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Instruments for Self-Monitoring of Blood Glucose: Comparisons of Testing Quality Achieved by Patients and a Technician

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Background: **Instruments for self-monitoring of blood glucose (SMBG) are increasingly used by patients with diabetes. The analytical quality of meters in routine use is poorly characterized.**

Methods: **We compared SMBG performance achieved by patients and by a medical laboratory technician. Imprecision was calculated from duplicate measurements, and deviation as the difference between the first measurement and the mean of duplicate laboratory-method results (calibrated with NIST material). Analytical quality for five groups of SMBG instruments was compared with quality specifications for BG measurements. All participants completed a questionnaire assessing both SMBG training and use of the meters.**

Results: **We recruited 159 SMBG users from a hospital outpatient clinic and 263 others from 65 randomly selected general practices (total of 422). Most (two thirds) used insulin. CVs for the five meter types were 7%, 11%, 18%, 18%, and 20% in the hands of patients and 2.5–5.9% for the technician. For three of five meter types, patients' BG measurements had larger deviations from the laboratory results than did the technician's results. The technician's performance could not predict the patients'. No instrument when used by patients (but two operated by the technician) met published quality specifications. The analytical quality of patients' results was not related to whether they had chosen the instruments on advice from healthcare personnel (one-third of patients), were only self-educated in SMBG (50%), or performed SMBG fewer than seven times/week (62%).**

Conclusions: **The analytical quality of SMBG among patients was poorer than, and could not be predicted from, the performance of the meters in the hands of a technician. We suggest that new instruments be tested in the hands of patients who are trained on meter use in a routine way.**

Self-monitoring of blood glucose (SMBG)[1] with portable instruments became available for persons with diabetes mellitus in the mid-1970s and has been used on a regular basis in developed countries since 1980. Early published reports indicated benefits for the patient with improved metabolic control when blood glucose (BG) was measured at home *(1–3)*. Studies specifically designed to evaluate the association between SMBG and metabolic control are few *(4–6)*. On the other hand, large and well-controlled studies have shown the benefit of near-normal BG control for both type 1 and 2 patients *(7–9)*. Achieving this goal is regarded as difficult or impossible without SMBG, and the two largest randomized clinical diabetes trials both used frequent SMBG as a part of intensive treatment arm interventions *(7, 9)*.

Improving diabetes control using SMBG relies, in part, on the analytical quality and robustness of the instrument in the hands of the user. Studies performed to assess instrument quality have focused on technical and analytical performance, but testing has been performed by trained personnel, by manufacturing company representatives, or by patients who underwent special educational efforts before the evaluation *(10–22)*. These studies did not address the analytical quality in the hands of patients. Issues such as the influence of manufacturers or health professionals on instrument choice and purchase, the type of education when initiating SMBG, or patients' analytical quality control and their beliefs about instrument performance were also poorly examined. It is possible that such

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[1] Nonstandard abbreviations: SMBG, self-monitoring of blood glucose; BG, blood glucose; HbA_{1c}, hemoglobin A_{1c}; ADA, American Diabetes Association; and ISO, International Organization for Standardization.

factors also can influence a patient's ability to obtain and maintain recommended metabolic control. It is also well known that user error accounts for a large proportion of the total error in BG measurements performed with hand-held instruments *(23, 24)*.

We aimed to describe and evaluate the analytical quality of different instruments in the hands of patients as well as the associations between a personal diabetes profile, patterns of SMBG use, and the analytical quality of self-measured BG. We hypothesized that estimates of analytical quality for different instruments used in SMBG would fall short of current standards *(25, 26)* and patient-derived quality goals *(27)*. An essential question is whether it is possible to predict the analytical quality of a SMBG instrument in the hands of diabetic patients from results obtained under controlled conditions.

Materials and Methods

During the period from June 1997 to February 1998, patients performing SMBG were enrolled in a cross-sectional study. Patients were recruited consecutively from the outpatient clinic at Haukeland University Hospital (Bergen, Norway) and from 65 randomly selected general practices in the county of Hordaland, Norway. A total of 572 patients being seen by general practitioners and 213 from the hospital outpatient clinic were asked to participate. Of the patients recruited from general practices, 227 did not perform SMBG, 48 were unwilling to participate in the study, and 34 never showed up, giving a total of 263 included patients. If the patients recruited from the hospital clinic, 20 did not perform SMBG, 15 were unwilling to participate in the study, and 19 never showed up, giving a total of 159 included patients. All individuals signed a written informed consent describing the study background and aims and answered questions about age, sex, diabetes type and duration, and treatment. They also stated whether they performed SMBG. Consenting persons who performed SMBG were included in the study and were asked to come back for a specifically scheduled study visit. The visits took place at the hospital diabetes outpatient clinic or in a general practice surgery and were all attended by the same medical laboratory technician.

During the study visit, diabetic patients first performed two unassisted self-measurements using their own instruments and strips with blood from one lancet prick on their finger. Shortly afterward, the laboratory technician pricked the patient once in a different finger. With this blood sample, glucose measurements were performed twice on two different instruments and twice using the laboratory method (see *INSTRUMENTS*). For practical reasons, the numbers of measurements varied somewhat from instrument to instrument. Venous blood for hemoglobin A_{1c} (HbA_{1c}) and hematocrits was obtained after the patients had performed their BG measurements. HbA_{1c} was analyzed on a Diamat HPLC (Bio-Rad Laboratories) calibrated to give values similar to the Diabetes Control and Complications Trial method *(28)*. Total analysis time on the portable instruments was <5 min.

The analytical deviation (total error) for BG measurements was calculated for each patient, using the percentage of absolute deviation between the first BG measurement and the mean laboratory method result. The analytical precision of BG measurements was calculated from the difference between patients' duplicate glucose measurements.

All participants completed a questionnaire at the end of the visit (after the blood tests had been performed). The technician was available to clarify questions. In the questionnaire, participants were asked about their first year of BG measurements, their first year using a SMBG device, and the type of BG instrument. In addition, they reported details on the use of BG instruments, frequency, perceived instrument quality, and use of controls. The questionnaire was reviewed by senior academic faculty and by general practitioners. No revision of the questionnaire was necessary after a pilot phase of the study. The study plan was reviewed and approved by the Norwegian Regional Committee for Medical Research Ethics.

INSTRUMENTS

The subgroups of instruments from the same manufacturer (e.g., MediSense QID vs other MediSense models) had largely the same technology and used similar strips. BG results were similar among models from the same manufacturer, and the results were pooled accordingly. The comparability of results was assessed by comparing imprecision and number of results outside the quality specification limits within each subgroup. The following instruments were used by the patients: (*a*) in the MediSense group (Abbott Laboratories), the MediSense Companion 2, MediSense Card, MediSense Pen, and Precision QID; (*b*) in the Accutrend group (Roche Diagnostics), the Accutrend, Accutrend Mini, and Accutrend Alpha; (*c*) in the One Touch group (Lifescan), the One Touch II and One Touch Basic; (*d*) different models in the Glucometer Elite group (Bayer Diagnostics); and (*e*) the Gluco Touch (Lifescan). In addition, six or fewer patients used the Accutrend sensor, the Exactech, various older Glucometer models, Reflolux types, or manual visual strips. The analytical results for the patients using these instruments were not analyzed further. The technician used the following instruments and strips: Precision QID, Accutrend alpha, One Touch Basic, Glucometer Elite, and Gluco Touch. Only one batch of strips was used for each of the instruments in the technician testing. All instruments measure plasma glucose, and all but the Gluco Touch recalculate the results to BG. The Gluco Touch results reported here were recalculated from plasma values to whole blood values (15% lower) to be comparable to the conventional true values *(29)*. Measured hematocrits were all within the manufacturers' acceptable limits for individual instruments.

The conventional true value was established using the

whole-blood glucose 6-phosphate dehydrogenase method on a Cobas Fara centrifugal analyzer (Roche Diagnostics). The method was calibrated with NIST standards and is called the laboratory method in this report. For two quality-control samples monitored throughout the study (4.2 and 13.5 mmol/L in lyophilized human serum; Roche), the imprecision (CV_a) of the method was 1.8% and 1.7%, respectively (n = 54). External quality-control material (fresh serum) from the Norwegian center for quality improvement of primary healthcare laboratories (NOKLUS) was examined twice. This material was targeted with the isotope-dilution–gas chromatography–mass spectrometry laboratory method for glucose *(30)*. Results were within ±2% of the target value.

RECOMMENDATIONS FOR ANALYTICAL QUALITY

The American Diabetes Association (ADA) has stated that all SMBG systems should have a total error (bias and imprecision in the hands of the user) of <10% *(25)*. In a study estimating patient-derived quality specifications for instruments used in SMBG, it was concluded that most diabetic patients interpret analytical results as if the instruments had an analytical imprecision (CV) of <5% and an analytical bias of <5%, i.e., a total error of ~13% *(27)*. The draft of the International Organization for Standardization (ISO) standard for quality specifications for instruments used for self-monitoring of glucose has suggested that 95% of the measurements should be within ±20% for glucose concentrations >4.2 mmol/L and within ±0.83 mmol/L for concentrations ≤4.2 mmol/L *(26)*. In a recent study where quality specifications for glucose meters were addressed by a simulation modeling errors in insulin dose, it was concluded that a total error of <5–6% rarely leads to major errors in insulin dosage *(31)*. We compared our findings with these recommendations and standards.

STATISTICAL ANALYSIS

The imprecision of the instruments when handled by the patients or the technician as well as the imprecision of the laboratory method was calculated from the differences (as a percentage) of the duplicate samples for each of the instruments, using the formula:

$$SD = \sqrt{\frac{\sum d^2}{2n}}$$

where d is the difference between measurements, and n is the number of duplicate samples.

The imprecision was calculated from the percentage differences because the CVs were more constant than the SDs throughout the measurement range. Differences larger than $k \times SD_{diff}$ (k is sample size dependent) were considered as outliers and excluded from calculation of the CVs *(32)*. Differences between continuous variables were analyzed using a two-tailed t-test or a nonparametric test; proportions were compared using the χ^2 test.

A multiple logistic regression model was established to evaluate the association between both patient and SMBG characteristics, with the percentage of deviation between the BG results obtained with the SMBG instruments and those obtained with the laboratory method (deviation <10% = 0; deviation ≥10% = 1) as the dependent variable. The percentage of deviation chosen indicated the cutoff for "optimum" analytical quality as recommended by the ADA *(25)*. In developing the model, we evaluated the following independent variables: SMBG duration, SMBG educational mode, SMBG frequency, SMBG importance, questioning of SMBG results, instrument controls, type of instrument, diabetes type, diabetes duration, practice location, HbA_{1c} concentration, age, and sex. Multiple logistic regression analysis was also performed to evaluate the association between the same characteristics, with the HbA_{1c} concentration as the dependent variable (HbA_{1c} <7.5% = 0; HbA_{1c} ≥9% = 1). A level of significance of 5% was chosen.

Results

STUDY POPULATION

The study involved one recruitment visit and one inclusion visit. Age and diabetes duration were not significantly different among the 20 hospital patients not performing SMBG and the patients studied. Of the 227 nonperformers in general practice, 96% had type 2 diabetes; their mean age was higher (70 vs 54 years) and diabetes duration shorter (7 vs 12 years) than for the patients from general practice (P <0.001) who participated in the study.

A total of 53 (12.5% of consenting patients) patients dropped out between recruitment and the scheduled inclusion visit. Dropouts were younger [mean (SD) age, 46 ± 18 vs 54 ± 18 years; P <0.01] and included more patients with type 1 diabetes (51% vs 42%; P <0.05) than did the included group.

Patient characteristics and data on the different instruments used are shown in Table 1. Most patients used the MediSense type of instruments; One Touch was the least used instrument. Of the patients who attended the hospital clinic, 17% had type 2 diabetes compared with 80% of the patients monitored in general practice, and 67.5% of all patients in the study were treated with insulin injections (alone or in combination with tablets). Among type 2 patients, the proportion receiving insulin-containing treatments was higher in the group attending the hospital clinic than in those in general practice (74% vs 39%; P = 0.002). The HbA_{1c} results were higher in type 2 patients attending the hospital outpatient clinic compared with those treated by general practitioners (8.9% vs 7.9%; P = 0.001). Otherwise, no statistically significant differences were found in mean HbA_{1c} or other variables for the two types of diabetes, and the main results are not divided by diabetes type, but by hospital clinic vs general practice.

Table 1. Characteristics of patients included and instruments used.

	Hospital outpatients (n = 159)	General practice (n = 263)	*P*
Patients			
Age,[a] years			
Women	39 ± 13	64 ± 14	<0.001
Men	42 ± 15	62 ± 15	<0.001
Sex (female), %	51	47	0.48
Diabetes duration,[a] years	15 ± 11	10 ± 9	<0.001
HbA_{1c},[a] %	8.3 ± 1	7.9 ± 1	0.01
Diabetes type 1, %	82	20	
Instruments			
Glucometer Elite			
n (%)	38 (24)	58 (22)	
No. of years using instrument[a]	3 ± 2	2 ± 1	
MediSense			
n (%)	72 (45)	76 (29)	
No. of years using instrument[a]	3 ± 2	3 ± 2	
Accutrend			
n (%)	18 (11)	40 (15)	
No. of years using instrument[a]	3 ± 2	3 ± 2	
One Touch			
n (%)	8 (5)	25 (10)	
No. of years using instrument[a]	4 ± 2	4 ± 3	
Gluco Touch			
n (%)	9 (6)	31 (12)	
No. of years using instrument[a]	1 ± 1	1 ± 1	
Other			
n (%)	14 (9)	33 (13)	
No. of years using instrument[a]	6 ± 3	6 ± 3	

[a] Mean ± SD.

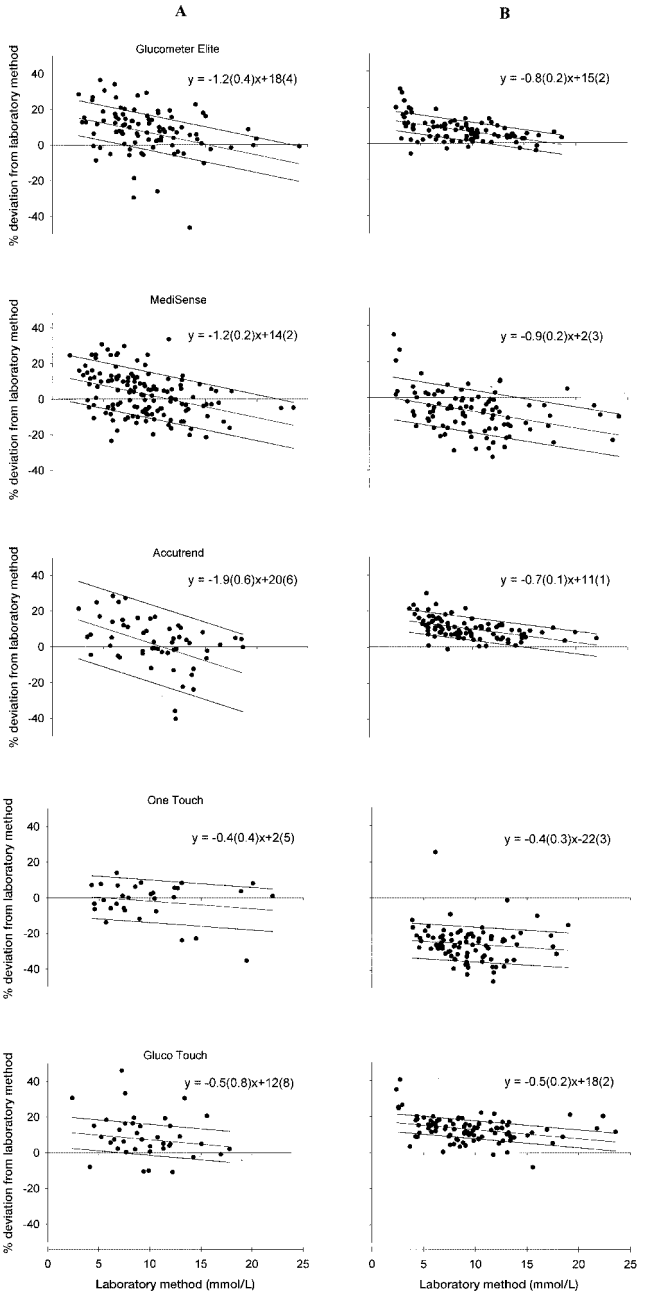

Fig. 1. Difference plots for instruments (first sample) and the laboratory method (mean of two samples) plotted against the laboratory method for patients (*A*) and the technician (*B*).

The regression line $y = ax + b$ is plotted with the estimated theoretical total imprecision (± $1.96CV_{total}$) for the technician and patients for the different instruments (see Table 2). Slopes and intercepts are given for each regression line according to the formula: $y = [a(SE_a) \times x] + b(SE_b)$.

ANALYTICAL QUALITY

The relationship between the measurements (first sample) by the diabetic patients for each instrument and the conventional true value (mean of the two samples) is shown in Fig. 1A. In the same manner, the relationship between the result obtained by the technician for each instrument and the conventional true value is shown in Fig. 1B. More than 90% of the BG results were in the range 3.8–17.2 mmol/L. The regression lines and 95% prediction intervals for the differences (regression line ± $1.96CV_{total}$; see Table 2) are plotted in Fig. 1, which also shows the regression equation, including the SE, based on the formula: $y = [a(SE_a) \times x] + b(SE_b)$.

The percentages of results obtained by diabetic patients and the technician that deviated from the conventional true value by more than the ADA criterion of 10% *(25)* or by more than the differences allowed in the proposed ISO standard *(26)* are shown in Table 3. Clearly, none of the instruments could satisfy the ADA recommendation. For different instruments, 19–58% of patients' measurements deviated more than the 10% allowed in the ADA recommendation, whereas 15–97% of the technician's results were outside this limit. All the studied instruments failed to reach the ISO standard quality goal that 95% of measurements by diabetic patients be within ±20% of the laboratory method (or within ±0.83 mmol/L for BG ≤4.2

Table 2. Imprecision as calculated from duplicate samples from diabetic patients or from the technician.

Instrument	Examined by	n	Mean, mmol/L	CV, (outliers included), %	Outliers excluded		CV_{total}[c]
					n[a]	CV (95% CI),[b] %	
Laboratory method	Technician	412	9.5	1.6	3	1.5 (1.4–1.6)	
Glucometer Elite	Technician	95	9.4	2.5	0	2.5 (2.0–3.0)	2.7
	Patients	77	9.8	20	7	4.9 (3.8–6.0)	5.0
MediSense	Technician	98	9.1	5.9	0	5.9 (4.7–7.1)	6.0
	Patients	140	9.1	7.2	1	6.5 (5.4–7.6)	6.6
Accutrend	Technician	93	10.5	3.0	0	3.0 (2.4–3.6)	3.2
	Patients	50	10.1	18	1	11 (8.0–14)	11
One Touch	Technician	87	7.0	4.8	0	4.8 (3.8–5.8)	4.9
	Patients	29	10.1	11	1	6.0 (3.8–8.2)	6.1
Gluco Touch	Technician	90	10.5	3.5	3	2.3 (1.8–2.8)	2.5
	Patients	33	10.5	18	4	4.3 (2.9–5.7)	4.4

[a] Number of samples excluded because they were outliers (see *Materials and Methods*).
[b] CI, confidence interval.
[c] $CV_{total} = \sqrt{CV^2 + \frac{CV_{lab}^2}{2}}$

mmol/L). The values obtained by the technician were better overall, with the Glucometer Elite and Gluco Touch instruments fulfilling the criteria of the ISO standard. The results obtained by the technician with the One Touch instrument were systematically lower than the laboratory values (Fig. 1B). This was probably attributable to the specific batch of strips that was provided by the manufacturer. For the MediSense and One Touch instruments, the BG results showed a decrease with increasing hematocrit compared with the laboratory method (results not shown). Thus, in these cases hematocrits influenced the results, although the hematocrits were within the acceptable limits stated by the manufacturer.

The imprecision with and without outliers, as calculated from the differences of the duplicate samples for each of the instruments or the laboratory method, is shown in Table 2. In the hands of the diabetic patients, the Glucometer Elite and Gluco Touch instruments had an imprecision <5%, although in these cases 10% of the results were excluded because they were outliers. The imprecision was <5% for all the instruments used by the technician except for MediSense. For the Glucometer Elite, Accutrend, and Gluco Touch instruments, the CVs for the technician's measurements were markedly lower than the CVs for diabetic patients' measurements. Only the Glucometer Elite and Gluco Touch could meet the patient-derived quality specifications of 5% *(27)*.

SMBG by diabetic patients

Approximately 50% of the patients started SMBG based on a purchase recommendation from healthcare personnel, ~30% decided on their own, and the rest had been influenced by advertising (including recommendations from salespeople) or other reasons. Hospital patients

Table 3. Percentage of measurements by patients or the technician that deviated from the laboratory method by >10% or by more than the difference allowed by the ISO standard.

	Examined by	n	Deviation,[a] % of measurements	
			>10%[b]	>ISO standard[c]
Glucometer Elite	Technician	94	27 (18–37)	2 (0.2–8)
	Patients	95	48 (38–59)	16 (9–25)
MediSense	Technician	95	45 (35–56)	15 (8–24)
	Patients	140	43 (35–52)	11 (6–17)
Accutrend	Technician	93	47 (37–58)	7 (2–14)
	Patients	56	43 (30–57)	16 (8–28)
One Touch	Technician	87	97 (90–99)	82 (72–89)
	Patients	31	19 (7–38)	10 (2–26)
Gluco Touch[d]	Technician	93	15 (9–24)	1 (0–6)
	Patients	40	58 (41–73)	15 (6–30)

[a] Mean (95% confidence interval).
[b] ADA recommendation: SMBG systems should have a total error (bias and imprecision) <10% *(25)*.
[c] ISO standard: BG values within ±20% at >4.2 mmol/L and ±0.83 mmol/L at ≤4.2 mmol/L *(26)*.
[d] Gluco Touch results were recalculated from plasma values to whole blood values (15% lower) to be comparable to the conventional true values *(29)*.

based their choice to start SMBG more on recommendations from healthcare personnel and less on advertisements or recommendations from salespeople than did patients in general practice (55% and 4% vs 45% and 11%, respectively; $P < 0.001$). When asked about the reasons for their current instrument choice, approximately one third had chosen their current instrument based on recommendations from healthcare personnel or pharmacies, approximately one third had based their choice on advertising, and approximately one third had based their choice on personal initiative and various other reasons. Thus, for the majority of patients, the choice of a specific instrument was not related to whether it was based on advice from healthcare personnel (data not shown).

The results obtained on the questionnaire concerning SMBG characteristics and patterns are shown stratified for practice site in Table 4. A total of 51% of the patients claimed to be self-educated in performing SMBG, and doctors educated only 2%. Of the responders, 74% never or rarely questioned the correctness of their instruments. Instrument controls were performed by 37% of the patients, but only a minority of them performed an internal quality control using commercial control materials. Comments revealed that controls were mainly performed by measuring twice or by comparing results from self-monitoring with results obtained at a doctors' office or on different instruments. Independent of diabetes type, patients performing SMBG more frequently rated the importance of SMBG significantly higher ($P < 0.001$) than did individuals performing SMBG less frequently. Individuals performing SMBG frequently had performed SMBG for a longer time period ($P < 0.05$).

Table 4. SMBG characteristics and patterns of patients reported in the questionnaire.

	Hospital outpatients (n = 159)	General practice (n = 263)
Duration of SMBG (mean ± SD), years		
Total duration of SMBG	11 ± 6	5 ± 5
Use of BG instrument	7 ± 5	4 ± 3
Use of current BG instrument	3 ± 2	3 ± 2
How did you learn to use your instrument?, %		
Self-educated	56	47
Salesperson	13	14
Friend with diabetes	1	4
Nurse	26	27
Physician	2	2
Other	3	6
How frequently do you usually perform BG measurements?, %		
1–3 times/month	13	19
1–3 times/week	26	40
4–6 times/week	11	10
7–10 times/week	11	14
>10 times/week	39	17
Regarding control of your diabetes, how important do you think self-monitoring of BG is?, %		
Essential	26	12
Very important	43	30
Important	19	42
Somewhat important	8	12
Not very important	4	2
Do you ever question whether your instrument shows the correct BG result?, %		
Never	36	40
Rarely	39	34
Sometimes	24	21
Often	1	4
Nearly always	1	1
Do you ever control that your instrument shows the correct result?, %		
No, never	49	47
No, unaware how to	14	16
Yes	37	37

ANALYTICAL DEVIATION AND METABOLIC CONTROL

In the multiple logistic regression model we investigated whether background characteristics, SMBG characteristics, or type of instrument used could influence the probability of a having a BG measurement that deviated <10% or ≥10% from the laboratory method. Adjusting for other variables, patients from the hospital setting had an odds ratio of 1.9 (1.2–3.1) for a deviation ≥10% compared with patients who were monitored by a general practitioner, i.e., the analytical quality of measurements performed by the hospital patients was poorer. Treatment category and SMBG frequency did not seem to be associated with deviation. Other background or SMBG factors did not show any association.

In a second multiple logistic regression model, only diabetes duration showed a significant influence on the probability of having HbA_{1c} ≥9% compared with HbA_{1c} <7.5% (results not shown).

Discussion

Describing and assessing SMBG performance among diabetes patients can be done through observation or by asking the SMBG users. Our design included planned visits, which possibly could influence patients to prepare for the study. However, the questionnaire was designed and formulated to avoid the impression that a particular answer was correct. If anything, user-related errors involved in performing SMBG are likely to be underestimated in this research setting. No significant differences in analytical quality could be demonstrated between type 1 and 2 patients. This was an unexpected finding because SMBG generally is more important to and strongly recommended to type 1 patients.

When we compared instrument analytical quality with the ADA recommendation, all instruments failed to reach this criterion. We therefore focused mainly on the quality specifications of the ISO draft standard. This ISO standard *(26)* proposes quality specifications for instruments and strips examined under controlled conditions. It seems reasonable that similar quality specifications should also be relevant when diabetic patients use the instruments and strips, and we have applied the specifications to both

situations. Overall, a total of 86% of the BG measurements performed by patients showed deviation within the limits recommended by the ISO standard (Table 3). This is lower than the ISO standard recommendation of 95% of measurements performed being within ±20% deviation *(26)*. None of the studied instruments reached this goal in the hands of the patients. When BG was measured by the technician, both the Glucometer Elite and Gluco Touch fulfilled the criteria of the ISO standard (Table 3). Many of the instruments seem to overestimate glucose at low concentrations (Fig. 1). This might be a problem when patients become hypoglycemic.

The precision of the BG results obtained using the Glucometer Elite, Accutrend, and Gluco Touch was significantly better for the technician than for the patients (Table 2). On the basis of patient-derived quality specifications, it has been suggested that imprecision should be <5% *(27)*, and a simulation study showed that imprecision below this value rarely leads to major errors in insulin dosing *(31)*. When the precision of an instrument is better in the hands of the technician than for the diabetic patients, quality improvement might be achieved through patient education *(23–25, 33, 34)*. For the Glucometer Elite and Gluco Touch, this is underlined by the large number of outliers, which probably reflect user errors. As expected and shown in Table 2, the inclusion of outliers increased some of the CVs substantially. In addition, the results would probably have been poorer if instrument testing was moved even further into patients' daily life, i.e., performed in locations other than the hospital clinic or general practitioners' office.

It has been argued that in method comparisons, the between-method difference should be plotted against the average value of the two methods, thus avoiding a negative correlation between the differences and the laboratory method *(35)*. However, in method comparison studies in clinical chemistry, the imprecision in the laboratory method is often very low compared with the new method. Therefore, it can be an advantage to plot the between-method difference against the laboratory method because this will reduce the uncertainty along the *x* axis *(36)*. This has been done in the present study, but our conclusions would not have been different if we had used the between-method difference along the *x* axis, although the negative correlation would have been slightly less.

If all the differences between the instruments and the laboratory method could have been explained by the total imprecision of the methods, i.e., been within the prediction interval, only 5% of the results (plus the outliers) would have been located outside the limits shown in Fig. 1. Matrix and hematocrit effects can probably explain the situation when approximately the same number of results are located outside the limits independent of whether the diabetic patients or the technician analyzed the samples. This is the situation for the MediSense, One Touch, and Gluco Touch groups of instruments. This finding was confirmed in a recent study with the MediSense QID *(22)*. To reduce the hematocrit effects and to be able to compare results from instruments for self-measurements with results from larger laboratories, all measurements should be made in plasma and reported as such. When the number of results outside the limits is larger for results from patients, batch-to-batch variation, user errors, or instrument-to-instrument variation might be the explanation. This may be the situation for the Glucometer Elite.

It is obvious that testing of BG under controlled conditions does not necessarily reflect the quality of the measurements obtained in the hands of ordinary patients. An important question is, however, whether results obtained under controlled conditions can predict results obtained from diabetic patients using the same instruments. The percentages of results deviating more than the limits given in the ISO standard for each instrument for both the technician and patients are shown in Fig. 2. As can be seen, there was no relationship between results obtained by patients and the technician and no differences between instruments when tested by the patients. Similarly, the correlation between imprecision (CV) for measurements obtained by patients and the technician is shown in Fig. 3. Again a poor relationship was found. Thus, it is not possible to predict patients' analytical quality performance from results obtained by the technician in this study.

Only one instrument and one lot of strips were used by the technician, in contrast to many lots of strips and instruments by the diabetic patients. This could explain some of the systematic differences found by the technician (e.g., One Touch). If the technician had used more batches and/or instruments, the deviation of results from the laboratory method, as shown in Fig. 1B, could have been larger. It is not obvious, however, whether more or fewer results would have been within the limits for the quality

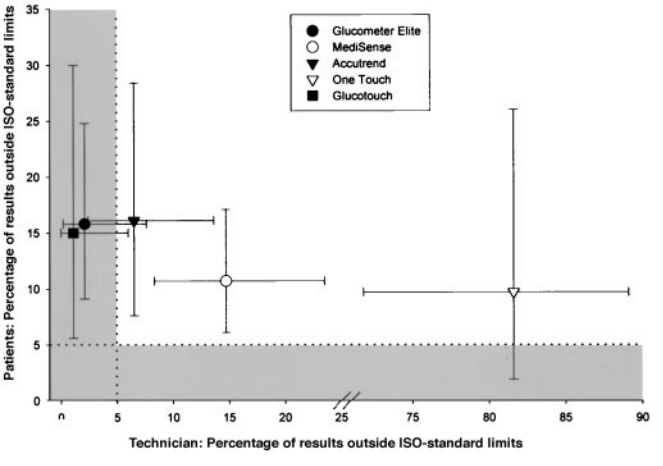

Fig. 2. Relationship between the percentage of results [with 95% confidence intervals (*error bars*)] outside the limits of the ISO standard obtained by the technician and the diabetic patients (see Table 3).

Shaded areas denote the quality goal that only 5% of the results can be outside the ISO standard recommendations *(26)*.

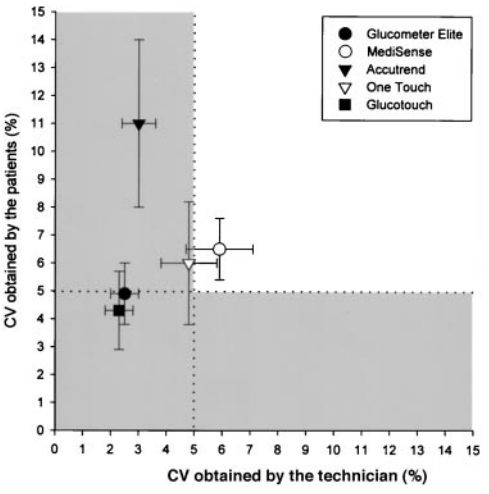

Fig. 3. Relationship between the imprecision [with 95% confidence intervals (*error bars*)] obtained by the technician and the diabetic patients (see Table 2).

Shaded areas denote the 5% imprecision quality goal.

specifications. The (within-batch) precision (Table 2) probably would have been unchanged. It is still probable that user errors and lack of instrument robustness, both of which are dependent on the specific instrument used, accounted for most of the differences between technician and patient results. Further studies are necessary to address this issue in more detail. On the basis of the present study, we suggest that, before being marketed, such instruments should also be tested among diabetic patients and that quality specification should be set for performance. These "pragmatic" quality specifications probably have to change over time as both instrument robustness and patient education improve. However, only when testing under controlled conditions is satisfactory should instruments be tested among diabetic patients. We currently are designing a protocol for user evaluation that includes 100 diabetic patients and three lots of strips.

Recommendations from the ADA and others encourage SMBG for all patients treated with insulin or sulfonylurea drugs to monitor BG to prevent hypoglycemia *(25, 37, 38)*. In addition, SMBG is recommended for all patients taking insulin to achieve near-normal glucose values, although adherence to this is known to be variable *(39, 40)*. For type 1 patients, the ADA recommends SMBG three or more times daily *(38)*, whereas patients in our study measured BG only 1.6 times daily (mean value) *(27)*. It is unknown what optimal SMBG frequency is and whether increased frequency leads to better metabolic control *(38, 41, 42)*.

Among the patients asked to participate, we found that as many as 91% of patients at the hospital clinic and 60% in general practice performed SMBG. This illustrates the need for tailored SMBG information and education, not only in specialized centers but also in general practice. The finding that 51% of patients claim to be self-educated together with the fact that one-third of the patients' chose their current instrument on the basis of commercial influence can also illustrate a potential for improved patient education. Many patients have poor instrument quality-control routines. The necessity and value of establishing such routines should be examined.

After adjusting for other variables, multiple logistic regression analysis for BG deviations ≥10% (compared with <10%) showed significance only for practice site, subgroups of treatment category, and SMBG frequency. For SMBG frequency, the multivariate results were not convincing for all subgroups. Overall, the analysis did not give us definite clues on characteristics or factors favoring a better analytical quality outcome. In addition, other factors not examined might be more important than those evaluated in this study.

Studies designed to show a specific benefit of SMBG on metabolic control have not been convincing *(43–48)*. SMBG does not automatically lead to changes in treatment or behavior, and many patients are reluctant to adjust therapy on their own and seem to use SMBG mainly to monitor for hypoglycemia *(49, 50)*. We found that diabetes duration, but not SMBG factors, overall significantly influences the chance of having HbA_{1c} ≥9% compared with <7.5%.

In conclusion, when a technician can perform BG measurements with lower deviation and better precision, the potential to improve performance among the patients is demonstrated. All meters tested failed to reach the ADA recommendations, the ISO standard for BG measurements, and patient-derived quality specifications *(25–27)* when tested in the hands of the patients. In this study, instrument analytical quality performance in the hands of randomly selected patients could not be predicted from the results obtained by a trained technician. To give patients better instrument recommendations, we suggest testing of new instruments in the hands of a population of patients who are educated and instructed (for the instrument in question) according to the usual procedure in the region where they live. We are currently developing a protocol where 50% of the patients are trained and the other 50% only get the instruction manual. The majority of patients seem to be influenced by commercial interests and other nonhealthcare personnel when choosing an instrument and initiating SMBG. Many patients do not receive structured education in SMBG. Educational efforts can possibly improve patient SMBG performance *(10, 24, 34)*. We believe that healthcare professionals should be more strongly involved in SMBG initiation, education, and follow-up.

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