Abstract

Background: Recent studies suggest that patients at greatest risk for diabetes complications are least likely to self-monitor blood glucose. However, these studies rely on self-reports of monitoring, an unreliable measure of actual behavior. The purpose of the current study was to examine the relationship between patient characteristics and self-monitoring in a large health maintenance organization (HMO) using test strips as objective measures of self-monitoring practice.

Methods: This cross-sectional study included 4,565 continuously enrolled adult managed care patients in eastern Massachusetts with diabetes. Any self-monitoring was defined as filling at least one prescription for self-monitoring test strips during the study period (10/1/92–9/30/93). Regular SMBG among test strip users was defined as testing an average of once per day for those using insulin and every other day for those using oral sulfonylureas only. Measures of health status, demographic data, and neighborhood socioeconomic status were obtained from automated medical records and 1990 census tract data.

Results: In multivariate analyses, lower neighborhood socioeconomic status, older age, fewer HbA1c tests, and fewer physician visits were associated with lower rates of self-monitoring. Obesity and fewer comorbidities were also associated with lower rates of self-monitoring among insulin-managed patients, while black race and high glycemic level (HbA1c>10) were associated with less frequent monitoring. For patients taking oral sulfonylureas, higher dose of diabetes medications was associated with initiation of self-monitoring and HbA1c lab testing was associated with more frequent testing.

Conclusions: Managed care organizations may face the greatest challenges in changing the self-monitoring behavior of patients at greatest risk for poor health outcomes (i.e., the elderly, minorities, and people living in low socioeconomic status neighborhoods).
component of diabetes management. While the efficacy of self-monitoring independent of other self-management practices is still uncertain, the practice is recommended for patients using either insulin or oral drug therapy.[2] As a result, managed care organizations (MCOs) are under increasing pressure to cover the cost of self-monitoring equipment[3] and to improve rates of SMBG among their diabetes patients.[4]

In addition to logistic barriers to SMBG[5], some recent evidence suggests that adult diabetes patients who may be at greatest risk for poor outcomes (e.g., minorities, elderly, lower SES) may be least likely to self-monitor.[4,6] In a study of more than 44,000 managed care patients with type 1 (2,818) and type 2 (41,363) diabetes, Karter et al.[4] identified older age, male gender, non-white race, lower socioeconomic status, English language difficulty, higher out of pocket test strip costs, intensity of insulin therapy, greater alcohol consumption, and smoking as independent predictors of less frequent self-monitoring in diabetes patients. This study was the first to move beyond simple reporting of descriptive statistics in order to assess predictors of SMBG in managed care settings. Unfortunately, the validity of the study findings is limited by the reliance on self-reports of self-monitoring, an unreliable measure of actual behavior.[7]

The purpose of the current study was to examine the relationship between patient characteristics and SMBG in a large health maintenance organization (HMO) using objective measures of self-monitoring practice. Specifically, we tested the hypothesis that, controlling for type of drug therapy and severity of illness, diabetes patients at greatest risk for poor health outcomes (e.g., older age, multiple chronic conditions, non-white race, lower neighborhood SES) are less likely to practice SMBG. The study population included more than 4,500 adult managed care patients using insulin, oral, or a combination of the two drug therapies. Our use of objective measures of SMBG distinguishes this study from previous attempts to identify predictors of SMBG in managed care. This paper represents the first phase of a larger study to evaluate the effect of distributing free home glucose monitors to diabetes patients at this New England HMO.

Methods

Study Setting and Data Sources

Harvard Vanguard Medical Associates (HVMA) is a multispecialty group practice serving nearly 300,000 people in diverse ethnic and socioeconomic communities in and around Boston, Massachusetts. At the time of the study, nearly all of the patients at HVMA’s fourteen health centers were insured in Harvard Pilgrim Health Care (HPHC), one of the largest HMOs in New England. Home glucose monitoring test strips were covered by HPHC and all members had coverage for prescription medications. The automated medical records system (AMRS) at HVMA/HPHC captured data from all ambulatory and inpatient encounters between plan members and providers in a combination of both coded and narrative fields. The AMRS has been previously used for research purposes.[8,9] In addition to AMRS data, we mapped patients’ addresses to census tract information to control for the socioeconomic characteristics of the patient’s neighborhood of residence.

Study Cohort

In order to be eligible for inclusion in the study, patients had to be at least 18 years old and to have been diagnosed with diabetes or to have received at least one prescription for insulin or an oral sulfonylurea at some time between December 1, 1991 and November 30, 1993. This study represents the first phase in an evaluation of the implementation of a policy to provide free home glucose monitors to HPHC patients. All data for this study were collected from medical records covering the year preceding the policy change (10/1/92–9/30/93). For continuity of the study cohort, we included only those patients with no more than 45 days disenrollment between 01/01/92 and 09/30/95. Patients with gestational diabetes were excluded.

Dependent Variables

Our outcomes of interest were the likelihood of any SMBG and regularity of SMBG once initiated. Patients were classified as having ever self-monitored if they filled at least one prescription for self-monitoring test strips during the study period. Test strip use has been employed in previous studies as a reliable indicator of actual SMBG in diabetes patients.[10–12] As only a very small number of patients were using urine test strips to monitor glycemic levels (1.5%), we did not include urine testing as a measure of self-monitoring. Regular SMBG among patients with any test strip use was defined as filling prescriptions for 90 or more test strips per quarter (i.e., testing an average of at least once per day) for those using insulin or combination therapy, and 45 or more per quarter (i.e., testing an average of at least once every other day) for those using oral sulfonylureas only. Cut points for regular use were based on dispensing patterns and recent guidelines recommending testing three to four times per day for insulin users and less frequent testing for non-insulin users.[2] We assumed that test strips were used evenly over the period between test strip dispensings. Test strips were prorated over a minimum of 30 days if the next dispensing occurred sooner than that, and over a maximum of 60 days if there was no subsequent dispensing during that period. Multivariate analyses were limited to patients using drug therapy and stratified by
Independent Variables

We identified variables in the AMRS that represented factors that may influence preventive health behavior[13] as well as those identified in the literature as being predictive of SMBG.[4,6] Available demographic information included gender, age, race, and Medicare or Medicaid insurance status as recorded by the provider or health plan. Given the small numbers of other minority groups at HV-MA, we combined all racial groups other than white or black into a single category labeled other. We then created two dichotomous variables, black and other, with white race as the reference group.

Census tract level data were used to represent the socioeconomic status of the patient and their neighborhood of residence. We created an index composed of the sum of four weighted census tract measures (i.e., percent with a college education, median household income, percent of households in which English was the primary language, and percent home ownership). The variables included in the index were standardized for summation by centering them around a mean of zero. Their relative weightings in the index were determined using factor analysis. Among several measures created from census tract variables to measure neighborhood SES, the index created using the factor analysis approach proved to be the strongest predictor of SMBG in univariate analyses.

Clinical assessments of health status as measures of susceptibility or potential for the threat of poor health outcomes included two dichotomous measures of body mass index[14] (i.e., overweight: 25 kg/m² < BMI < 30 kg/m²; obese: BMI ≥ 30 kg/m²) and an age- and gender-weighted chronic disease score (CDS)[15] based on the presence or absence of 29 specific comorbidities determined from pharmacy dispensing data. In several HMO settings, the CDS has performed as well or better than Ambulatory Disease Groups as a measure of illness severity, explaining 50–60% of variation in health care utilization, costs, and mortality.[16] We included deciles of the CDS in multivariate regression analyses. We categorized the last recorded HbA1c test value for each individual into two dichotomous measures representing poor and very poor glycemic control (i.e., poor: HbA1c > 8.0%; very poor: HbA1c > 10%), with HbA1c ≤ 8.0 as the reference group.

Average standard monthly dose of oral diabetes medication used was also included as an indicator of severity of illness. These standardized measures were constructed by first calculating median monthly dose of each drug type received in the entire study cohort during the study period. The actual dose received in a month divided by this median dose yielded a standardized monthly amount for each patient. We then calculated the median of these patient-level standardized measures for the year and included it as a covariate in the multivariate analyses.

Dichotomous variables representing the number of HbA1c lab tests ( = 1 if # tests ≥ 2) and the number of physician visits ( = 1 if # visits ≥ 4) were included as measures of predisposition to use health services. The HVMA primary care site, defined as the health center where at least 75% of outpatient visits occurred (defined for 78% of patients), was included as a fixed effect to control for variations in practice patterns. As the vast majority of patients (>96%) paid a $5 copayment for test strips during the study period, cost to the patient was not included as a covariate of interest.

Statistical Analysis

Statistical analyses were carried out using SAS V8.04.[17] All analyses were stratified by type of drug therapy (none, insulin alone or in combination with oral sulfonylureas, and oral sulfonylureas only) in accordance with the literature which suggests greater rates of monitoring among those using insulin therapy.[18–20] We used chi-square tests to compare baseline differences in demographic status and health care utilization by type of drug therapy, and in glycemic control by level of SMBG (e.g., none, any, regular use). For patients using either form of drug therapy, we used logistic regression to estimate the factors associated with the likelihood of initiating SMBG and regularity of SMBG for those with some test strip use. We first examined the univariate relationships between each candidate predictor and our two SMBG outcomes. Age, gender, chronic disease score, the number of HbA1c tests, and primary care location were controlled for in all models. Other variables were included in the multivariate models if univariate p-values fell below 0.20. We used backward selection to remove variables not significant at the .05 level. Overall model fit, including the necessity for interaction terms, was ascertained using likelihood ratio statistics.[21] Tests of mixed (i.e., hierarchical or random effects) models,[22] where census tract was defined as a higher-level random effect, produced no evidence of clustering at the census tract level, indicating that the fixed effects approach was adequate.

Results

Characteristics of the Sample

The total study sample consisted of 4,565 patients, among whom 30% used no drug therapy, 31% used insulin therapy alone or in combination with oral agents, and 39% were taking only oral sulfonylureas. The study cohorts defined by type of therapy varied considerably with respect to several important demographic and clinical characteristics. Compared to those using drug therapy, the non-
drug therapy group was more likely to be female (55% vs. 47%; \( p < 0.001 \)), white (76% vs. 67%; \( p < 0.001 \)), and to have no comorbidities (33% vs. 2%; \( p < 0.001 \)). As shown in Table 1, insulin-managed patients were more likely to be female (51% vs. 44%, \( p < 0.001 \)), of younger average age (51 vs. 56; \( p < 0.001 \)), and Black (31% vs. 25%; \( p < 0.001 \)) compared to those using sulfonylureas. They were also less likely to be enrolled in Medicare (17% vs. 24%; \( p < 0.001 \)), which was consistent with the differences in age. While sulfonylurea-managed patients were more likely to be obese (55% vs. 46%; \( p < 0.001 \)), insulin patients had a higher number of comorbidities, on average, than either the sulfonylurea only or the no drug group (3.1 vs. 2.8 vs. 1.6; respectively; \( p < 0.001 \) in both group comparisons). There were no significant (\( p < 0.05 \)) differences in neighborhood SES by type of drug therapy.

As shown in Table 2, insulin-managed patients had more health center visits on average (14.2 ± 11.9) than those using either oral (10.7 ± 8.5) or no drug therapy (10.1 ± 8.8); this difference was statistically significant (\( p < 0.001 \)). Compared to sulfonylurea-managed patients, insulin-managed were more likely to have been hospitalized during the study period (20% vs. 13%; \( p < 0.001 \)) and to have had an emergency room visit (25% vs. 17%; \( p < 0.001 \)).

### SMBG, Lab Testing, and Glycemic Control
SMBG frequency was well below recommended guidelines for both insulin and sulfonylurea patients (Table 2). Insulin-managed patients were more likely to self-monitor compared to those using oral medications (66% vs. 24%; \( p < 0.001 \)). However, regular SMBG was far less prevalent among insulin-managed and sulfonylurea-managed patients (22% vs. 7% respectively, \( p < 0.001 \)). Only 7% of patients managed without drugs used any test strips during the year.
Approximately 77% of drug therapy patients had at least one HbA1c lab test per year. In contrast, fewer than half of patients managed without drugs were tested (48%, p < 0.001). Among patients with at least one lab test, insulin-managed patients had higher average HbA1c levels (8.9% ± 1.7%) compared to sulfonylurea-managed (8.3% ± 1.7%) and non-drug managed (7.1% ± 1.3%) patients (p < 0.001 for both comparisons). Over half (58%) of all patients on drug therapy who were tested had at least one HbA1c value greater than 8.0% during the study period and 17% of those not on drug therapy who were tested had similarly elevated glycemic levels (p < 0.01). There were no significant differences in glycemic level by level of SMBG for those without any drug therapy and for patients using sulfonylureas. However, for the insulin-managed group, patients who monitored regularly were much less likely to be in very poor control (14% with HbA1c > 10%) compared to patients with no test strip use (31%) or with irregular test strip use (32%) (p < 0.001 for both comparisons).

**Predictors of SMBG**

Results of the multivariate analyses examining the likelihood of any SMBG are presented in Table 3. For insulin-managed patients, higher SES of the census tract was significantly associated with greater odds of SMBG (Odds Ratio: 1.41; 95% Confidence Interval: 1.18–1.70) as hypothesized. Further, older age (OR: 0.80; CI: 0.70–0.91), male gender (OR: 0.69; CI: 0.52–0.90), and obesity (OR:0.64; CI:0.44–0.95) were significantly associated with lower odds of SMBG. However, higher level of comorbidity was associated with greater odds of SMBG, an effect that ran counter to our hypothesis (OR: 1.63; CI: 1.21–2.20). Two or more laboratory HbA1c tests (OR: 1.60; CI: 1.19–2.20) and four or more physician visits (OR: 2.06; CI: 1.40–3.01), and the standard monthly dose of diabetes medications (OR: 1.13; CI: 1.04–1.23) were associated with greater odds of SMBG in the oral managed group.

**Predictors of Regularity of SMBG**

As in the insulin-managed group, higher SES of the census tract was significantly associated with greater odds of any SMBG among patients using oral sulfonylureas (OR: 1.26; CI: 1.07–1.47). Older age (OR: 0.85; CI: 0.76–0.96) was associated with lower odds of SMBG. Two or more laboratory HbA1c tests (OR: 1.45; CI: 1.14–1.86), four or more physician visits (OR: 2.06; CI: 1.40–3.01), and the standard monthly dose of diabetes medications (OR: 1.13; CI: 1.04–1.23) were associated with greater odds of SMBG in the oral managed group.
group, lack of glycemic control (e.g., HbA1c > 10.0) was SMBG except for patients using insulin. Among this evidence to suggest that glycemic level was associated with being urged to monitor more frequently. There was no ev-

sional. This result may be consistent with sicker patients associated with less than half the odds of frequent SMBG.

in a recent study using data from the third National Health and Nutritional Examination Survey (1988–1994), Harris[18] found no association between glycemic levels and SMBG controlling for type of drug therapy.

There are several limitations to this study which merit dis-

The policy to cover the cost of home glucose monitors at this HMO was implemented in anticipation of the DCCT results. In further analyses of the policy, we found that the barriers to SMBG identified in this study did not change over time. Further, the rate of SMBG changed very little pre- and post-release of the DCCT findings and the policy change at HPHC. Lastly, similarities between our results and those from more recent studies of diabetes self-man-

Discussion

Our findings suggest that managed care patients who may benefit the most from intensive diabetes management may be least likely to self-monitor blood glucose. Among insulin users, older age and lower neighborhood SES were associated with lower odds of any SMBG. Further, black race and lack of glycemic control were significantly associated with less frequent SMBG, suggesting that these characteristics may represent significant barriers to adherence. For patients using oral medications, older age and lower neighborhood SES were also associated with lower odds of initiating SMBG.

Our findings for lower SES, older age, and black race were consistent with those of other studies.[4–6] In contrast to our hypothesis, having multiple comorbidities was associated with higher odds of any SMBG for the insulin group. However, this result may be consistent with sicker patients being urged to monitor more frequently. There was no evidence to suggest that glycemic level was associated with SMBG except for patients using insulin. Among this group, lack of glycemic control (e.g., HbA1c > 10.0) was associated with less than half the odds of frequent SMBG.

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Table 3: Predictors of Any and Regular Self-Monitoring of Blood Glucose (SMBG) by Drug Treatment Categories*

<table>
<thead>
<tr>
<th>Predictors</th>
<th>Any SMBG</th>
<th>Regular SMBG†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Insulin-Managed</td>
<td>Sulfonylurea-Managed</td>
</tr>
<tr>
<td>Age (in units of 10 yrs)</td>
<td>0.80 [0.70, 0.91]</td>
<td>0.88 [0.76, 0.96]</td>
</tr>
<tr>
<td>Male</td>
<td>0.69 [0.52, 0.90]</td>
<td>0.90 [0.71, 1.14]</td>
</tr>
<tr>
<td>Chronic Disease Score (Deciles)</td>
<td>1.63 [1.21, 2.20]</td>
<td>0.97 [0.91, 1.03]</td>
</tr>
<tr>
<td>Total # HbA1c Tests (≥ 2) (Y/N)</td>
<td>1.60 [1.19, 2.14]</td>
<td>1.45 [1.14, 1.86]</td>
</tr>
<tr>
<td>Socioeconomic Status (SES)‡</td>
<td>1.41 [1.18, 1.70]</td>
<td>1.26 [1.07, 1.47]</td>
</tr>
<tr>
<td>Total # Physician Visits (≥ 4) (Y/N)</td>
<td>1.80 [1.16, 2.81]</td>
<td>2.04 [1.40, 3.01]</td>
</tr>
<tr>
<td>Standard Monthly Dose</td>
<td>--</td>
<td>1.13 [1.04, 1.23]</td>
</tr>
<tr>
<td>Black Race (vs. White Race)</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Other Race (vs. White Race)</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Overweight§ (vs. BMI ≥ 24.9 kg/m²)</td>
<td>0.90 [0.61, 1.35]</td>
<td>--</td>
</tr>
<tr>
<td>Obese§ (vs. BMI ≥ 24.9 kg/m²)</td>
<td>0.64 [0.44, 0.95]</td>
<td>--</td>
</tr>
<tr>
<td>Poor Control§ (vs. HbA1c ≤ 3.0)</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Very Poor Control§ (vs. HbA1c ≤ 8.0)</td>
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</tr>
</tbody>
</table>

*For all multivariate logistic regression models, ORs (Odds Ratios) were adjusted for differences among primary health centers. Significant predictors are in bold. †Regular self-monitoring was defined as 90 or more test strips per quarter (i.e., testing an average of at least once per day) for those using insulin therapy, and 45 or more per quarter (i.e., testing an average of at least once every other day) for those using oral sulfonylureas only. §Socioeconomic Status is represented by an index based on education, income, language, home ownership in the census tract of residence. ‡Overweight = 30 kg/m² > BMI ≥ 24.9 kg/m²; Obese = BMI ≥ 30 kg/m²; Poor Control = 8.0 < HbA1c ≤ 10.0; Very Poor Control = HbA1c > 10.0.

(OR: 0.46; CI: 0.26–0.81) and very poor glycemic control (OR: 0.38; CI: 0.21–0.69). The only covariate identified as a significant predictor of regular SMBG in the sulfonylurea-managed group was having two or more HbA1c tests (OR: 1.89; CI: 1.18–3.04). The lack of significant predictors of regular SMBG for patients managed with sulfonylureas may be due to the small proportion (7%) of regular users in this group.
agement would lend additional support to our conclusions regarding SMBG.

Test strip dispensings are not a perfect measure of actual use, but are likely to be more objective than self-reports. Also, failure to control for individual SES may have caused us to overestimate the effect of neighborhood SES. [24–26] Still, other studies have found a significant effect of neighborhood SES on individual health and mortality even when individual-level SES was controlled for in the analyses. [27–32] Using an index similar to our own, Diez Roux et al.[32] recently found that living in a relatively disadvantaged neighborhood was associated with greater incidence of coronary heart disease among whites, even after adjusting for individual-level SES (Hazard Ratio: 1.6; 95% CI: 1.1–1.2).

Missing data may have introduced bias into our results. In particular, we only included patients who were continuously enrolled, thereby limiting the generalizability of our study to continuously enrolled managed care patients with diabetes. Further, approximately 22% of the study population did not receive an HbA1c test during the study period, and we anticipate that patients with lower average HbA1c levels were less likely to have had a lab test. Race data were unavailable for 31% of the study population. However, in a comparison of race data from the AMRS to member self-reports, it was found that blacks were only slightly more likely to be incorrectly categorized (2% of blacks vs. 0% of whites) or counted as missing (38% of blacks vs. 32% of whites) relative to whites (unpublished data, Choo P, Platt R).

Data on duration of diabetes and type of diabetes, which Karter et al.[4] identified as predictors of SMBG adherence, were not consistently available in the AMRS. Therefore, we controlled for severity of illness using type and intensity of drug therapy, the number of comorbidities, glycemic level, and health service use. Still, it is possible that the association of younger age with higher likelihood of SMBG may in part reflect differences in type or duration of diabetes among insulin users.

The greatest strength of our study is the use of more objective measures of SMBG. Data on test strips are less vulnerable to response biases that may hinder the detection of meaningful associations. While our data were gathered from one HMO, the large and diverse patient population at HPHC increases the generalizability of our results to other managed care settings.

Conclusions
While the efficacy of SMBG has yet to be demonstrated, MCOs are under increasing pressure to cover the cost of SMBG equipment for their patients and to improve rates of SMBG. Our findings provide troubling evidence that MCOs may face the greatest challenges in changing the self-monitoring behavior of the patients at greatest risk for poor health outcomes. Concern over health disparities has drawn increased attention toward community-based interventions for diabetes. Results of ongoing interventions may provide managed care organizations with useful strategies for reaching the groups most at risk for poor diabetes outcomes. In addition, well-controlled longitudinal studies of the relationship between the factors identified in this study and patterns of SMBG and self-management more generally can inform future interventions.

Competing Interests
None declared.

Authors’ Contributions
ASA participated in the design and analysis of the study and drafted the manuscript. CM and FZ participated in the design and coordination of the study and performed the statistical analysis. SBS conceived of the study and participated in its design. MB lent clinical expertise to the project. DRD conceived of the study and participated in its design.

All authors read and approved of the final manuscript.

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