The Impact of Blood Glucose Self-Monitoring on Metabolic Control and Quality of Life in Type 2 Diabetic Patients

An urgent need for better educational strategies

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OBJECTIVE — The role of self-monitoring of blood glucose (SMBG) in type 2 diabetes is still a matter of debate. In the framework of a nationwide outcomes research program, we investigated the frequency of SMBG and its association with metabolic control and quality of life (QoL).

RESEARCH DESIGN AND METHODS — The study involved 3,567 patients with type 2 diabetes who were recruited by 101 outpatient diabetes clinics and 103 general practitioners. Patients completed a questionnaire investigating SMBG practice and QoL (diabetes-related stress, diabetes health distress, diabetes-related worries, and Centers for Epidemiologic Studies-Depression scale).

RESULTS — Data on SMBG were available for 2,855 subjects (80% of the entire study population). Overall, 471 patients (17%) stated that they tested their blood glucose levels at home ≥1 time per day, 899 patients (31%) tested their blood glucose levels ≥1 time per week, and 414 patients (14%) tested their blood glucose levels <1 time per week, whereas 1,071 patients (38%) stated that they never practiced SMBG. A higher frequency of SMBG was associated with better metabolic control among subjects who were able to adjust insulin doses, whereas no relationship was found in all other patients, irrespective of the kind of treatment. Multivariate analyses showed that an SMBG frequency ≥1 time per day was significantly related to higher levels of distress, worries, and depressive symptoms in non–insulin-treated patients.

CONCLUSIONS — Our findings suggest that SMBG can have an important role in improving metabolic control if it is an integral part of a wider educational strategy devoted to the promotion of patient autonomy. In patients not treated with insulin, self-monitoring is associated with higher HbA_{1c} levels and psychological burden. Our data do not support the extension of SMBG to this group.

Diabetes Care 24:1870–1877, 2001

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Received for publication 14 March 2001 and accepted in revised form 30 July 2001.

Abbreviations: CES-D, Centers for Epidemiologic Studies-Depression; GP, general practitioner; ISM, insulin dose self-management; OR, odds ratio; QoL, quality of life; SMBG, self-monitoring of blood glucose; TIBI, Total Illness Burden Index.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

According to the position statement of the American Diabetes Association, self-monitoring of blood glucose (SMBG) is considered an important component of diabetes care and is recommended for all insulin-treated patients (1). It is also considered desirable in patients treated with sulfonylureas and in all subjects not achieving glycemic goals. Nevertheless, its role and optimal frequency in type 2 diabetes is still matter of debate (2), and it has been underlined that its indiscriminate use can cause a waste of resources and psychological harm (3).

In the framework of the Qualità ed Esito in Diabetologia (QuED) Project, a nationwide initiative aimed at assessing the relationship between the quality of care delivered to subjects with type 2 diabetes and outcomes, we investigated the frequency and the factors associated with the practice of SMBG, as well as its association with quality of life (QoL).

RESEARCH DESIGN AND METHODS

Study design

The study involved 101 outpatient diabetes clinics and 103 general practitioners (GPs). For the recruitment of diabetes centers, we asked the two Italian diabetes associations (Società Italiana di Diabetologia and Associazione Medici Diabetologia) to identify in each of the 21 regions of Italy a minimum of five candidate centers, to be chosen from those with longer experience in epidemiological research. Similarly, GPs were identified through the Italian Center for Research in General Practice following the same criteria. Physicians were selected according to their willingness to participate in the project.

All patients with type 2 diabetes were considered eligible for this study, irrespective of age, duration of diabetes, and

treatment. In diabetes clinics, patients were sampled by using random lists, stratified by patient age (<65 or ≥65 years). Each center was asked to recruit at least 30 patients, whereas GPs only enrolled patients in whom they were primarily responsible for diabetes care. The present analysis refers to the data collected at study entry; patients will be followed for 5 years, and information will be collected at 6-month intervals.

All data concerning general medical history and specific diabetes history were collected by the patient's physician by using study forms specifically developed for the project. Doctors were also asked to report whether patients were able to adjust insulin doses.

For all clinical variables, the last value in the previous 12 months was requested. Because normal ranges for glycated hemoglobin varied among the different centers, the percentage change with respect to the upper normal value (actual value/upper normal limit) was estimated and multiplied by 6.2.

All patients recruited were requested to complete a questionnaire investigating SMBG practice, the presence and severity of diabetes complications and comorbidities, and QoL. In particular, the performance of SMBG was assessed by questioning frequency on a six-point scale ranging from >1 time per day to never. This information was cross-checked with another question, present in a completely different section of the questionnaire, regarding the number of times blood glucose had been measured in the last 2 weeks. The answers to these two questions showed to be strongly correlated (Spearman correlation coefficient = 0.84, $P < 0.0001$), thus providing reassurance regarding the reliability of the information. Patients were also asked to report the frequency of hypoglycemic symptoms (sweating, weakness, trembling) on a five-point scale ranging from ≥1 time per week to never.

The presence and severity of diabetes complications and comorbidities were summarized by using the Total Illness Burden Index (TIBI), a widely used measure of comorbidity that was specifically developed for outpatient populations (4). This index can be used as a continuous measure or categorized into four classes of increasing severity.

QoL was investigated by using the following diabetes-specific measures developed in the framework of the Patient Outcomes Research team (PORT) —Diabetes 2 (5):

1. Diabetes-related stress. Composed of eight items, this measure is derived from the questionnaire developed by Dunn et al. (6) and explores emotional adjustment in patients with diabetes. In particular, this scale assesses feelings of being "different" and leading a different life style, of living under a life sentence, and of diabetes being "the worst thing that ever happened." Answers are given on a five-point Likert scale, ranging from "strongly disagree" to "strongly agree."

2. Diabetes health distress. This measure is composed of five items and explores the extent to which diabetes is a source of frustration, discouragement, nuisance, or concern. Patients are asked how often in the past 4 weeks diabetes was responsible for such feelings, and answers are based on a five-point Likert scale, ranging from "all of the time" to "none of the time."

3. Diabetes-related worries. The questionnaire includes seven items investigating how much patients are worried or concerned about the consequences of diabetes (complications, disability, early death). The answers are based on a five-point Likert scale, ranging from "extremely worried" to " not worried at all."

For all of the scales, the scores range between 0 and 100, with higher scores indicating higher levels of stress, distress, and worries. To evaluate the presence of depressive symptoms, we also used the Centers for Epidemiologic Studies-Depression (CES-D) scale (7), composed of 20 items, with a score ranging from 0 to 60. Higher scores indicate higher levels of depressive symptoms.

The translation, cultural adaptation, and validation of the Italian version of the instruments were performed specifically for this study. Standard forward/backward techniques were used to ensure conceptual equivalence (8).

The Italian health care system

All Italian citizens are covered by government health insurance and are registered with a GP. Primary care for diabetes is provided by GPs and outpatient diabetes clinics, which are staffed by diabetologists and/or internists. Patients can choose between the two health care systems according to their preference or can be referred to diabetes clinics by their GPs. It is estimated that ~50% of patients with type 2 diabetes are treated by GPs only. Diabetes education is often provided by the personnel operating in diabetes clinics as well as by GPs. The costs of reagent strips and glucometers are usually covered by the national health system; due to variations in regional policies, a maximum yearly amount is fixed for non–insulin-treated patients in some regions. No national guideline is available for SMBG, and practices vary among the different providers.

Statistical analysis

Analysis was initially performed based on a series of univariate comparisons. The χ^2 test was used to detect association between patient characteristics and frequency of SMBG. When a continuous variable was categorized in more than two levels, the χ^2 Mantel-Haenszel test for linear association was applied. Values of continuous variables and QoL scores across SMBG frequency classes were compared using the Kruskall-Wallis one-way analysis of variance. To account for the multilevel nature of the data (patients clustered within physician/practice) and to control simultaneously for the possible confounding effects of the different variables, we also used multilevel models (9,10). These models allow consideration of the separated contribution to the total variance given by patient and physician-related characteristics, thus minimizing the risk of false-positive results. The deviance test with a χ^2 distribution was used to assess whether the proportion of variance at physicians' level significantly differed from 0 or, put in another way, whether the multilevel structure of the data needed to be taken into account. Setting of care (GPs versus diabetes clinics), number of physicians practicing within diabetes clinics, and average number of patients per physician seen in 1 month were considered level 2 variables, whereas all patient characteristics were considered level 1 variables.

In particular, multilevel logistic regression (namely, a random intercept model) was applied to evaluate factors associated with performing SMBG with a frequency ≥1 time per day. Results are expressed in terms of odds ratios (ORs) and 95% CI. The following patient characteristics (level 1 variables) were tested, with the first category of each considered the reference: age (<55, 55–65, >65

years); gender (men, women); living alone (yes, no); years of education (>5, ≤5); BMI (>27 kg/m^2 in men or >26 kg/m^2 in women, ≤27 kg/m^2 in men or ≤26 kg/m^2 in women); duration of diabetes (<5, 5–10, >10 years); TIBI (class 1, class 2, class 3, class 4); diabetes treatment (diet ± oral agents, insulin, insulin + oral agents); frequency of hypoglycemic symptoms (never to <1 time per month, ≥1 time per month, ≥1 time per week); and ability to adjust insulin doses (no, yes).

Multilevel linear regression (i.e., random intercept models) was applied to evaluate correlates of HbA_{1c} levels. The analysis was run separately for insulin-treated and non–insulin-treated subjects. The following covariates were considered: gender, living alone, education, setting of care (all coded as in the logistic model), age, BMI, duration of diabetes, TIBI, and HbA_{1c} (continuous variables). Additional variables tested in insulin-treated patients were the following: frequency of hypoglycemic symptoms, ability to adjust insulin doses (both coded as in the logistic model), and number of insulin injections per day (1, 2, >2).

To test the combined effect of insulin dose self-management (ISM) and frequency of SMBG on metabolic control, patients were classified into four categories: ISM yes and SMBG ≥1 time per day (reference category); ISM yes and SMBG ≥1 time per week; ISM yes and SMBG <1 time per week; and ISM no, irrespective of the frequency of SMBG.

The independent association between SMBG frequency and QoL was initially tested with a series of multilevel linear regression models with stress, distress, worries, and CES-D scores as dependent variables. All the analyses were run separately for insulin-treated and non–insulin-treated subjects. Because for all the QoL scores the amount of variance explained by level 2 variables was trivial and statistically not significant, two-level structure was deemed not necessary and ordinary least-squares models were applied. The following covariates were considered: gender, living alone, education, setting of care (all coded as in the logistic models), age, BMI, duration of diabetes, TIBI, and HbA_{1c} (continuous variables). Additional variables tested in insulin-treated patients were the following: frequency of hypoglycemic symptoms, ability to adjust insulin doses (both coded as in the logistic model), and number of insulin injections per day (1 [reference category], 2, >2). The association of SMBG frequency with the aforementioned scales is expressed in terms of β parameters with standard error of the mean (SEM).

For the validation of QoL questionnaires, a multitrait, multi-item method was used (11–13). This method allows determination of whether each item in a scale is substantially related ($r \geq 0.40$) to the total score computed from the other items in that scale (item convergent validity criterion). Reliability of internal consistency was estimated for each multi-item scale by the Cronbach's α coefficient (14). Furthermore, the percentages of respondents achieving either the highest score (ceiling) or lowest score (floor) were calculated.

All of the instruments used showed excellent psychometric characteristics. In particular, for all of the scales, the Cronbach's α coefficient largely exceeded the minimum accepted value of 0.70 (Stress 0.81, Distress 0.91, Worries 0.92, CES-D 0.89). On the same line, item-scale correlation was extremely satisfactory (>0.40) for all but one item on the CES-D scale (0.20) and one on the Stress scale (0.37). Percentages at ceiling and floor were also in an acceptable range (Stress 0.4 and 0.6; Distress 11.5 and 1.4; Worries 5.7 and 4.4; CES-D 0.5 and 0; respectively).

All analyses were performed using SAS statistical software (Version 8.1; SAS Institute, Cary, NC) (15).

RESULTS

SMBG correlates

Of 3,567 type 2 diabetic patients recruited, 2,968 (83%) completed the questionnaire. The information relative to the frequency of SMBG was available for 2,855 subjects (96% of respondents, 80% of entire study population).

Overall, 471 patients (17%) stated that they tested their blood glucose levels at home at least once per day, 899 (31%) at least once a week, and 414 (14%) less than 1 time per week, whereas 1,071 (38%) never practiced SMBG. A glucometer was used by 99% of the patients who tested their blood glucose levels at least one time per day, by 95% of those who tested their blood glucose levels at least once per week, and by 73% of the remaining patients. The characteristics of the study population according to the frequency of SMBG are shown in Table 1.

Independent correlates of practicing SMBG at least once per day were investigated with a multilevel logistic regression, showing that a statistically significant proportion of the variance (15%; deviance test $P < 0.0001$) was explained at the physicians' level.

Women (OR 1.35, 95% CI 1.07–1.72), insulin-treated patients (2.86, 1.82–4.48 for insulin alone and 2.27, 1.42–3.60 for combination with oral agents), patients experiencing hypoglycemic symptoms (2.86, 1.95–4.20), and patients who were able to self-adjust insulin doses (2.31, 1.47–3.64) were more likely to perform self-monitoring. On the other hand, patients older than 65 years (0.71, 0.53–0.96), patients with ≤5 years of education (0.63, 0.49–0.81), and patients treated by GPs (0.60, 0.41–0.87) were less likely to frequently test their blood glucose levels.

SMBG and metabolic control

The analysis of metabolic control in the entire study population showed a statistically significant increase in mean HbA_{1c} levels with increasing frequency of SMBG (Table 1). No association between HbA_{1c} levels and SMBG frequency was found in patients treated with insulin ($P = 0.24$). Nevertheless, when ISM was taken into account, a statistically significant association emerged; mean HbA_{1c} levels were 7.5 ± 1.8% (ISM yes, SMBG ≥1 time per day), 7.8 ± 1.7% (ISM yes, SMBG ≥1 per week), 7.9 ± 1.8% (ISM yes, SMBG <1 time per week), and 8.3 ± 1.9% (ISM no, irrespective of SMBG frequency) ($P < 0.002$). The independent association between frequency of SMBG and metabolic control was investigated separately for non–insulin-treated and insulin-treated patients by using hierarchical linear models. Among the former, 27% of the total variance was explained at physicians' level (deviance test $P < 0.0001$). A frequency of SMBG ≥1 time per day or ≥1 time per week was related to significantly higher HbA_{1c} levels. A poorer metabolic control was also associated with increasing BMI, female gender, and longer duration of diabetes, whereas patients treated with diet alone showed lower HbA_{1c} levels as opposed to those taking oral agents. Level 2 variables were not independently associated with HbA_{1c} levels (Table 2).

In the model involving insulin-

Table 1—*Frequency of SMBG according to patient characteristics* (n = 2,855)

	Frequency of blood glucose self-testing				
	≥1/day	≥1/week	<1/week	Never	*P**
Overall patient characteristics					
n	471	899	414	1,071	
Sex					0.04
Males	49.8	56.5	53.4	57.2	
Age (years)	61.1 ± 11.2	62.0 ± 10.2	63.0 ± 10.4	63.7 ± 9.6	0.001
Education (years)					0.001
≤5	57.1	52.0	49.3	45.3	
Living alone					0.96
No	88.1	87.3	87.0	87.7	
BMI (men)	26.9 ± 4.8	27.1 ± 3.6	27.0 ± 3.5	28.0 ± 3.7	0.001
BMI (women)	27.9 ± 4.9	28.1 ± 5.0	28.6 ± 4.9	28.9 ± 5.4	0.07
Duration of diabetes (years)	12.7 ± 9.0	11.5 ± 8.7	10.7 ± 8.7	8.7 ± 7.6	0.001
TIBI	15.5 ± 13.5	13.3 ± 12.4	13.7 ± 13.2	12.6 ± 12.4	0.0007
Treatment					0.001
Diet only	5.5	10.7	16.2	27.3	
Oral agents	46.1	64.7	63.5	66.4	
Insulin	30.7	14.8	10.1	2.7	
Insulin + oral agents	17.7	9.8	10.2	3.6	
HbA_{1c}	7.5 ± 1.8	7.4 ± 1.7	7.3 ± 1.6	7.0 ± 1.6	0.0001
Frequency of hypoglycemic symptoms					0.001
≥1/week	15.9	6.7	3.2	5.8	
≥1/month	31.8	22.4	20.4	11.1	
<1/month–never	52.3	70.9	74.4	83.1	
Setting of care					0.001
Diabetes clinic	84.5	82.1	75.1	70.6	
Insulin-treated patient characteristics					
n	212	209	80	65	
No. of insulin injections/day					0.001
1	23.2	24.4	37.7	37.1	
2	22.1	33.8	28.5	32.3	
>2	54.7	41.8	33.8	30.6	
Ability to adjust insulin doses					0.001
Yes	77.9	67.5	50.0	44.6	

Data are % for categorical variables and means ± SEM for continuous variables. *χ^2 for categorical variables or Kruskall-Wallis one-way analysis of variance for continuous variables.

treated patients, physicians' level still played an important role (i.e., mean HbA_{1c} levels significantly varied across centers/practices). In fact, 20% of the total variance was explained by level 2 variables ($P < 0.0001$). In this subgroup, SMBG frequency was not independently related to metabolic control, whereas the association with the ability to adjust insulin doses was marginally significant ($\beta = -0.38$, $P = 0.05$). To further elucidate the interplay between SMBG frequency and insulin self-management, a second multilevel linear model was performed, including the variable testing the combined effect of the two practices. This analysis showed that patients able to adjust insulin doses and practicing SMBG with a frequency of ≥1 time per day had highly significant lower HbA_{1c} levels as opposed to those not practicing ISM (Table 2). The association of ISM with lower frequencies of SMBG was not significantly related to HbA_{1c} levels. Of the other variables investigated, female gender and increasing BMI were significantly related to higher HbA_{1c} levels.

QoL evaluation

Mean scores for the different scales according to SMBG practice are reported in Table 3, showing that stress, distress, worries, and depressive symptoms tended to significantly increase with the frequency of blood glucose testing. Multivariate analyses showed that, after adjusting for all patient characteristics, SMBG frequency of at least one time per day was still significantly related to higher levels of distress, worries, and depressive symptoms among non–insulin-treated patients (Table 4). In this subgroup, higher scores for diabetes health distress and diabetes-related worries were also significantly related to SMBG frequency of at least one time per week (reference category: frequency less than one time per week). On the other hand, the frequency of monitoring was not significantly related to QoL in insulin-treated subjects, with the exception of a lower level of diabetes-related stress in those testing their blood glucose level at least one time per

Table 2—*Results of multilevel linear regression for HbA_{1c} levels*

	Non–insulin-treated patients		Insulin-treated patients	
Fixed effects	β	*P*	β	*P*
Level 1 covariates				
Women	0.22	0.001	0.33	0.038
BMI	0.02	0.003	0.04	0.050
Diabetes duration	0.02	<0.001	0.01	0.320
Diabetes treatment				
Diet alone versus oral agents (rc)	−0.71	<0.001	—	—
SMBG frequency				
≥1/day	0.30	0.008	—	—
≥1/week	0.27	<0.001	—	—
<1/week or never (rc)	—	—		
Combined effect of SMBG and ISM				
ISM yes/SMBG ≥1/day			−0.55	0.015
ISM yes/SMBG ≥1/week	—	—	−0.31	0.178
ISM yes/SMBG <1/week	—	—	−0.33	0.244
ISM no/SMBG any (rc)			—	—
Random effects	Estimate	Proportion of total variance	Estimate	Proportion of total variance
Level 2 variance (random intercept)	0.62	27%	0.62	19%
Level 1 variance (residual)	1.71	73%	2.61	81%
Deviance test for the random intercept	χ^2	*P*	χ^2	*P*
	237.62	<0.0001	36.70	<0.0001

rc, reference category.

week, as opposed to those not practicing SMBG (Table 4).

CONCLUSIONS — Despite the lack of clear evidence linking self-monitoring of blood glucose with improved glycemic control in patients with type 2 diabetes, the adoption of this practice is constantly increasing. In a study performed in Italy in 1994 (16), the proportion of insulin-treated patients with type 2 diabetes who practiced SMBG at least once per day was 13.9%, whereas our data show that the proportion has increased to more than one third, reaching 46% among subjects treated with three or more insulin injections per day and 56.6% among those reporting frequent hypoglycemic symptoms. Consistent with previous findings, SMBG is still less frequently used in older and less educated patients and in those treated by GPs (16).

From the evaluation of a large population with type 2 diabetes, it is shown that, under routine clinical practice conditions, a correlation between self-monitoring and better metabolic control is present for insulin-treated subjects only. In fact, among patients not treated with insulin, a higher frequency of SMBG was related to higher HbA_{1c} levels, thus suggesting that patients with poor metabolic control have a greater tendency to self-monitor (17). The different patterns of association between glycemic control and SMBG in subjects treated or not treated with insulin are unlikely to be attributable to differences in the ability to perform this practice. In fact, non–insulin-treated patients who monitored their blood glucose level at least once per week were younger and more educated than those treated with insulin (age >65 years, 36 vs. 42%, respectively; ≤5 years of education, 45 vs. 51%, respectively).

Among insulin-treated patients, the benefit of SMBG for metabolic control seems to be restricted to those who are able to adjust their insulin doses, supporting the concept that glucose self-monitoring is effective only when used for self-management (3). In two recent articles, no association was found between SMBG and HbA_{1c} in insulin-treated subjects with type 2 diabetes (17,18); nevertheless, no attempt was made to evaluate the joint effect of SMBG practice and ability to self-manage insulin doses on metabolic control. In this respect, our data strongly suggest that SMBG can have an important role in improving metabolic control if it is an integral part of a wider educational strategy devoted to the promotion of patient autonomy in the management of the disease. These aspects of diabetes care seem to be particularly unsatisfactory in patients treated by GPs, despite their central role in ensuring the continuity of care in a large proportion of patients with type 2 diabetes in Italy. In this respect, there is an urgent need to improve the coordination between GPs and diabetes centers and to redefine the responsibilities of each of the two health care systems, particularly as far as educational aspects are concerned.

Multilevel analysis also showed that a substantial variation in the percentage of patients practicing SMBG and mean HbA_{1c} levels is present among different centers/practices. Nevertheless, aside from the findings relative to general practice, none of the level 2 variables tested showed independent predictive value. More complex organizational and structural aspects, not captured by the infor-

Table 3—*QoL scores according to the frequency of SMBG*

	Frequency of SMBG				
QoL domain	≥1/day	≥1/week	<1/week	Never	*P**
n	471	899	414	1,071	
Diabetes-related stress	51.6 ± 20.5	47.7 ± 19.9	49.5 ± 19.0	44.1 ± 19.2	0.0001
Diabetes health distress	44.1 ± 26.0	37.9 ± 25.8	37.1 ± 25.6	28.5 ± 24.5	0.0001
Diabetes-related worries	60.6 ± 24.6	53.7 ± 27.1	50.2 ± 28.2	48.5 ± 28.6	0.0001
Depressive symptoms (CES-D)	23.3 ± 10.7	20.9 ± 10.8	21.6 ± 10.4	19.9 ± 10.4	0.0001

Data are means ± SEM unless otherwise indicated. *Kruskall-Wallis one-way analysis of variance.

Table 4—*Relationship between blood glucose self-testing and QoL: results of multiple regression analyses*

	Insulin-treated patients				Non–insulin-treated patients			
	Frequency of blood glucose self-testing				Frequency of blood glucose self-testing			
	≥1/day (n = 212)		≥1/week (n = 209)		≥1/day (n = 227)		≥1/week (n = 641)	
QoL domain	β (SEM)	*P*	β (SEM)	*P*	β (SEM)	*P*	β (SEM)	*P*
Diabetes-related stress	−2.49 (2.20)	0.26	−5.49 (2.17)	0.01	2.06 (1.51)	0.17	1.07 (1.00)	0.29
Diabetes health distress	−2.44 (2.71)	0.37	−2.86 (2.68)	0.29	8.17 (1.87)	0.0001	5.52 (1.25)	0.0001
Diabetes-related worries	3.22 (2.61)	0.22	−0.42 (2.59)	0.87	10.88 (2.21)	0.0001	3.67 (1.47)	0.01
Depressive symptoms	−1.03 (1.77)	0.56	−3.16 (1.75)	0.07	2.27 (1.17)	0.05	0.71 (0.78)	0.36

All analyses are adjusted for the following variables: age, gender, living status, education, TIBI, BMI, duration of diabetes, treatment, number of insulin injections, frequency of hypoglycemic symptoms, ability to self-adjust insulin doses, HbA_{1c} value, setting of care. The β parameters are estimated by considering a frequency <1/week as the reference category.

mation available, can thus be responsible for our findings.

The analyses relative to QoL add another important element against the indiscriminate use of SMBG in non–insulin-treated patients with type 2 diabetes. In fact, in these subjects, self-monitoring was not significantly related to better metabolic control and was associated with higher levels of frustration, worries, and depression. As suggested by other authors, the correlation with poorer psychological well-being could be related to the feeling of powerlessness caused by unsatisfactory results patients are not able to improve (3). The association between SMBG and poorer QoL was not evident in insulin-treated subjects, for whom one can speculate that the positive effect on metabolic control can counterbalance the psychological and physical discomfort and the inconvenience of testing (3).

Given these findings, the evidence that SMBG would benefit the metabolic control of type 2 diabetic patients is limited to 380 patients who are able to adjust insulin doses (13% of the whole sample; 66% of insulin-treated patients). Unfortunately, less than half of these patients (44%) tested their blood glucose at least once per day, a frequency that was associated with better metabolic control.

As a final point, some of the possible limitations of our study need to be discussed. First, the cross-sectional nature of our analysis does not allow any causal inference for the associations emerged. Although we tried to minimize confounding effects by taking into consideration a large array of patient and care-related characteristics, only properly designed randomized clinical trials could ensure that the associations observed do not reflect a tendency to prescribe more frequent SMBG to those who are in worse metabolic control or have poorer quality of life. Furthermore, a factorial design could be useful to examine whether any effect of SMBG is contingent on uses of SMBG in making treatment decisions.

Second, we classified patients as practicing SMBG on the basis of the reported average number of blood glucose measurements per day, with no possibility of assessing the true frequency and scheduling of blood glucose tests. However, surveys are commonly used to explore patient practices (17); furthermore, the high correlation between the answers given to the two separate questions regarding SMBG frequency give reassurance regarding the reliability of the information. It is also unlikely that more strict criteria regarding SMBG practice would have changed the overall picture emerging from our data.

Third, we did not investigate whether the non–insulin-treated patients were instructed to use SMBG to vary their carbohydrate intakes, exercise levels, or oral agent doses or to detect hypoglycemia. Therefore, at least in theory, there could be some subgroups for which SMBG could be of benefit. Nevertheless, it should be underlined that, at least in Italy, SMBG is seldom recommended for these purposes, mainly because of the lack of any substantial evidence supporting the effectiveness of this practice for reasons other than insulin self-management.

Finally, both diabetes clinics and GPs were selected on the basis of their willingness to participate. Nonetheless, the great number of participants, reflecting different settings of care and practice styles, offer sufficient reassurance relative to the generalizability of our findings.

In conclusion, our results indicate that it seems prudent to recommend SMBG practice to those type 2 diabetic patients who are able to use the information for their day-by-day glycemic control to adjust insulin doses. We do not have evidence to support the extension in the use of this practice to the majority of type 2 diabetic patients. To further elucidate these aspects, future research should carefully investigate the joint role of SMBG and education on life-style changes.

Acknowledgments— This study was supported by Pfizer Italiana S.p.A. G.D.B. is supported by a Sergio Cofferati fellowship.

Parts of this study were presented in abstract form at the 61st annual meeting of the American Diabetes Association, Philadelphia, Pennsylvania, 22–26 June 2001.

APPENDIX

The QuED Study Group —Quality of care and outcomes in type 2 diabetes

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