Is Self-Monitoring of Blood Glucose Appropriate for All Type 2 Diabetic Patients?

The Fremantle Diabetes Study

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OBJECTIVE — We sought to determine whether self-monitoring of blood glucose (SMBG) is associated with better glycemic control in type 2 diabetes.

RESEARCH DESIGN AND METHODS — We used cross-sectional and longitudinal data from type 2 diabetic participants in the observational, community-based Fremantle Diabetes Study (FDS) who reported SMBG status at study entry (n = 1,286) and annual reviews over 5 years (n = 531).

RESULTS — At study entry, 70% of patients performed SMBG, with a median of four tests per week (interquartile range two to seven). Patients with shorter diabetes duration; who were attending diabetes education, diabetes-related clinics, or medical specialists; who were taking insulin with or without oral hypoglycemic agents (OHAs); and who were self-reporting hypoglycemic events were more likely to use SMBG. Both cross-sectional and longitudinal FDS data showed that HbA_{1c} (A1C) was not significantly different between SMBG users and nonusers, either overall or within diabetes treatment groups (diet, OHAs, and insulin with or without OHAs). There was also no independent cross-sectional relationship between A1C and SMBG frequency. The average annual societal cost of using SMBG (in year 2000 Australian dollars [A$], excluding glucometers) was A$162 per type 2 diabetic patient or A$51 million when projected to the Australian diagnosed type 2 diabetic population.

CONCLUSIONS — Neither SMBG testing nor its frequency was associated with glycemic benefit in type 2 diabetic patients regardless of treatment. Our data did not include methods of SMBG delivery and application, factors that require further assessment in the evaluation of SMBG utility in non–insulin-treated type 2 diabetes. SMBG may be still of value in the identification and prevention of hypoglycemia and in dose adjustment in insulin-treated patients.

Diabetes Care 29:1764–1770, 2006

There is strong evidence that intensive glycemic control cost-effectively reduces chronic, particularly microvascular, complications of type 2 diabetes (1,2). However, the role of self-monitoring of blood glucose (SMBG) in type 2 diabetes management is less clear (3–5). As well as increasing the burden of self-care, SMBG contributes significantly to diabetes-attributable (6) and total (7) direct health care costs. There is a need for well-designed studies addressing the benefits and cost effectiveness of SMBG in community-based type 2 diabetes. This includes insulin-treated patients for whom SMBG is recommended without substantive supportive evidence (8–10).

Five randomized controlled trials have validly addressed the question of whether SMBG reduces A1C (11–15). Only one had sufficient statistical power to detect a 0.5% A1C difference between intervention and control groups (14), but SMBG was associated with a modest 0.3% A1C reduction in the OHA-treated, poorly controlled patients. Other non–randomized controlled trial studies have had problems involving design, subject selection, definition of outcomes, and/or use of additional interventions, which question the validity and/or limit the generalizability of the data (16–26).

The Fremantle Diabetes Study (FDS) was a longitudinal observational study carried out in representative community-based patients. Information relating to SMBG was collected as a part of comprehensive annual assessments. We have analyzed these data to assess the relationship between SMBG, diabetes treatment, and glycemia in type 2 diabetes. Although not randomized controlled trial derived, such observational data can be useful in determining the effect of an intervention (27).

RESEARCH DESIGN AND METHODS

— Descriptions of FDS recruitment and sample characteristics have been published elsewhere (28,29). Of 2,258 patients identified between 1993 and 1996, 1,426 (63%) were recruited and 1,294 (91%) had type 2 diabetes. Nonparticipants were an average of 1.4 years older than participants, but the proportions with type 2 diabetes and the distributions of treatment modalities were similar (28,29). The present FDS substudy was comprised of *1*) a cross-sectional study of 1,286 type 2 diabetic patients reporting SMBG status at entry (99.4% of all type 2 diabetic patients) and *2*) a longitudinal study of a subgroup of 531 who attended six annual assessments (baseline plus five reviews). In the cross-sectional arm, we ascertained *1*) the proportion performing SMBG, *2*) SMBG

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Received for publication 1 February 2006 and accepted in revised form 5 May 2006.
Abbreviations: DQOL, diabetes qualilty of life; FDS, Fremantle Diabetes Study; FPG, fasting plasma glucose; OHA, oral hypoglycemic agent; SMBG, self-monitoring of blood glucose.
A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.
DOI: 10.2337/dc06-0268

Table 1—*Univariate associates of SMBG at study entry*

	No SMBG	Any SMBG	*P* value
n	386	900	
Age (years)	66.1 ± 12.3	63.2 ± 10.7	<0.001
Sex (male)	47.4	49.3	0.54
Diabetes duration (years)	4.0 (1.4–10.0)	3.9 (0.9–8.9)	0.08
BMI (kg/m^2)	29.7 ± 6.1	29.5 ± 5.2	0.65
A1C (%)	7.6 (6.4–8.9)	7.3 (6.4–8.8)	0.12
FPG (mmol/l)	8.4 (6.9–11.3)	8.5 (6.8–10.7)	0.35
Diabetes control			
Diet and exercise	35.9	30.4	0.06
OHA	56.8	55.7	0.76
Insulin (±OHA)	7.3	13.9	0.001
Self-reported hypoglycemia	21.3	33.5	<0.001
Ever attended diabetes education	40.7	79.3	<0.001
Coronary heart disease	34.0	30.6	0.24
Cerebrovascular disease	10.6	9.4	0.54
Urinary ACR			
Normal	54.6	60.0	0.08
Microalbuminuria	33.2	32.1	0.74
Macroalbuminuria	12.2	7.8	0.017
Retinopathy	16.8	16.2	0.80
Neuropathy	32.3	30.1	0.46
Educated > primary level	72.4	74.9	0.36
Not fluent in English	16.8	14.6	0.31
Married/de facto relationship	57.9	69.1	<0.001
Indigenous Australian	2.3	1.0	0.07
General practitioner			
Attended in previous year	81.9	83.0	0.63
Diabetes clinic/medical specialist			
Attended in previous year	23.6	38.3	<0.001
Any exercise in past 2 weeks	67.1	74.1	0.012
Smoking status			
Never	45.4	44.4	0.76
Ex	40.5	40.0	0.90
Current	14.1	15.5	0.55
Daily alcohol consumption (standard drinks/day)	0 (0.0–0.8)	0 (0.0–0.3)	0.027
Rosser Index	0.986 (0.967–1.000)	0.986 (0.956–0.995)	0.040
DQOL			
Satisfaction	1.5 (1.2–2.0)	1.6 (1.2–2.1)	0.37
Worry	1.5 (1.2–2.0)	1.5 (1.2–2.0)	0.56
Frequency	1.8 (1.5–2.2)	1.8 (1.5–2.2)	0.68
Total	1.7 (1.4–2.1)	1.7 (1.4–2.1)	0.88

Data are percent, means ± SD, or median (interquartile range). ACR, albumin-to-creatinine ratio.

frequency, *3*) associates of SMBG use and frequency and A1C, and *4*) SMBG cost. In the longitudinal arm, we determined *1* and *2* above and *3*) glycemic control and *4*) hypoglycemic episodes, by SMBG status.

At each FDS assessment, we recorded detailed diabetes-related data (including self-reported SMBG and hypoglycemia), comorbidities, medications, smoking status, alcohol use, socioeconomic and educational status, ethnicity, English fluency, and exercise history (28,30,31). Patients were classified as adherent SMBG users if they were *1*) treated with OHAs and/or insulin and performed SMBG one or more time per day or *2*) managed by diet and undertook any SMBG (32). Two health status questionnaires were administered (31), *1*) a modified diabetes quality-of-life (DQOL) scale (33), assessing satisfaction, worry, and impact and *2*) a general health status instrument that generates the Rosser Index (34) and covers mobility, self-care, activity, social/personal relationships, feelings, and general health in two dimensions (namely disability and distress). The Rosser Index scores inversely to the DQOL.

All subjects had a physical examination and standard fasting biochemical tests, including plasma glucose, A1C, and urinary albumin-to-creatinine ratio (28,29). Micro- and macroalbuminuria were defined as an albumin-to-creatinine ratio ≥3.0 and ≥30.0 mg/mmol, respectively, in a first-morning urine sample (35). Neuropathy was defined as a score of >2/8 on the Michigan Neuropathy Screening Instrument clinical portion (36). Retinopathy was taken as any grade in one or both eyes on direct and/or indirect ophthalmoscopy and/or detailed specialist assessment. Self-report and hospitalizations were used to identify cerebrovascular disease (stroke and transient ischemic attack) (37) and coronary heart disease (myocardial infarction, angina, and coronary revascularization) (38).

The total direct cost of SMBG (to government, health fund, and patient [i.e., societal cost]) was calculated in year 2000 Australian dollars (A$1.00 = U.S.$0.70). Sources of unit costs were the Australian National Diabetes Supply Scheme (test strips A$54.11 per 100) and nonmember prices of Diabetes Australia Western Australia (A$0.10 per lancet with an assumed usage of one time per week, A$100 for glucometers with lifespan 5 years). Equitable access to SMBG is assured by Australian government subsidies.

Statistical analysis

The computer package SPSS for Windows (version 11.5) was used. Data are presented as proportions, means ± SD, geometric mean (SD range), or, for variables not conforming to a normal or log-normal distribution, median (interquartile range). Two-sample comparisons were by Fisher's exact test for proportions and by Student's *t* test and Mann-Whitney *U* test for normally and non–normally distributed variables, respectively. Multiple related proportions were compared using Cochran's Q-test. The Kruskal-Wallis was used for multiple non–normally distributed independent samples. A *P* value of 0.05 was used. Multiple logistic and linear regression analyses (forward conditional modeling; $P < 0.05$ for entry, $P > 0.10$ for removal) were performed to assess associations between multiple variables, with all univariate variables other than DQOL and health status considered for model entry.

Table 2—*Independent associates of SMBG and √(SMBG frequency) at study entry*

Any SMBG use	Odds ratio (95% CI)	*P* value
Ever attended diabetes education	5.40 (4.11–7.09)	<0.001
Diabetes duration (increase of 5 years)	0.83 (0.74–0.92)	<0.001
Married/de facto relationship	1.86 (1.41–2.46)	<0.001
Self-reported hypoglycemia	1.72 (1.25–2.37)	0.001
Attended diabetes clinic/medical specialist in previous year	1.72 (1.26–2.34)	0.001
Insulin (±OHA) use	2.16 (1.24–3.76)	0.006
√(SMBG frequency)	**Regression coefficient, β**	***P* value**
Insulin (±OHA)	1.21	<0.001
Ever attended diabetes education	0.62	<0.001
Diabetes duration (increase of 5 years)	−0.14	<0.001
Self-reported hypoglycemia	0.35	<0.001
Attended diabetes clinic/medical specialist in previous year	0.28	<0.001
√(Daily alcohol consumption) (increase of 1 standard drink)	−0.17	0.001
Married/de facto relationship	0.17	0.020
Any exercise in past 2 weeks	0.16	0.035

RESULTS

Cross-sectional study

The present 1,286 patients were aged 64.1 ± 11.3 years at baseline, and 48.8% were male. Their mean BMI was 29.6 ± 5.5 kg/m^2, median diabetes duration 4.0 years (interquartile range 1.0–9.0), and median A1C 7.4% (6.4–8.8). Thirty-two percent were diet treated, 56% were taking OHAs, and 12% were on insulin with or without OHAs.

Prevalence and predictors of SMBG. Most patients (70.0%) reported performing SMBG, with a median of four tests per week (interquartile range two to seven). The 30% who did not monitor at baseline were asked to provide reasons. Although formal analysis of such qualitative data was not possible, responses included *1*) no education on how to do SMBG (45%), *2*) no motivation to start or to continue SMBG (31%), *3*) fear of finger pricks (9%), and *4*) physical or mental disability preventing its use (5%). Over half (64%) of the 82% of insulin-treated patients performing SMBG were adherent compared with 25% of the 69% of OHA-treated patients who monitored and, reflecting much less stringent criteria for adherence, all of the 66% of diet-treated patients performing SMBG. There were no differences in fasting plasma glucose (FPG) or A1C between adherent and nonadherent users by treatment group ($P \geq 0.09$).

Tables 1 and 2 show the univariate and independent multivariate associates of patients who used (adherent or not) compared with those who did not use SMBG. Patients with longer diabetes duration were less likely to self-monitor. Patients attending diabetes education, diabetes-related outpatient clinics, or medical specialists; taking insulin with or without OHAs; and those self-reporting hypoglycemic events were more likely to use SMBG, as were patients in a stable relationship. General health status was worse in those self-monitoring, although DQOL measures were not associated with SMBG.

We divided patients into four groups based on frequency of testing and previously published criteria (39), specifically *1*) never (group 1, 30.4%), *2*) less than one time per week (group 2, 5.4%), *3*) one or more time per week and less than one time per day (group 3, 43.8%), and *4*) one or more time per day (group 4, 20.3%). Univariate analyses of SMBG frequency showed that in comparison with group 1, subjects in group 3 were younger (63.9 ± 10.8 vs. 66.1 ± 12.3 years; $P = 0.004$), had shorter diabetes duration (median 3.0 [interquartile range 0.8–7.0] vs. 4.0 years [1.4–10.0]; $P = 0.004$), and had worse general health status (0.986 [0.956–0.995] vs. 0.986 [0.967–1.000]; $P = 0.045$); however, these patients also had a lower median A1C (7.2 [6.3–8.6] vs. 7.6% [6.4–8.9]; $P = 0.012$) and consumed less alcohol (0.0 [0.0–0.3] vs. 0.0 [0.0–0.8]; $P = 0.007$), and higher proportions exercised (75.0 vs. 67.1%; $P = 0.010$), attended diabetes education (82.2 vs. 40.7%; $P < 0.001$), and a diabetes-related clinic/medical specialist (34.5 vs. 23.6%; $P < 0.001$). Only group 4 patients had more intense treatment regimens than group 1 subjects (31.0% insulin treated vs. 7.3%; $P < 0.001$); they were also more likely to have attended diabetes education (75.6%; $P < 0.001$) and diabetes-related outpatient clinics/medical specialists (50.4%; $P < 0.001$) and were younger (62.4 ± 10.0 years; $P < 0.001$). The greatest proportions of patients reporting hypoglycemic events were in groups 3 and 4 (28.2 and 45.3%, respectively, vs. 21.3% in group 1; $P = 0.021$ and <0.001, respectively). SMBG testing frequency was not associated with FPG (trend $P = 0.19$). There were no significant associations between FPG or A1C and SMBG frequency within diabetes treatment groups ($P \geq 0.08$).

Since SMBG frequency and alcohol consumption were highly right skewed, these variables were square-root transformed (√) before analysis. √(SMBG frequency) was negatively associated with diabetes duration and √(alcohol consumption). Patients with the highest SMBG frequency were on insulin, had attended diabetes education and diabetes-related outpatient clinics/medical specialists, self-reported hypoglycemia, exercised, and were in a stable relationship (Table 2). There were no significant interactions between A1C and diabetes treatment.

We used multiple linear regression stepwise (forward conditional) modeling to determine independent baseline associates of A1C, including SMBG and its frequency. Younger age, longer diabetes duration, insulin or OHA therapy versus diet alone, no diabetes education, indigenous ethnicity, and lower √(alcohol consumption) were independently associated with higher A1C ($P < 0.05$; adjusted $R^2 = 12.1\%$). √(SMBG frequency) was not a significant independent associate in the model ($P = 0.71$) and neither were the interactions between √(SMBG frequency) and OHA or insulin treatment ($P \geq 0.06$).

Costs of SMBG. For participants performing SMBG at study entry, the average annual cost per patient (strips and lancets) was A$162. A glucometer would add A$20 per patient per year. SMBG costs for diet- and OHA-treated patients were similar (A$135 and A$143 per patient, respectively, $P = 0.83$) but lower than the A$298 for insulin-treated patients ($P <$

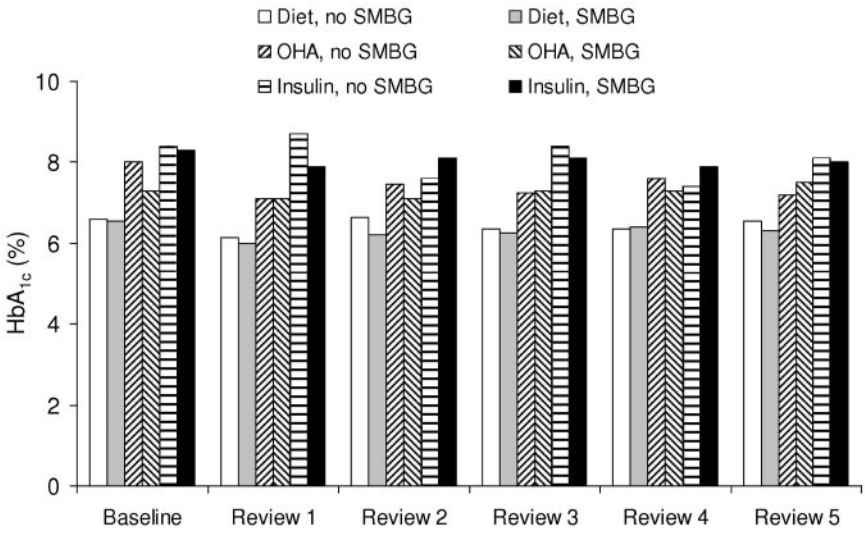

Figure 1—*A1C by diabetes treatment type, year of follow-up, and SMBG status for the 531 FDS participants with type 2 diabetes who attended at least six annual assessments.*

0.001). The proportion of total diabetes-attributable direct health care costs due to SMBG (excluding glucometers) averaged 8.7% for all type 2 diabetic participants. If these figures were applied to the 448,000 Australians with diagnosed type 2 diabetes in 2000 (40), assuming that 70% used SMBG, the projected annual cost of SMBG would be A$51 million with an additional A$6 million for glucometers.

Longitudinal cohort

Compared with the 763 other patients with type 2 diabetes at baseline, the 531 who attended five or more reviews before study end (1 November 2001) were significantly younger, were more likely to be male, had shorter diabetes duration, had better glycemic control, had fewer diabetes complications, and were less likely to have died during follow-up ($P \leq 0.001$). Follow-up time for the longitudinal cohort was 5.4 ± 0.5 years.

The proportion of the longitudinal cohort using SMBG increased over time (trend $P < 0.001$), from 75.2% at entry to 85.5% at third review ($P < 0.001$), before leveling off to 82.3% at fifth review ($P = 0.001$ vs. baseline). The percentage of diet-treated patients decreased from 34.8% at baseline to 19.4% at fifth review (trend $P < 0.001$), OHA users increased from 57.5 to 64.9% (trend $P = 0.001$), and those using insulin with or without OHAs doubled from 7.8 to 15.7% (trend $P < 0.001$). Throughout follow-up, neither A1C nor FPG differed either overall or within treatment groups in patients who self-monitored compared with those who did not ($P \geq 0.05$; Fig. 1). The frequency of SMBG testing in those who monitored remained stable over time by treatment group, with diet-treated patients averaging 3.6 tests per week, OHA-treated patients averaging 4.7 tests per week, and insulin users averaging 10.4 tests per week. There were no significant differences in the proportion of patients self-reporting one or more hypoglycemic event(s) in the previous year by SMBG group in any diabetic treatment group at any time point ($P \geq 0.05$).

CONCLUSIONS — In the justifiable quest for optimal glycemic control in type 2 diabetes, SMBG has been promoted as a beneficial adjunctive management strategy. The impetus for the present study was the relative paucity of data supporting SMBG as part of usual care in community-based type 2 diabetic patients. Both cross-sectional and longitudinal FDS data showed that A1C was not significantly different between SMBG users and nonusers. There was also, after adjustment for other significant associates, no cross-sectional relationship between the frequency of SMBG and A1C among type 2 diabetic patients regardless of treatment type.

In OHA-treated patients, our finding that there was no significant glycemic benefit associated with a median SMBG frequency of four times per week is consistent with published data involving relatively low frequency SMBG interventions. For example, in one managed care study (41), patients were instructed to perform SMBG twice per week over 6 months. This reduced test strip use from 9.5 to 4.7 per week without significant change in glycemic control. In a second study (42), the intervention was provision of free blood glucose meters, which increased average SMBG in sulfonylurea-treated patients from 0.5 to 2.0 tests per week without a significant A1C reduction in all but the worst-controlled patients. By contrast, in the only valid randomized controlled trial with sufficient power to detect a significant SMBG effect in OHA-treated patients (14), the required testing frequency was six times per week, which was associated with a reduction in A1C of 0.28%. In an underpowered study (13), an even greater frequency (six times per day for 4 weeks, two times per day for 16 weeks, and then as determined by the patient for 24 weeks) was associated with a nonsignificant 0.69% A1C reduction. However, it is likely that even if beneficial, sustained frequent SMBG would be difficult to achieve in real life in this treatment group. Only 20.9, 8.1, and 0.1% of our OHA-treated patients reported monitoring six times per week, two times per day, and six times per day, respectively, at baseline.

Although one managed care study found that A1C was 0.4% lower in diet-treated patients using SMBG at any frequency compared with no testing (32), the present data and the results of two other studies, one population based (39) and the other a before-and-after intervention trial (41), showed no glycemic benefit associated with SMBG in this treatment group. This was also the case for our insulin-treated patients, despite an average testing frequency of 10 times per week at baseline. Two population-based studies, in which 31% (39) and 17% (43) of insulin-treated patients tested one or more time per day, also showed no glycemic benefit. Data from two studies support SMBG use in insulin-treated type 2 diabetes. However, glycemic benefit was restricted to patients who were able to adjust insulin doses in the first study (44) and applied to adherent SMBG users testing seven or more times per week in the second study (32). An early randomized controlled trial included insulin-treated patients (11), but they were not differentiated from those taking only OHAs.

The benefits of SMBG may be greatest in patients with poor glycemic control across treatment modalities. In a study of sulfonylurea-treated patients in which SMBG frequency increased from 0.5 to 2.0 tests per week (42), a significant 0.6% decrease in A1C was observed in those

with a baseline value >10.0%. In another study of insulin-treated type 2 diabetic veterans, intensified SMBG benefited only those who were compliant or had a baseline A1C >8.0% (45). It was not possible to assess the relationship between A1C and the effect of SBMG in the same way in the present longitudinal cohort since the relatively long follow-up provided the opportunity for community-based therapeutic change that was not based on predetermined glycemic thresholds. This would have obfuscated the effects of SMBG per se.

The present data provide evidence of factors associated with SMBG. The cross-sectional association between SMBG and shorter diabetes duration is consistent with published data (43) and suggests that recent diagnosis and provision of diabetes education were motivational. Indeed, we found that patients who had attended diabetes education were five times more likely to self-monitor. In contrast to an Italian study (44), we found no difference in SMBG use by sex or education level, but our patients who were in a stable relationship were more likely to self-monitor. Other associates were insulin treatment, self-reported hypoglycemia, and diabetes outpatient clinic/medical specialist attendance, which are all factors that could increase the use of SMBG to identify or anticipate hypoglycemia.

The longitudinal data were complex because of substantial therapeutic progression (46). Those patients changing treatment adopted the pattern of SMBG use of their new group. This resulted in an increase in SMBG and its frequency with time, but there was no difference in A1C by SMBG status, either overall or when stratified by treatment, at any FDS annual assessment. This finding was consistent with a study of 1,896 non–insulin-treated type 2 diabetic patients followed for 3 years at 6-month intervals for SMBG practice in which performance and frequency of SMBG did not predict better metabolic control either overall or in any subgroup (47). We did not examine the multivariate relationship between testing frequency and A1C in the longitudinal arm because of the temporal changes in treatment and relatively low patient numbers.

One economic implication of our results is that the money and time currently spent on SMBG in non–insulin-treated patients might be better utilized on alternative, proven interventions to improve glycemic control until more effective SMBG strategies are devised and implemented. However, adequately powered, inclusive, and long-term trials examining the steps between SMBG and changes in management are needed before this view can be supported. One such a trial may be the DiGEM (Diabetes Glycemic Education and Monitoring) study, the findings from which are due to be reported in 2007. DiGEM should establish whether SMBG is effective over a 12-month period when results are *1*) interpreted by the patient and applied to lifestyle (self-monitoring group), in addition to *2*) nurse-practitioner interpretation to inform medication adjustment (self-testing group), compared with, and in addition to, *3*) standardized usual care and 3-monthly A1C measurements (control group) (48). Non–insulin-treated type 2 diabetic patients aged ≥25 years are eligible. Although the associated health economic analyses will investigate the cost-effectiveness of two levels of patient education and training in the use of SMBG compared with standard delivery of usual care, this will not address the basic question as to whether funds consumed by SMBG could be spent more effectively in other ways to improve glycemic control.

The present study has limitations. Because the design was observational, the patients who used SMBG might have had worse glycemic control if they had not monitored. SMBG and hypoglycemia were self-reported. Although our data show no glycemic benefit for SMBG in insulin-treated subjects, this may reflect lack of statistical power since only 12% of our baseline cohort were using insulin and very few insulin-treated patients in the longitudinal arm did not perform SMBG (two at baseline and seven at 5th review). In the longitudinal arm, the patients were younger and healthier than the baseline FDS sample. The study was not designed to assess the complex steps between SMBG and its effect on glycemic control, including the interpretation of the result and its consequent application to changes in management. The strengths of the present study are its large, representative, community-based cohort with detailed cross-sectional and longitudinal data. The observational, rather than interventional, design allows inclusion of a broader, more representative sample of patients in a usual care setting. In addition, there is little evidence that estimates of intervention effects in observational studies are consistently larger than, or qualitatively different from, those obtained in randomized controlled trials (27).

In conclusion, our data do not support a role for SMBG in type 2 diabetic patients in improving glycemic control, irrespective of treatment. Current American Diabetes Association recommendations are that SMBG should be performed three or more times per day for type 2 diabetic patients using multiple insulin injections but that for patients using once-daily insulin, OHAs, or diet alone, there is low-level evidence of benefit (10). Our data add to the evidence relating to diet- and OHA-treated patients, but we did not subdivide our insulin-treated patients by injection frequency because of relatively low numbers. As stated in the American Diabetes Association recommendations (10) and supported by variables independently associated with SMBG in the present study, SMBG can be valuable in the identification and prevention of hypoglycemia and in dose adjustment, which are particular characteristics of multidose insulin regimens.

Acknowledgments— We thank the Raine Foundation, University of Western Australia, for funding.

We also thank the FDS and Fremantle Hospital staff and the FDS patients for their participation and Andrew St. John for encouragement.

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