuracy fall into 2 general categories: technical improvements in glucose monitoring systems and improved patient education to decrease user error.⁷ Not surprisingly, many of the technological advances over the last few years have focused on decreasing user error. The spectrophotometric technology used in older glucose meters required wiping test strips at timed intervals after the application of blood and then placing the strips in a reflectance meter to obtain the glucose reading. Because of the potential for error, older glucose meters that require wiping of test strips are no longer in common use. The newer third-generation systems use a “nonwipe” method and read test strips using optical, amperometric, or potentiometric sensors.^{24,30,31,33,42,48,49} Other technological improvements include error signals for inadequate sample volume, “lock out” if control solutions are not assayed, and electronic memories that store hundreds of SMBG results.²⁶

Although written logbooks are a key component of diabetes care, self-reported data may not always be accurate because of carelessness, visual impairment, or a desire on the part of a patient to receive the clinician’s approval for

Many modern glucose meters achieve a high level of accuracy as it relates to decisions regarding diabetes management. Continuing technological improvements can be expected to further improve precision and accuracy.

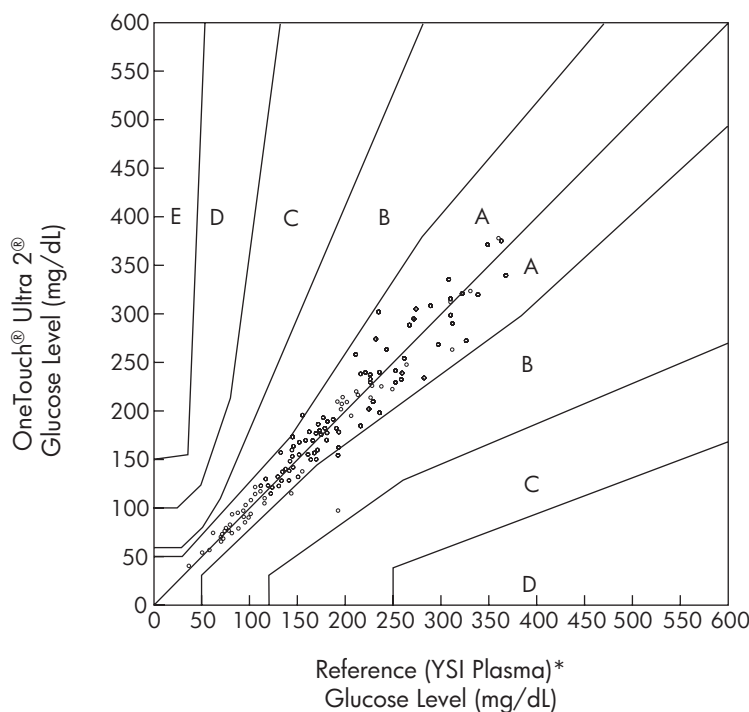


Figure 2. Accuracy study data plotted on a Consensus (Parkes) Error Grid³⁸ for a representative glucose monitoring system. Figure shows an example of a plot of blood glucose measurements obtained by 172 patients with type 1 diabetes mellitus, using the OneTouch® Ultra® 2 Blood Glucose Monitoring System (LifeScan, Inc., Milpitas, California) together with the owner's booklet. In this study, 97.3% of measurements fell in zone A and 100% of measurements in zones A or B (unpublished data). Similar studies have shown high levels of clinical accuracy using other glucose monitoring systems, including the Ascensia® Confirm® Blood Glucose Monitoring System (Bayer HealthCare Diabetes Care Division, Tarrytown, New York),³⁹ the Liberty™ Blood Glucose Monitoring System (Liberty Medical Supply, Inc., Port St. Lucie, Florida),⁴⁰ the EasyTouch™ glucose self-monitoring system (Biotek Technology Inc., Hsinchu, Taiwan),⁴¹ and the OneTouch® Ultra® Blood Glucose Monitoring System (LifeScan).⁴² *Yellow Springs Instrument (YSI, Inc. [formerly Yellow Springs Instruments Company], Yellow Springs, Ohio) biochemistry analyzer.

“good numbers.”^{10,50,51} Data storage functions and the ability to download data to diabetes management software have the potential to improve the accuracy of data reviewed by the clinician.^{51,52} However, a study of 151 patients using glucose meters with memory capabilities revealed that only 40.4% of these patients had date and time settings on their glucose meters that were within 1 hour of the actual time,⁵³ which could compromise the ability of the patient or the provider to recognize blood glucose patterns. Future technological advances may include automatic date/time calibration, alarms to alert the patient that blood glucose needs to be checked, more user-friendly keypads and displays, and internal algorithms to track current and past glucose readings, time of day, food intake, previous insulin doses, and exercise.^{7,53}

As may be expected, the most significant source of errors in blood glucose measurement is related to the broad variability in the skill of the user and not to the instrument.²³ Two studies compared the analytical quality of measurements performed by patients with those performed by a

Future technological advances may include automatic date/time calibration, alarms to alert the patient that blood glucose needs to be checked, more user-friendly keypads and displays, and internal algorithms to track current and past glucose readings, time of day, food intake, previous insulin doses, and exercise.

medical laboratory technician and found that patient measurements had substantially poorer precision.^{12,54} Additionally, blood glucose meters appear to vary in their tolerance to specific types of user error. A recent study of 5 commercially available glucose meters showed that patients achieved accurate results (98.5% of measurements were clinically acceptable) when the devices were used according to the instructions for use.⁵⁵ However, when patients applied intentional mechanical stress to strips during testing, clinical accuracy varied widely (37.1%–99.1%) among the 5 devices.

Table II. Comparison of glucose meter accuracy with laboratory glucose analyzers during insulin-induced hypoglycemia test.*

Variable	OneTouch® Ultra®†	YSI,‡ Beckman,§ i-STAT®	P¶
Difference (mg/dL)#			
Median (25th, 75th percentiles)	2 (-3, 6)	2 (-1, 6)	0.03
Relative absolute difference**			
Median (25th, 75th percentiles)	7% (4, 12)	6% (3, 11)	0.58
Modified Error Grid A + B, %	>99	>99	NA††
ISO criteria met, %‡‡	95	96	0.69
Values within 10%, %	69	69	1.00
Values within 15%, %	83	85	0.49

YSI = Yellow Springs Instruments; NA = not available; ISO = International Organization for Standardization.

* There were 353 reference values pairing to both an Ultra and a YSI, Beckman, i-STAT value. The mean reference glucose value was 70 mg/dL (3.9 mmol/L).

† LifeScan, Inc., Milpitas, California.

‡ YSI, Inc. (formerly Yellow Springs Instruments Company), Yellow Springs, Ohio.

§ Beckman Coulter, Inc., Brea, California.

|| Abbott Laboratories, Abbott Park, Illinois.

¶ Treated as paired data values. The test statistic was calculated separately for each subject based on ranks (percentage of pairs in which the Ultra had the higher value) with inference based on the across-subject variation.

Difference is the sensor glucose value minus the reference value. To convert mg/dL values to mmol/L, multiply by 0.0555.

**Relative absolute difference is the absolute difference divided by the reference value (expressed as a percentage).

†† P value not computed because there were only 3 cases (all the same subject) where either instrument was outside zone A + B.

‡‡ ISO criteria: for reference glucose value ≤ 75 mg/dL (≤ 4.2 mmol/L), Ultra value within ± 15 mg/dL (± 0.8 mmol/L) for 95% of values; for reference glucose value > 75 mg/dL (> 4.2 mmol/L), Ultra value within ± 15 mg/dL (± 0.8 mmol/L) for $\pm 20\%$ of values.

Adapted with permission from DIABETES TECHNOLOGY AND THERAPEUTICS, Vol. 9. New Rochelle, NY: Mary Ann Liebert, Inc.; 2007.⁴³

Table III. Specimens falling into each of the categories of Clarke Error Grid analysis.

Zone	Category	Meter A, n (%)	Meter B, n (%)	Meter C, n (%)	Meter D, n (%)
A	Accurate	339 (74)	450 (97.6)	454 (98)	435 (94)
B	No error in treatment	117 (25)	5 (1.1)	5 (1)	22 (5)
C	Overtreat	1 (0)	1 (0)	1 (0)	1 (0)
D	Failure to detect	5 (1)	6 (1.3)	2 (0)	4 (1)
E	Wrong treatment	0 (0)	0 (0)	0 (0)	0 (0)

Adapted with permission from DIABETES TECHNOLOGY AND THERAPEUTICS, Vol. 5. New Rochelle, NY: Mary Ann Liebert, Inc.; 2003.¹

The silver lining to these findings is that they demonstrate the potential to improve meter accuracy in the hands of patients through improved patient education.¹² Key to this effort is identifying the common sources of user-related errors and devising effective patient training. A study in which 280 patients performed SMBG with their personal

meters while being observed by a trained diabetes nurse educator identified problems in 13 variables related to meter technique (**Table IV**).⁸ Although newer-generation meters have addressed several of these errors, other issues do not lend themselves as easily to a technological solution. For example, patients often neglected to wash or completely dry

Table IV. Common errors in meter technique made by patients during self-monitoring of blood glucose.

Error in Meter Technique	Patients, %
Used improper wiping technique, if required	74
Control test not performed correctly	62
Fingers not cleaned with soap and water or alcohol	26
Meter appeared dirty	19
Target area not covered	15
Inadequate blood drop obtained	9
Timer not started according to manufacturer's guidelines	8
Blood incorrectly applied	8
Wiped at incorrect time, if required	7
Inserted strip incorrectly	5
Alcohol not allowed to dry before testing, if used	5
Used expired strips	4
Meter coded incorrectly	3

Adapted with permission.⁸

their hands prior to testing, and meter cleanliness was frequently suboptimal.⁸ However, following a review by a nurse educator of proper technique, 69% of patients who had initially failed to achieve results within 15% of the reference instrument were able to meet this criterion. These results underscore the importance of teaching and periodically reevaluating user technique. Unfortunately, only 14% of the participants in this study had had their technique evaluated within the prior year.⁸

Errors in SMBG results can also occur if the quality control solution or the test strips have expired, or if the meter and/or test strips have been exposed to high heat or humidity.^{2,36} A study in which 111 adults with type 1 or type 2 DM were observed performing SMBG found that, to save time and money, patients did not use the electronic function strips and control solutions regularly, as is required.⁵⁶ Only 13% of the patients used electronic function strips daily, and only 62% regularly used an up-to-date control solution to check meter accuracy. Patients have reported that the expiration date has worn off of their test strip vial.³⁶ Additionally, patients may be using generic glucose reagent strips rather than those developed by the manufacturer for use with the meter. If the manufacturer changes the meter or the corresponding test strips and the generic product is not changed accordingly, the generic strips will be incompatible with the meter, and errors will result.³⁶ The proper use of control solutions can identify problems related to the meter or strips, but patient use of these solutions is low.^{8,12}

The obvious solution to user-related errors is improved patient training. Skeie et al¹² surveyed 422 patients and found that 51% had trained themselves in SMBG, only 2% were educated by their doctors, and many had poor technique for instrument quality control. The ADA recommends that a provider

“instruct the patient in SMBG and routinely evaluate the patient’s technique and ability to use data to adjust therapy.”⁵⁷

The obvious solution to user-related errors is improved patient training. The ADA recommends that a provider “instruct the patient in SMBG and routinely evaluate the patient’s technique and ability to use data to adjust therapy.”

The AAFP offers recommendations for instructing patients in SMBG and for guiding interpretation of the results (Table V).² In addition, an external quality-assessment scheme for SMBG has been designed for office laboratories, and control blood, which can be used to standardize glucose meters, is commercially available.⁵⁸ Although it may seem time-consuming for providers to help patients learn how to self-monitor, SMBG is an essential component of diabetes care.⁵⁹ Whether information on SMBG is provided by providers or is taken from instructional manuals, it should be practical and user-friendly to assist patients in overcoming barriers to SMBG testing. The information should demonstrate how to use the meter and charts or data logs, as well as suggestions for dealing with out-of-target readings.^{2,59} With

SMBG is important for all patients with diabetes, as it provides valuable feedback on the effects of diet, exercise, and medications.

Table V. Recommendations from the American Academy of Family Physicians for using self-monitoring of blood glucose (SMBG) in clinical practice.

- Provide specific instructions about how many times patients should test per day and when you want tests performed. Communicate these instructions to patients and to other members of the diabetes care team (eg, diabetes educator) to ensure that patients receive consistent messages.
- Provide an SMBG chart or logbook. Many glucose meter manufacturers provide these free or for a nominal fee. Recording the data electronically is also encouraged.
- Ask your office staff to remind patients to bring their SMBG logbooks and meters to their routine office visits. If your office makes reminder calls the day before a visit, add a reminder for these items as well.
- Ask for patients' SMBG logbook during the visit. Remember that patients have expended effort to collect this information. If reviewing the data is not important to you, collecting it may become less important for them.
- Ask patients for their interpretation of the SMBG data. Their interpretation of patterns and aberrations can be very revealing. Reinforce good decision-making and health habits. Provide specific advice on changes patients can make to their treatment plan in response to specific glucose values.

Adapted with permission.²

structured patient education when initiating SMBG and when reviewing patient technique during follow-up visits, user proficiency can be improved, and most patients can achieve acceptable precision, accuracy, and reliability of SMBG.^{8,60}

DISCUSSION

SMBG is important for all patients with diabetes, as it provides valuable feedback on the effects of diet, exercise, and medications. The evolution of glucose meter technology has led to newer systems that are more accurate than earlier systems and which incorporate innovations that decrease the likelihood of user error.

Although glucose meters must meet the ISO standard for accuracy, the more stringent goal of a total analytical error <5% recommended by the ADA currently appears to be uncommon in studies evaluating accuracy in routine clinical practice. Understanding accuracy studies depends on having an appreciation for how the studies are conducted and being familiar with sources of inaccuracy. Accuracy studies can be confounded by variables in the reference instrument, the blood sample, patient factors, and how accuracy is reported.

Clinicians are primarily concerned with whether patient-generated SMBG results have clinical accuracy sufficient to guide proper management decisions. Modern glucose meters have demonstrated very good clinical accuracy when used by an experienced technician. However, the most significant source of SMBG error is user related, not instrument related. Common problems with patient technique include inadequate hand cleaning, failure to obtain an adequate blood

sample, failure to apply the blood sample to the test strip correctly, failure to use quality control solutions to verify meter accuracy, using expired quality control solutions, improper maintenance of the meter, and improper handling and storage of test strips.

Although second-generation glucose meters that require wiping of test strips are no longer in common use because of the potential for error, the accuracy of SMBG with newer meters can be further improved by ongoing patient education and continued improvements in meter technology to minimize user error. Studies have shown that user-friendly, structured patient education is effective for improving accuracy when initiating SMBG; however, providers should also verify meter settings and review patient technique at follow-up visits to ensure user proficiency.

CONCLUSIONS

SMBG has proven to be a valuable tool for the management of diabetes whether the readings are used to guide insulin dosing, provide feedback on the effect of meals, or detect hypoglycemia. Health care providers can be confident in the clinical accuracy of most modern glucose meters. Efforts to improve meter accuracy should concentrate on minimizing user error through technological advances and enhancing patient education.

ACKNOWLEDGMENT

This manuscript was supported by an educational grant from LifeScan, Inc.

REFERENCES

1. Chen ET, Nichols JH, Duh SH, Hortin G. Performance evaluation of blood glucose monitoring devices. *Diabetes Technol Ther.* 2003;5:749-768.
2. Mayfield J, Havas S, for the AAFP Panel on Self-Monitoring of Blood Glucose. Self-control: A Physician's Guide to Blood Glucose Monitoring in the Management of Diabetes. An American Family Physician Monograph. <http://www.aafp.org/2004uspresident/PreBuilt/smbgmonograph.pdf>. Accessed December 29, 2007.
3. American Diabetes Association. Standards of medical care in diabetes—2008. *Diabetes Care.* 2008;31(Suppl 1):S12-S54.

4. Schwedes U, Siebolds M, Mertes G, for the SMBG Study Group. Meal-related structured self-monitoring of blood glucose: Effect on diabetes control in non-insulin-treated type 2 diabetic patients. *Diabetes Care*. 2002;25:1928–1932.
5. Walford S, Gale EA, Allison SP, Tattersall RB. Self-monitoring of blood-glucose. Improvement of diabetic control. *Lancet*. 1978;1:732–735.
6. Sönksen PH, Judd SL, Lowy C. Home monitoring of blood-glucose. Method for improving diabetic control. *Lancet*. 1978;1:729–732.
7. Winter WE. A Rosetta stone for insulin treatment: Self-monitoring of blood glucose. *Clin Chem*. 2004;50:985–987.
8. Bergenstal R, Pearson J, Cembrowski GS, et al. Identifying variables associated with inaccurate self-monitoring of blood glucose: Proposed guidelines to improve accuracy. *Diabetes Educ*. 2000;26:981–989.
9. International Organization for Standardization. ISO 15197 in vitro diagnostic test systems—Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. 2003.
10. American Diabetes Association. Self-monitoring of blood glucose. *Diabetes Care*. 1994;17:81–86.
11. Solnica B, Naskalski JW, Sieradzki J. Analytical performance of glucometers used for routine glucose self-monitoring of diabetic patients. *Clin Chim Acta*. 2003;331:29–35.
12. Skeie S, Thue G, Nerhus K, Sandberg S. Instruments for self-monitoring of blood glucose: Comparisons of testing quality achieved by patients and a technician. *Clin Chem*. 2002;48:994–1003.
13. Sánchez-Margalet V, Rodríguez-Oliva M, Sánchez-Pozo C, et al. Educational intervention together with an on-line quality control program achieve recommended analytical goals for bedside blood glucose monitoring in a 1200-bed university hospital. *Clin Chem Lab Med*. 2005;43:876–879.
14. Novis DA, Jones BA. Interinstitutional comparison of bedside blood glucose monitoring program characteristics, accuracy performance, and quality control documentation: A College of American Pathologists Q-Probes study of bedside blood glucose monitoring performed in 226 small hospitals. *Arch Pathol Lab Med*. 1998;122:495–502.
15. Nichols JH. What is accuracy and how close must the agreement be? *Diabetes Technol Ther*. 2005;7:558–562.
16. Weitgasser R, Gappmayer B, Pichler M. Newer portable glucose meters—analytical improvement compared with previous generation devices? *Clin Chem*. 1999;45:1821–1825.
17. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med*. 1993;329:977–986.
18. Ohkubo Y, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: A randomized prospective 6-year study. *Diabetes Res Clin Pract*. 1995;28:103–117.
19. Sarol JN Jr, Nicodemus NA Jr, Tan KM, Grava MB. Self-monitoring of blood glucose as part of a multi-component therapy among non-insulin requiring type 2 diabetes patients: A meta-analysis (1966–2004). *Curr Med Res Opin*. 2005;21:173–184.
20. Welschen LM, Bloemendal E, Niipels G, et al. Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin: A systematic review. *Diabetes Care*. 2005;28:1510–1517.
21. Martin S, Schneider B, Heinemann L, et al. Self-monitoring of blood glucose in type 2 diabetes and long-term outcome: An epidemiological cohort study. *Diabetologia*. 2006;49:271–278.
22. Jansen JP. Self-monitoring of glucose in type 2 diabetes mellitus: A Bayesian meta-analysis of direct and indirect comparisons. *Curr Med Res Opin*. 2006;22:671–681.
23. Lewandrowski K, Cheek R, Nathan DM, et al. Implementation of capillary blood glucose monitoring in a teaching hospital and determination of program requirements to maintain quality testing. *Am J Med*. 1992;93:419–426.
24. Chmielewski SA. Advances and strategies for glucose monitoring [published correction appears in *Am J Clin Pathol*. 1996;105:134]. *Am J Clin Pathol*. 1995;104(Suppl 1):S59–S71.
25. Poirier JY, Le Prieur N, Campion L, et al. Clinical and statistical evaluation of self-monitoring blood glucose meters. *Diabetes Care*. 1998;21:1919–1924.
26. Sacks DB, Bruns DE, Goldstein DE, et al. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. *Clin Chem*. 2002;48:436–472.
27. Weissman M, Klein B. Evaluation of glucose determinations in untreated serum samples. *Clin Chem*. 1958;4:420–422.
28. NCCLS. Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition. NCCLS document C30-A2 [ISBN 1-56238-471-6]. Clinical and Laboratory Standards Institute (formerly NCCLS), Wayne, Pa.
29. Chan AY, Swaminathan R, Cockram CS. Effectiveness of sodium fluoride as a preservative of glucose in blood. *Clin Chem*. 1989;35:315–317.
30. Kimberly MM, Vesper HW, Caudill SP, et al. Variability among five over-the-counter blood glucose monitors. *Clin Chim Acta*. 2006;364:292–297.
31. Kristensen GB, Christensen NG, Thue G, Sandberg S. Between-lot variation in external quality assessment of glucose: Clinical importance and effect on participant performance evaluation. *Clin Chem*. 2005;51:1632–1636.
32. Barreau PB, BATTERY JE. The effect of the haematocrit value on the determination of glucose levels by reagent-strip methods. *Med J Aust*. 1987;147:286–288.
33. Quinn L. Glucose monitoring in the acutely ill patient with diabetes mellitus. *Crit Care Nurs Q*. 1998;21:85–96.
34. Tang Z, Lee JH, Louie RF, Kost GJ. Effects of different hematocrit levels on glucose measurements with handheld meters for point-of-care testing. *Arch Pathol Lab Med*. 2000;124:1135–1140.
35. American Diabetes Association. Self-monitoring of blood glucose. *Diabetes Care*. 1994;17:81–86.
36. US Food and Drug Administration. Glucose meters & diabetes management. <http://www.fda.gov/diabetes/glucose.html>. Accessed July 13, 2006.

37. Clarke WL, Cox D, Gonder-Frederick LA, et al. Evaluating clinical accuracy of systems for self-monitoring of blood glucose. *Diabetes Care*. 1987;10:622–628.
38. Parkes JL, Slatin SL, Pardo S, Ginsberg BH. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. *Diabetes Care*. 2000;23:1143–1148.
39. Kendall DM, Kaplan RA, Paulson CF, et al. Accuracy and utility of a 10-test disk blood glucose meter. *Diabetes Res Clin Pract*. 2005;67:29–35.
40. Performance of the Liberty™ Blood Glucose Monitoring System by AgaMatrix, Inc. http://www.libertymedical.com/pdf/aga_whitepaper.pdf. Accessed December 13, 2007.
41. Dai KS, Tai DY, Ho P, et al. Accuracy of the EasyTouch blood glucose self-monitoring system: A study of 516 cases. *Clin Chim Acta*. 2004;349:135–141.
42. The Diabetes Research in Children Network (DirecNet) Study Group. A multicenter study of the accuracy of the OneTouch® Ultra® home glucose meter in children with type 1 diabetes. *Diabetes Technol Ther*. 2003;5:933–941.
43. Mahoney JJ, Ellison JM. Assessing glucose monitor performance—a standardized approach. *Diabetes Technol Ther*. 2007;9:545–552.
44. Nichols JH. Analysis: The evolution of glucose meters [published correction appears in *Diabetes Technol Ther*. 2005;7:581]. *Diabetes Technol Ther*. 2005;7:295–297.
45. Weinzimer SA, Beck RW, Chase HP, et al, for the Diabetes Research in Children Network Study Group. Accuracy of newer-generation home blood glucose meters in a Diabetes Research in Children Network (DirecNet) inpatient exercise study. *Diabetes Technol Ther*. 2005;7:675–680, discussion 681–683.
46. Cohen M, Boyle E, Delaney C, Shaw J. A comparison of blood glucose meters in Australia. *Diabetes Res Clin Pract*. 2006;71:113–118.
47. Mohan V, Deepa R, Shefali AK, et al. Evaluation of One Touch HORIZON—a highly affordable glucose monitor. *J Assoc Physicians India*. 2004;52:779–782.
48. Hawkins RC. Evaluation of Roche Accu-Chek Go and Medisense Optium blood glucose meters. *Clin Chim Acta*. 2005;353:127–131.
49. Savoca R, Jaworek B, Huber AR. New “plasma referenced” POCT glucose monitoring systems—are they suitable for glucose monitoring and diagnosis of diabetes? *Clin Chim Acta*. 2006;372:199–201.
50. Gonder-Frederick LA, Julian DM, Cox DJ, et al. Self-measurement of blood glucose. Accuracy of self-reported data and adherence to recommended regimen. *Diabetes Care*. 1988;11:579–585.
51. Mazze RS. Computers and diabetes therapy: Key variables and quality of data for clinical decision-making. *Horm Metab Res Suppl*. 1990;24:97–103.
52. Hirsch IB. Blood glucose monitoring technology: Translating data into practice. *Endocr Pract*. 2004;10:67–76.
53. Meneghini LF, Arce RL. Blood glucose data from meter memories often not useful for pattern recognition. Abstract presented at: American Diabetes Association 65th Annual Meeting; June 10–14, 2005; San Diego, Calif.
54. Kristensen GB, Nerhus K, Thue G, Sandberg S. Standardized evaluation of instruments for self-monitoring of blood glucose by patients and a technologist. *Clin Chem*. 2004;50:1068–1071.
55. Mohr TA, Pfützner A, Forst S, et al. Self-monitoring of blood glucose levels requires intensive training for use of meters to obtain reliable and clinically relevant measurements. *J Diabetes Sci Technol*. 2007;1:56–61.
56. Alto WA, Meyer D, Schneid J, et al. Assuring the accuracy of home glucose monitoring. *J Am Board Fam Pract*. 2002;15:1–6.
57. American Diabetes Association. Standards of medical care in diabetes—2006. *Diabetes Care*. 2006;29(Suppl 1):S4–S42.
58. Kristensen GB, Nerhus K, Thue G, Sandberg S. Results and feasibility of an external quality assessment scheme for self-monitoring of blood glucose. *Clin Chem*. 2006;52:1311–1317.
59. Moreland EC, Volkening LK, Lawlor MT, et al. Use of a blood glucose monitoring manual to enhance monitoring adherence in adults with diabetes: A randomized controlled trial. *Arch Intern Med*. 2006;166:689–695.
60. Kabadi UM, O’Connell KM, Johnson J, Kabadi M. The effect of recurrent practice at home on the acceptability of capillary blood glucose readings. Accuracy of self blood glucose testing. *Diabetes Care*. 1994;17:1110–1123.

Address correspondence to: Richard M. Bergenstal, MD, Executive Director, International Diabetes Center at Park Nicollet, 3800 Park Nicollet Boulevard, Minneapolis, MN 55416. E-mail: richard.bergenstal@parknicollet.com