Assuring the Accuracy of Home Glucose Monitoring

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Background: **An estimated 2.5 million diabetic patients in the United States practice self-monitoring of blood glucose (SMBG). The validity of the glucose values they obtain is in doubt. An American Diabetes Association consensus panel reported that up to 50% of SMBG determinations might vary more than 20% from their true value. Accurate glucose values are an integral part of intensive treatment and reduction of long-term complications. The objective of this study was to determine the technical skill and accuracy of SMBG in an outpatient population.**

Methods: **This study was conducted in two family practice residency sites where 111 patients with type 1 and type 2 adult diabetes were observed testing their blood glucose values on their own glucose monitors. Patient-measured glucose levels were immediately compared with a laboratory value obtained from a calibrated hand-held glucose monitor.**

Results: **Fifty-three percent of patient glucose values were within 10% of the control value, 84% were within 20% of the control value, and 16% varied 20% or more from the control value. Two patients had dangerously inaccurate glucose determinations. Four glucose monitors required replacement. The patients were observed using a 13-point checklist of critical steps in calibration and operation of their glucose monitor. Only 1 patient made no errors in testing.**

Conclusions: **Despite multiple technical errors when using SMBG, most patients obtained clinically useful values. This project can be easily introduced into a medical office. (J Am Board Fam Pract 2002; 15:1–6.)**

Of the 16 million persons in the United States with diabetes mellitus, 300,000 patients who have type 1 diabetes and 30% to 40% of the 7 to 7.5 million patients who have type 2 diabetes are receiving insulin therapy.[1] Most could benefit from home glucose monitoring to evaluate their response to therapy more carefully, to improve glycemic control, and to reduce the risk of hypoglycemia and microvascular complications.[2,3] The actual number of home glucose monitors in use is unknown, but it

is estimated that 1.0 to 2.5 million patients with diabetes self-monitor their blood glucose.[4,5]

A consensus panel of the American Diabetes Association (ADA) has encouraged the use of self-monitoring of blood glucose (SMBG) by those patients and caregivers who are able to learn the technique, are motivated to collect accurate results, and are willing to adjust their treatment depending on the monitored levels in consultation with their health provider.[1] During carefully controlled conditions, hand-held glucose meters have been shown to have good correlation and acceptable clinical accuracy in determining blood glucose levels when compared with standard laboratory testing.[6] Accuracy of glucose determinations by diabetic patients obtained in their homes is suspect, however[7,8] An ADA consensus panel reported that up to 50% of SMBG determinations might vary more than 20% from the true value.[9] It is therefore surprising that there has been no report of patients directly observed while obtaining their glucose levels. In 1997 the worldwide market for hand-held blood glucose

Table 1. Glucose Testing Evaluation Checklist.

Items	Number	Percent Yes
1. Reports checking monitor with electronic function strip daily	108	13.0
2. Code on monitor matches code on glucose test strip vial	108	97.2
3. Glucose test strips stored in original container	110	96.4
4. Test strips within expiratory date	102	94.4
5. Pricks lateral side of finger with puncture device	109	42.2
6. Wipes off first drop of blood, then tests hanging drop	111	37.8
7. Correctly applies blood to cover all of test strip	111	80.2
8. Inserts strip at appropriate time	106	97.2
9. Cleans monitor weekly or as needed	82	73.2
10. Records blood glucose value properly	99	85.9
11. Uses control solution	29	26.1
12. Uses control solution, and control solution is within expiratory date	18	62.1
13. Uses within-date control solution, and control solution and control values are within 10 percent of expected	11	61.1

Note: not all checklist items were applicable with various monitors.

monitors and supplies was estimated to be $2.05 billion, with a growth rate of 11% per year,[10] an expensive price to pay for possibly inaccurate, potentially misleading, and occasionally dangerous information.

In an attempt to reduce the variation in SMBG values to less than 10% from the reference values, and to improve the appropriate use of information gained through this potentially valuable technique, the ADA recommends (1) periodic simultaneous comparisons of patients' monitors with that of a reference laboratory, (2) patient education, and (3) further research toward determining those characteristics of patient-health care provider relationships that influence interactions and improve glycemic control and health outcomes.[1,4,11] With these goals in mind, we studied the accuracy of SMBG among outpatient diabetic patients through direct observation of their techniques and comparison with a laboratory blood glucose monitor.

Methods

Adult diabetic patients who were enrolled in two residency practices and who were known to conduct SMBG were contacted by telephone and invited to enroll in the study. Self-determination of blood glucose was conducted on the patient's analyzer and simultaneously from the same finger stick on a One Touch II Hospital Blood Glucose Monitoring System (Lifescan, Johnson & Johnson, Milpitas, Calif), which was calibrated twice daily according to the manufacturer's guidelines.

As they operated their glucose monitor, patients were observed by a trained medical or laboratory assistant who completed a checklist of critical points during the SMBG (Table 1). The checklist was derived from instruction manuals for home glucose monitors and teaching outlines used by diabetes educators at our institution. If a critical error occurred, the laboratory technician invited the patient to try another glucose determination after appropriate coaching.

Patients whose most recent laboratory values indicated leukemia, paraproteinemia, hypertriglyceridemia (> 500 mg/dL), or a hematocrit of more than 55% or less than 35% were excluded from the study because of the variable accuracy of hand-held glucose meters under these conditions. Laboratory monitor values of more than 299 mg/dL (16.6 mmol/L) and less than 50 mg/dL (2.8 mmol/L) were verified twice in accordance with laboratory policy; the first value obtained was used in analysis. There were no instances of second values having more than a 10% variance.

Statistical Analysis

Agreement of blood glucose (BG) values was determined by calculating percent error (PE), with less than 10% and 20% PE considered benchmarks for accuracy,

$$PE\% = \frac{BG \text{ (patient determined)} - BG \text{ (laboratory)} \times 100}{BG \text{ (laboratory)}}$$

An error grid analysis (Error Grid Analysis Software, University of Virginia) was used to define clinically significant errors in the accuracy of SMBG determinations.[12] Two-tailed chi-square tests using $P < .05$ were performed to analyze the relations of percentage of error (0%–10%, > 10%–20%, > 20%) with frequency of monitor use per month (0–29, 30–89, 90+) and with sex (male vs female). For those patients who tested their blood glucose more than once, the first determination was used in the accuracy analysis. Chi-square tests were used to test for a relation between accuracy (0% – 10% error, 11% – 20% error, and > 20% error) and sex (male vs female) or reported frequency of testing (averages of < 1 test per day, 1–3 tests per day, > 3 tests per day). Approval of the study protocol was obtained from the Institutional Review Board of Maine General Hospital and the Dartmouth Committee for the Protection of Human Subjects. All patients signed an informed consent form before their participation.

Results

There were 177 diabetic patients who used glucose monitors in the two practices, and 140 (79.1%) were able to be contacted and agreed to participate in the study. Of the patients who agreed to bring their glucose monitors to the office for testing, 116 (82.9%, 65.5% of total sample) actually participated. The demographic characteristics of the study population are displayed in Table 2. One hundred eleven patients were evaluated for the technical skills, and 108 provided a blood glucose value for accuracy analysis. Three participants successfully completed the SMBG technical steps, but their monitors failed to provide a number value. All glucose meters and test strips were referenced to blood, not plasma, glucose. Figure 1 displays the selection of the final study population.

Slightly more than one half (52.8%) of patients had SMBG values that varied less than 10% from the control monitor values, which fell within the ADA guidelines. A further 31.5% of SMBG values varied 10% to 20% from the control values. Sixteen percent of patients had SMBG values that varied in excess of 20% from the control values (Figure 2.) Only 49 (46%) of the random blood glucose values were less than 180 mg/dL, a target set by the Diabetes Control and Complications Trial.[3] Eighty-nine (82.4%) of the participants' monitors

Table 2. Characteristics of the Study Population.

Characteristic	Value
Average age (years)	56.0 ± 14.1, range 21–85
Sex, %	
Female	54.6
Male	45.4
	No. (%)
Diabetes mellitus	
Type 1	19 (16.4)
Type 2	92 (83.6)
Using insulin	45 (40.9)
Years using glucose meter	2.8 ± 3.0, range 0–15
Times meter used per month	48.5 ± 36.3, range 0–150
Glucose meter ever checked for accuracy	30 (27.9)
Type of glucometer:	
One Touch Basic	36
One Touch II	13
Accu-check Advantage	25
Other (18 types)	42

reported glucose values that were less than those of the control monitor. No statistically significant association was found between SMBG accuracy and sex, frequency of testing, type 1 or type 2 diabetes,
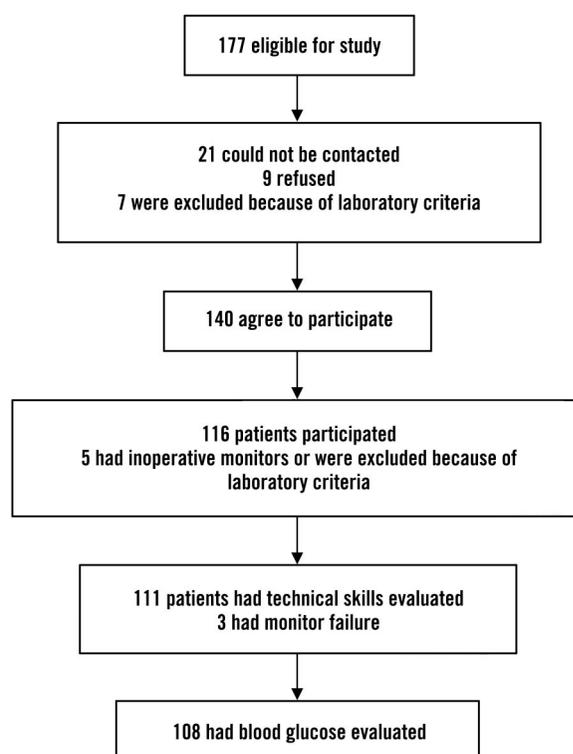

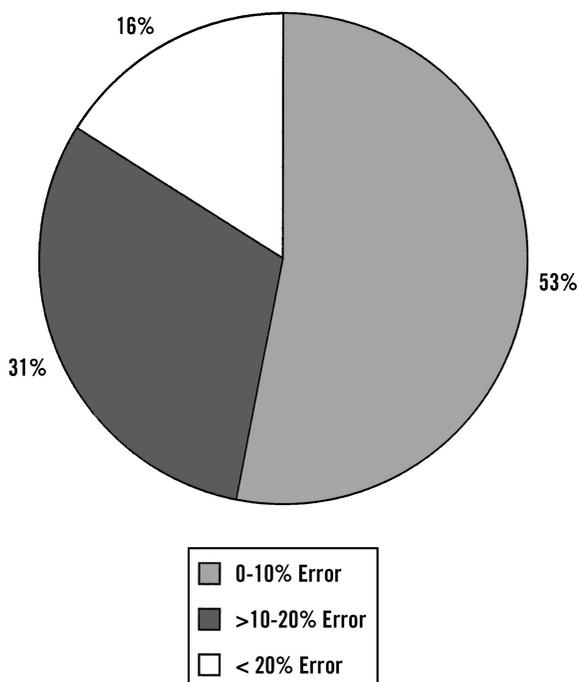**Figure 1. Flow chart of selection of study population.**

Figure 2. Distribution of percentage of error in self-monitoring of blood glucose (SMBG) determinations.

insulin use, or a previous check of the accuracy of the glucose meter.

Not all errors in SMBG are clinically important. To evaluate the clinical effect of errors, patient-generated glucose values were compared with control values using an error grid analysis[12,13] (Figure 3). This method of comparing glucose determinations allows for the separation of pairs of data into zones that suggest different levels of clinical concern and urgency of intervention. The patient-determined blood glucose value plotted as the Y-axis (estimated blood glucose) is compared with the reference value on the X-axis (measured blood glucose). The graph is divided into nine segments, which make up five zones.

Zone A represents an area of less than a 20% difference between patient-generated and reference blood glucose determinations, or hypoglycemia of less than 70 mg/dL (3.9 mmol/L). SMBG values within this range of accuracy would most likely lead to little difference in the clinical management of the disease. Our patients' values fell within zone A 83.5% of the time.

Zone B has an upper and lower segment where SMBG values varied 20% or more from the reference blood glucose determination. This inaccuracy

could lead to inappropriate treatment changes. Zone B contained 14.7% of glucose determinations. Two patients' values (1.8%) fell into the right side of zone D; their SMBG values were considerably less than the reference values, and the patients had unrecognized hyperglycemia. Both had consistently defective meters, which required replacement. No patient value fell within zone C (potential to change treatment to overcorrect acceptable blood glucose levels), or zone E, which might lead to inappropriate change in treatment.

Results of the evaluation checklist are displayed in Table 1. The patients scored poorly in their performance of many critical quality control tests. Only 14 patients (13%) used the electronic function strip daily, and only 18 patients (62.1%) used an up-to-date control solution. Most used improper techniques in the collection of their blood samples. Twenty percent of patients failed to cover the entire test strip correctly with blood. One read his monitor's display upside down, recording erroneous results. Only two items on the checklist were associated with a significant difference in blood glucose determination: failure to insert the test strip at the appropriate time (mean percent error 12.2 vs 41.9, $P < .001$) and not using a glucose logbook (mean percent error 11.8 vs 17.6 $P < .05$). Of the 7 patients who were retested after coaching, 4 were found to have incorrectly functioning meters, which required replacement, and 3 improved in accuracy, 2 to an acceptable ($< 10\%$) variation level. Nine other patients (8.1%) were judged to require additional counseling and were referred to diabetes educators.

Conclusions

SMBG has the potential to improve the management of diabetes mellitus in those patients who are able to collect accurate results and change their behavior based on their blood glucose determinations. This study, with a single observed patient encounter, suggests that only about one half of patients were able to obtain reliable blood glucose values within 10% of the reference value recommended by the ADA. Most patients (84.3%), however, were within 20% of a reference value (error grid analysis zone A). We believe this range of variation is more suitable for the clinical management of many patients. One of 6 study patients was obtaining inaccurate information, which required
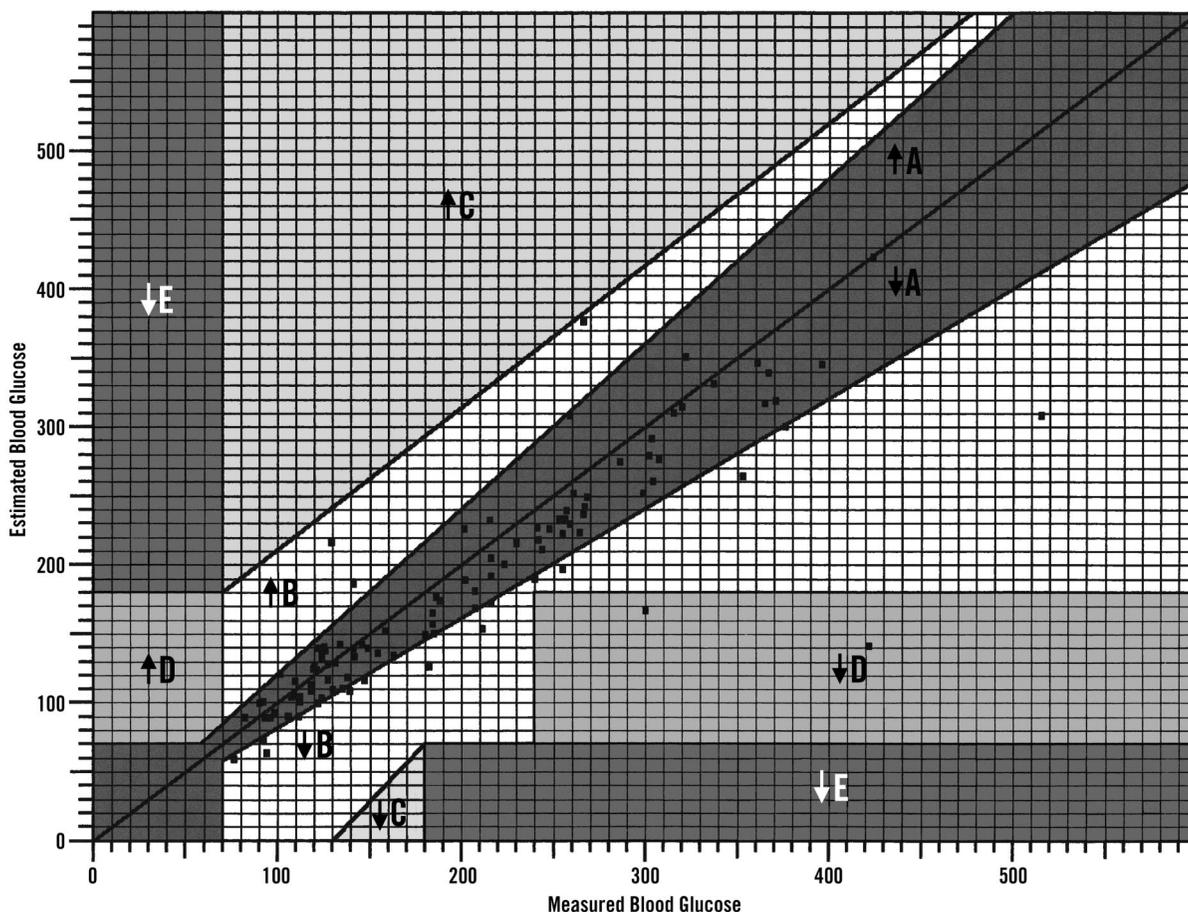
Figure 3. Grid analysis of errors in accuracy of self-monitoring of blood glucose (SMBG) determinations. Zone A = <20% difference between patient-generated and reference blood glucose determinations. Zone B = ≥ 20% difference. Zone C = SBMG values with potential to change treatment. Zone D = patient-generated values within target zone, but actual values dangerously high or low. Zone E = values that could lead to inappropriate change in treatment

correction. Only 19 patients obtained a glucose value greater than the reference value ($P = .0001$, $\chi^2 = 83.1$). This finding suggests that patient technical errors tended to produce lower blood glucose values.

Our patients took shortcuts to minimize the time required to obtain a blood glucose value. Electronic function strips and control solutions were seldom used because the test strips were expensive and using them required time. Patients therefore missed opportunities to verify that a monitor was inaccurate. Only 1 (0.9%) study patient received a perfect score on the evaluation checklist. Fewer than 1 in 10 patients successfully completed the following critical items of the checklist: electronic function checks; use of correct, up-to-date, and properly stored test strips that were completely

covered with blood and inserted for analysis at the appropriate time; and the regular use of up-to-date control solutions to validate the accuracy of the monitor. Despite the poor technical methods displayed by our study population, glucose values were, for the most part, clinically acceptable.

There are several weaknesses in this study. Its design allowed for only a single encounter for glucose comparison, and consistent accuracy of SMBG values over time is a more important goal. Although we excluded patients with known hypertriglyceridemia and abnormal hemoglobin levels, we did not have simultaneous values available at the time of testing. Some glucose monitors might provide inaccurate results if the patient has abnormal hemoglobin or lipid values or when blood samples contain certain interfering substances, such as

ascorbic acid or acetaminophen.[14] We believe these variables were unlikely to influence our results.

Although a dedicated glucose analyzer, available in many hospital laboratories, might have provided a more accurate glucose determination, comparisons between SMBG and laboratory values might have needed to be corrected for venous compared with capillary blood, plasma compared with whole blood glucose, and time until testing.[7,14] Our offices are not certified to use a dedicated glucose analyzer, and the goal was to provide immediate feedback and promote self-confidence in our patients. The monitor used as our reference standard has an acceptable accuracy and coefficient of variation when compared with dedicated analyzers.[14]

Our study population, a family practice residency patient panel, might not be representative of the larger population of patients with diabetes. Children with diabetes were not tested, and their SMBG techniques and glucose values could differ. Finally, there could have been a selection bias, because only patients willing to bring their glucose monitor to the office were evaluated. In addition, they might have practiced in preparation for testing at the family practice centers. As a result, our findings could overestimate the accuracy of SMBG. We were pleased that nearly two thirds of our diabetic patients participated in the study. Other medical care providers are encouraged to replicate this study with their patients.

In summary, this study reassured both patients and their medical providers of the accuracy of the SMBG. Patients were given the opportunity to improve their testing technique and reported that they appreciated the assistance they received. We were able to determine which patients were making clinically important errors and initiate interventions to correct problems. Further research will help clarify whether these interventions were helpful in the overall management of glycemic control of this population.

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