

Effects of Health Maintenance Organization Coverage of Self-monitoring Devices on Diabetes Self-care and Glycemic Control

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Background: Increasingly, government mandates require insurance coverage of blood glucose monitors and test strips for patients with type 1 and type 2 diabetes. No data exist on the effects of such coverage on self-monitoring of blood glucose (SMBG), medication compliance, or blood glucose control. We evaluated whether a policy providing free blood glucose monitors increased SMBG and whether initiating SMBG was associated with increased regularity of medication use and improved glucose control (hemoglobin A_{1c} [HbA_{1c}] level).

Methods: Using interrupted time-series analysis and controlling for preintervention trends, we determined changes in rates of SMBG 2 years before and after the policy among 3219 continuously enrolled patients with diabetes receiving drug therapy within a multispecialty medical group (part of a health maintenance organization) serving approximately 300 000 patients. We also compared changes over time in regularity of medication use (mean days between dispensings) and mean HbA_{1c} level among initiators and noninitiators of SMBG.

Results: The policy resulted in a small, significant increase in SMBG among insulin-treated patients (n=1428). Among sulfonylurea-treated patients (n=1791), the monthly initiation rate of SMBG increased by 14 new pa-

tients per 1000 (95% confidence interval [CI], 10 to 17), a doubling of the expected initiation rate. Test strip consumption increased during the first 6 months after the policy by 17.9 strips per cohort member (75% relative increase by 6 months; 95% CI, 50% to 101%). Compared with noninitiators of SMBG, initiators (n=593) showed sudden, significant improvements in regularity of medication use by 6 months after initiation (-19.5 days between dispensings among those with low refill regularity [95% CI, -27.7 to -11.3]; -9.7 days among those with moderate regularity [95% CI, -12.3 to -7.1]), and in glucose control (-0.63% mean HbA_{1c} level [as percentage of total hemoglobin] among those with poor baseline glycemic control [HbA_{1c} >10%; 95% CI, -1.14% to -0.12%]).

Conclusions: Providing free glucose monitors improved rates of self-monitoring in this health maintenance organization population, possibly by offering an initial incentive for patients to engage in more desirable patterns of care. Initiating SMBG was associated with increased regularity of medication use and a reduction in high blood glucose levels.

Arch Intern Med. 2004;164:645-652

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INCREASINGLY, PUBLIC AND PRIVATE insurers, including managed care organizations (MCOs), face challenging decisions regarding coverage of self-monitoring devices for managing major chronic illnesses, such as diabetes. Guided by clinical experience but little experimental data, self-monitoring of blood glucose (SMBG) has become a key feature of secondary prevention and treatment of diabetes.¹ The goal of such monitoring is to guide daily therapeutic management to achieve "tight" glycemic control and thereby reduce major complications of diabetes, including retinopathy, neuropathy, and cardiovascular and end-stage renal disease.

The Diabetes Control and Complications Trial (DCCT) confirmed that an intensive control program of 3 or more daily insulin injections guided by frequent blood glucose monitoring was effective in achieving large reductions (40%-76%) in the occurrence or progression of retinopathy, neuropathy, and kidney diseases among patients with type 1 diabetes (insulin dependent) compared with standard care.² Unfortunately, few comparable data exist for the much larger type 2 diabetic population (typically treated with insulin and/or sulfonylureas), many of whom self-monitor.³⁻⁸ Moreover, the small number (and size) of controlled trials of SMBG is inconclusive regarding its effects on glycemic control in this popula-

tion. Despite the lack of data, recent legislation has mandated insurance coverage of blood glucose monitors and test strips for both type 1 and type 2 diabetic patients in Medicare and in 38 states.⁹

Approximately 3.2 million diabetic patients obtain care in MCOs.¹⁰ No published data exist on the effects of MCO coverage of monitors on patient use of such devices, medication compliance, or blood glucose control. Because such devices cost up to \$100 each, it is likely that some vulnerable low-income and minority patients without coverage still lack access to home glucose monitoring. In addition, the availability of such free monitors may have a "promotional" effect of stimulating desirable self-care behavior.

Spurred by the DCCT results, Harvard Pilgrim Health Care (HPHC), a large health maintenance organization (HMO) in New England, began providing free blood glucose monitors for all patients with diabetes in December 1993. The costs of home glucose monitoring test strips continued to be covered as a pharmacy benefit both before and after initiation of coverage of glucose monitors. At the time of the study, HPHC spent over \$1 million annually for SMBG devices and supplies. This large natural experiment provided an opportunity to evaluate whether the provision of free self-monitoring equipment increased SMBG and to determine if increased rates of SMBG was associated with increased regularity of refills of oral sulfonylureas and improved glucose control (HbA_{1c} level), which is associated with improved outcomes of diabetes. Our use of objective measures of SMBG distinguishes this study from previous research relying on self-reports. We conducted an interrupted time-series analysis of a continuously enrolled diabetic population (4 years), using the longitudinal Automated Medical Record System (AMRS) of HPHC's multispecialty health centers (now Harvard Vanguard Medical Associates [HVMA]), including one of the most socioeconomically and ethnically diverse populations of HMO patients in the United States.

METHODS

RESEARCH DESIGN

Controlling for preintervention trends, we evaluated the effects of the change in coverage policy using an interrupted time-series design, which is one of the strongest quasiexperimental designs for studying sudden changes in reimbursement policy,¹¹⁻¹³ especially when study outcomes are stable over time. Such designs produce more valid evidence of policy effects than simple pre-post designs because they can control for previous underlying trends (eg, secular changes) in study outcomes.^{14,15} We measured changes in rates of SMBG 19 months before the change in coverage policy (defined as prepolicy [March 1992–September 1993]), during its initiation (defined as phase-in [October 1993–February 1994], 5 months from notification and pilot implementation to universal implementation), and after the policy (defined as postpolicy [March 1994–July 1995], 17 months after universal implementation) in a cohort of 3219 continuously enrolled adult patients with diabetes. In addition, we compared changes in trends in regularity of use of oral sulfonylureas (days between dispensings) and glucose control (HbA_{1c} levels), between patients who initiated monitoring (with no prior recorded experience of monitoring for at least 12 months) vs patients who never initiated SMBG (no recorded SMBG during 4 years of observation). These analyses were stratified by premoni-

toring rates of refill regularity or glucose control (3 strata for each outcome) to control for possible differential response to monitoring in these patient subgroups. By determining whether rates of study outcomes in a large population differed significantly from expected levels based on preintervention trends, we were able to control for secular trends and other threats to the validity of study findings to a much greater extent compared with simpler before-and-after designs.¹⁴

STUDY SETTING AND DATA SOURCES

Harvard Vanguard Medical Associates is a multispecialty group practice serving nearly 300 000 people in diverse ethnic and socioeconomic communities in and around Boston, Mass. At the time of the study, nearly all of the patients at HVMA's 14 health centers were insured by HPHC, the largest HMO in New England. All HPHC members had coverage for prescription medications and home glucose monitoring test strips; home blood glucose monitors were provided to all patients with diabetes beginning in December 1993. The automated medical records systems at HVMA/HPHC captured data from all ambulatory and inpatient encounters between plan members and providers in a combination of coded and narrative fields.^{16,17} Coded data also included all laboratory tests and results (eg, HbA_{1c}), diagnoses, procedures, and therapies. Members received prescription drug coverage through the in-house pharmacy system that generally provided 1 month's supply of medicine for a small copayment. Computerized pharmacy records were recorded for all transactions in the 14 health centers during the entire observation period. These data included patient identifiers, drug code, dose, and date of dispensing. Previous studies have documented the reliability and usefulness of these longitudinal records of medication use.¹⁸⁻²⁰

In addition, we used a previously validated measure of comorbidity to measure overall level of patient comorbidity called the chronic disease score, which is an index based on the presence or absence of 20 specific comorbid conditions ascertained using prescription data. In several HMO settings, the chronic disease score performed as well or better than another useful ambulatory case mix measure, the Ambulatory Disease Groups, explaining 50% to 60% of variation in health care utilization, costs, and mortality.²¹

The automated medical records also contained enrollment data including date of birth, sex, race, specific months of membership, ZIP code, and member address, which can be linked to socioeconomic characteristics of census tract (eg, income and education).²² These data systems have been used previously for a number of research studies.^{23,24}

STUDY COHORT

To be eligible for inclusion in the study, patients had to be at least 18 years old and to have received at least 1 prescription for insulin or an oral sulfonylurea at some time during the 2 years before the change in coverage policy. The newer metformin hydrochloride agents were not available during the observation period. Pediatric patients were excluded from the study because they represent a small fraction of diabetic patients at HPHC and because SMBG by children and adolescents is often different from that among adult patients.²⁵ Women with a diagnosis of gestational diabetes were also excluded.

MEASURES

Self-monitoring of Blood Glucose

The most direct measure of the success of the new coverage policy was whether it increased SMBG. We measured changes in test strip use because it is a more reliable indicator of actual

self-monitoring than self-report.²⁶⁻²⁹ Our measures included changes in trials of SMBG (time to SMBG measured as the first dispensing of test strips or cumulative probability of self-monitoring) as well as changes in the overall intensity of test strip use (number of test strips per study patient per month). We constructed time series for both insulin-treated and sulfonylurea-treated patients. Patients who received both insulin and a sulfonylurea (n=307) during the first 2 years were assigned to the insulin-treated category.

Refill Regularity

We hypothesized that starting SMBG would stimulate patients to be increasingly compliant with their sulfonylurea drug regimen and would increase regularity of use. Because insulin use is much more variable (depending on diet and self-monitoring) than sulfonylurea regimens, this analysis excluded insulin-treated patients. For each prescription dispensed in the 12 months before and after initiation of monitoring, we measured the gap in days from the previous prescription. We constructed time series of the means of these gaps for patients filling prescriptions in successive 60-day periods. We constructed separate time series of mean gaps in days between refills for 3 separate strata based on each patient's average rate of refill regularity in the premonitoring period (baseline): high (≤ 45 -day gap); moderate (>45 - to ≤ 70 -day gap); and low (>70 -day gap). For each patient, the zero point represented the period at which self-monitoring began (baseline). Assuming that some patients used and filled prescriptions irregularly before monitoring, we expected that initiation of monitoring would be associated with a reduction in the mean gaps between dispensings that would approach 30 days (the monthly supply). We also constructed time series of refill regularity for the same 3 strata among a comparison group of patients who never initiated SMBG. For this group, the zero point represented the start of the policy providing free blood glucose monitors.

Glucose Control

Blood glucose control represents an intermediate patient health outcome that is associated with reduced rates of major diabetes complications. The AMRS contained all HbA_{1c} measurements throughout the study period. We hypothesized that improved self-care, including regularity of medication management after initiating SMBG, would reduce HbA_{1c} levels. Among patients initiating SMBG, we measured the mean HbA_{1c} level among all laboratory tests taken during each 60-day period for 12 months before and after starting SMBG. For each patient, the zero point again represented the period of initiation of self-monitoring. We constructed separate time series of mean HbA_{1c} levels for 3 strata based on each patient's mean HbA_{1c} level in the premonitoring period (baseline) (good, $\leq 8.0\%$; adequate, $>8.0\%$ to $\leq 10.0\%$; and poor, $>10.0\%$). We present HbA_{1c} data in these 3 strata for a comparison group who never initiated SMBG, for whom the zero point represented the start of the policy.

To examine possible differences in the groups of patients who initiated monitoring before and after the policy, we performed additional analyses of both refill regularity and glucose control comparing these 2 groups, and the results were almost identical. We therefore report only the combined results.

STATISTICAL ANALYSIS

We measured the cumulative probability of self-monitoring (time to first use of test strips) before and after the change in coverage policy and determined whether there was a shift in the probabilities of such trials after the intervention, controlling for the pre-intervention hazard rates. We calculated whether there was a change in the relative risk of test strip use and calculated the 95% 2-sided

Table 1. Demographic and Clinical Characteristics of Diabetes Cohort by Drug Treatment Category*

Characteristic	Insulin-Treated Cohort (n = 1428)	Oral Sulfonylurea-Treated Cohort (n = 1791)
Mean age, y	51 ± 14.1	56 ± 12.3
Age, y		
18-44	478 (33.5)	341 (19.0)
45-64	668 (46.8)	965 (53.9)
≥65	282 (19.8)	485 (27.1)
Sex		
Male	697 (48.8)	1003 (56.0)
Female	731 (51.2)	788 (44.0)
Race		
White	652 (65.6)	814 (68.5)
Black	305 (30.7)	300 (25.2)
Other	37 (3.7)	75 (6.3)
Missing	434	602
Eligibility		
Medicaid	10 (0.7)	7 (0.4)
Medicare	242 (17.2)	420 (23.7)
Commercial	1159 (82.1)	1345 (75.9)
Missing	17	19
Body mass index†		
Underweight (≤ 18.5)	13 (1.1)	11 (0.8)
Normal (> 18.5 - < 25)	249 (21.2)	201 (13.9)
Overweight (≥ 25 - < 30)	377 (32.0)	441 (30.4)
Obese (≥ 30)	538 (45.7)	797 (55.0)
Missing	251	341
Comorbidities		
0	27 (1.9)	45 (2.5)
1-2	628 (44.0)	837 (46.7)
3-4	446 (31.2)	626 (35.0)
≥5	327 (22.9)	283 (15.8)
No. of comorbidities per year‡	3.1 ± 2.1	2.8 ± 1.7
No. of dispensings per year§	7.3 ± 3.9	5.5 ± 3.5
Hemoglobin A _{1c} level at baseline§	9.0 ± 1.6	8.4 ± 1.7

*Data are number (percentage) of patients or mean ± SD value.

Percentages are based on those with nonmissing data.

†Calculated as weight in kilograms divided by the square of height in meters.

‡One baseline year (January 1992–December 1992).

§One year before policy (October 1992–September 1993).

confidence intervals (CIs) for this change. We used segmented time-series regression models³⁰ to estimate changes in levels or trends in rates of test strip use (number per patient per month), mean gaps between dispensings (within strata of baseline rate of refill regularity), and mean HbA_{1c} levels (within strata of baseline HbA_{1c}). These models included a constant term, a linear time trend, and terms to estimate changes in rates after the policy (or, for gaps in medication dispensings and HbA_{1c} levels, after beginning SMBG). Models to assess changes in level or trends in mean gaps between dispensings or mean HbA_{1c} levels included an interaction term to compare initiators of SMBG with those who never initiated.³⁰

RESULTS

CHARACTERISTICS OF THE STUDY COHORT

Table 1 provides the baseline demographic and clinical characteristics of the study cohort. Among the 3219 patients with diabetes who met study eligibility criteria,

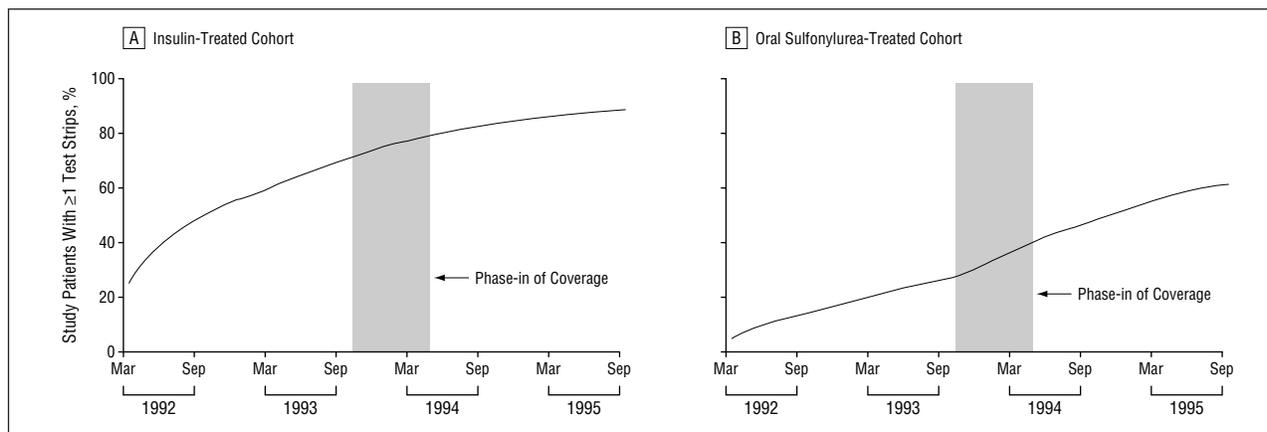


Figure 1. Cumulative proportion of patients with a trial of one or more test strips for self-monitoring of blood glucose stratified by insulin-treated (A; n=1428) vs oral sulfonylurea-treated (B; n=1791) patients. Solid bars indicate phase-in of coverage of glucose monitors. Measurements are based on quarterly moving averages.

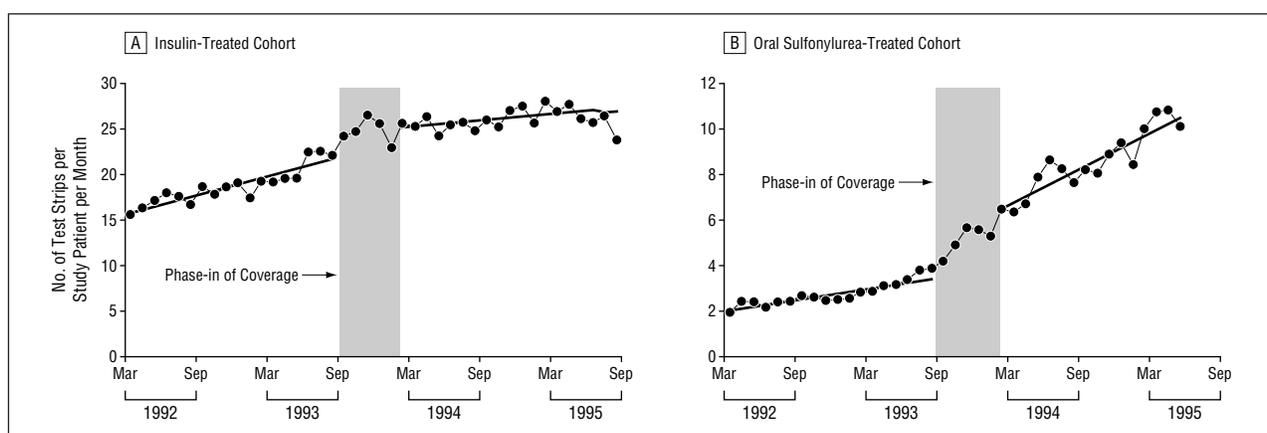


Figure 2. Time series of number of test strips for self-monitoring of blood glucose dispensed per patient per month stratified by insulin-treated (A; n=1428) vs oral sulfonylurea-treated (B; n=1791) patients. Solid bars indicate phase-in of coverage of glucose monitors. Solid lines represent fitted trend lines from segmented time-series regression.

44% were treated with insulin and 56% received oral sulfonylurea therapy. On average, insulin-treated patients were 51 years old; 20% were 65 years and older. The average age of oral sulfonylurea-treated patients was 56 years; 27% were 65 years and older. Of the two thirds of patients whose race was identified, over 25% were African American. Of oral sulfonylurea-treated and insulin-treated patients, 55% and 46%, respectively, were obese (body mass index [calculated as weight in kilograms divided by the square of height in meters] ≥ 30). On average, insulin-treated patients were dispensed 7 hypoglycemic prescriptions per year (SD=3.9), while oral sulfonylurea-treated patients were dispensed only 6 hypoglycemic prescriptions per year (SD=3.5) at baseline.

EFFECTS ON SMBG

Figure 1 provides longitudinal data on the cumulative probability of a trial of SMBG (first test strip dispensing). Among insulin-treated patients, approximately 70% had been dispensed test strips by the start of the new coverage policy; after controlling for prior trend, there was only a very minor additional effect of the policy change (Figure

1A). However, among oral sulfonylurea-treated patients, there was a marked rise in trials of SMBG associated with the change in coverage. In the 20 months prior to the policy change, 27% of patients had been dispensed test strips. After free monitors were made available, the cumulative proportion increased suddenly to 37% ($P < .001$ and $P = .046$ for changes in level and slope of hazard curve, respectively) and reached 60% by the end of follow-up. By 6 months after the policy and after controlling for the increasing baseline trend, the predicted absolute increase in the number of initiators of SMBG (over the expected increase) was 14 per 1000 oral sulfonylurea-treated patients per month (95% CI, 10-17), a relative increase of 98.7% (95% CI, 60.2%-144.0%).

Figure 2 plots the time series of the intensity of SMBG measured as the number of dispensed test strips per patient per month. Insulin-treated patients increased the overall quantity of test strips used immediately after coverage of self-monitoring equipment by 3.5 strips per person per month, with only a small additional increase during the postpolicy period (Figure 2A). However, there was a clinically and statistically significant effect of the coverage policy on the intensity of test

strips used among oral sulfonylurea-treated patients (Figure 2B). During the baseline period, patients receiving oral agents increased test strip use modestly from 2 per patient per month to 3.9 just prior to the policy change. This trend in test strip use increased markedly after the coverage change from 4 strips per patient per month to over 10 by the end of follow-up ($P = .01$ and $P = .003$ for increases in level and slope, respectively). During the first 6 months after the policy, the intensity of test strip use increased over the prepolicy expected levels by 17.9 strips per cohort member, representing a relative increase of 75.3% at 6 months after the policy (95% CI, 49.7%-100.9%).

These postpolicy changes in test strip use were confined to oral sulfonylurea-treated patients newly initiating monitoring. There were no clinically or statistically significant changes in test strip use after the policy among patients who were already monitoring their blood glucose levels before the provision of the free glucose monitors.

CHARACTERISTICS OF INITIATORS VS NONINITIATORS OF SMBG

Because of possible selection biases associated with initiating SMBG, we compared the baseline demographic and clinical characteristics of those who never initiated SMBG with those who initiated SMBG. As given in **Table 2**, the 2 groups were similar with respect to demographic variables, body mass index, number of comorbid conditions, and average number of dispensings per year. While noninitiators were more likely to be older than 65 years, controlling for age did not significantly alter the time-series findings given in the following section. In addition, by stratifying analyses of the effects of initiating SMBG by baseline HbA_{1c}, we controlled for slight differences in baseline HbA_{1c} level (Table 2).

EFFECTS ON REGULARITY OF MEDICATION USE

Figure 3 provides time-series data on gaps between successive prescriptions for oral sulfonylureas during the 12 months before or after the policy among patients who initiated SMBG compared with those who never initiated SMBG, stratified by baseline rate of refill regularity. Given that most prescriptions provide a 30 days' supply, a mean gap of 30 days would indicate a pattern of continuous consumption and filling of prescriptions.

The time series of mean gaps between prescription refills in initiators and noninitiators of SMBG (Figure 3) were stable and almost identical during the baseline period (mean gaps of 34.3 days for those with high refill regularity, 56.4 days for those with moderate regularity, and 98.7 days for those with low regularity). Controlling for baseline trends and temporal changes in the comparison group, initiation of SMBG was not associated with improved regularity of refills in the group with high refill regularity at baseline (Figure 3A). However, among those with moderate refill regularity (Figure 3B), by 6 months after initiation of SMBG, initiators reduced mean gaps between dispensings by 9.7 days compared with noninitiators (95% CI, -12.3 to -7.1). Among those with

Table 2. Demographic and Clinical Characteristics of Oral Sulfonylurea-Treated Cohort by Self-monitoring of Blood Glucose*

Characteristic	Never Initiated (January 1992– September 1995) (n = 678)	Initiated (January 1993– November 1994) (n = 593)
Mean age, y	59 ± 13	54 ± 11
Age, y		
18-44	103 (15.2)	129 (21.8)
45-64	328 (48.4)	345 (58.2)
≥65	247 (36.4)	119 (20.1)
Sex		
Male	388 (57.2)	333 (52.3)
Female	290 (42.8)	260 (47.7)
Race		
White	331 (73.6)	263 (66.8)
Black	91 (20.2)	109 (27.7)
Other	28 (6.2)	22 (5.6)
Missing	228	199
Eligibility		
Mdicaid	1 (0.2)	4 (0.7)
Medicare	215 (32.0)	109 (18.6)
Commercial	456 (67.9)	473 (80.7)
Missing	6	7
Body mass index†		
Underweight (≤18.5)	6 (1.1)	3 (0.6)
Normal (>18.5-<25)	80 (14.6)	50 (10.4)
Overweight (≥25-<30)	168 (30.6)	152 (31.7)
Obese (≥30)	295 (53.7)	275 (57.3)
Missing	129	113
Comorbidities		
0	27 (4.0)	7 (1.2)
1-2	301 (44.4)	272 (45.9)
3-4	238 (35.1)	215 (36.3)
≥4	112 (16.5)	99 (16.7)
No. of comorbidities‡	2.9 ± 1.8	2.9 ± 1.7
No. of dispensing per year§	5.2 ± 3.5	5.5 ± 3.5
Hemoglobin A _{1c} level at baseline per year	8.0 ± 1.6	8.8 ± 1.7

*Data are number (percentage) of patients or mean ± SD value.

Percentages are based on those with nonmissing data.

†Calculated as weight in kilograms divided by the square of height in meters.

‡One baseline year (January 1992–December 1992).

§One year before policy (October 1992–September 1993).

low baseline refill regularity (Figure 3C), controlling for reductions in gaps between refills observed in both groups (due to regression to the mean), initiators of SMBG had immediate reductions in mean gaps of 19.5 days compared with noninitiators (95% CI, -27.7 to -11.3). However, this effect abated during the 12-month follow-up.

GLUCOSE CONTROL

Figure 4 shows the patient-level time-series data on mean HbA_{1c} level by 60-day period, comparing initiators of SMBG with those who never initiated and stratifying by mean HbA_{1c} levels at baseline (about 20% to 40% took tests in any given 60-day period). Again, levels and trends of HbA_{1c} in initiators and noninitiators of SMBG were almost identical during the baseline period (mean levels of HbA_{1c} [as percentage of total hemoglobin] was 7.1% among those with good glycemic control, 8.8% among

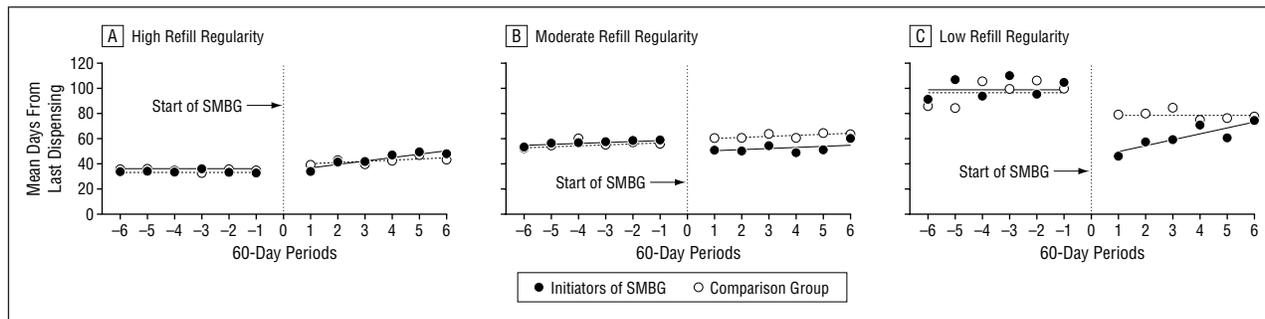


Figure 3. Temporal association between initiation of self-monitoring of blood glucose (SMBG) and refill regularity with antidiabetic agents among oral sulfonylurea-treated patients who initiated SMBG vs comparison group who never initiated SMBG, stratified by baseline rate of refill regularity (A, high refill regularity: ≤ 45 -day gap [initiators, $n=145$; controls, $n=185$]; B, moderate refill regularity: >45 - to ≤ 70 -day gap [initiators, $n=124$; controls, $n=157$]; and C, low refill regularity: >70 -day gap [initiators, $n=116$; controls, $n=183$]). Zero point represents start of SMBG for each initiator. Zero point for a patient in the comparison group represents the start of policy (September 1, 1993). Solid and dashed lines represent fitted trend lines from segmented time-series regression.

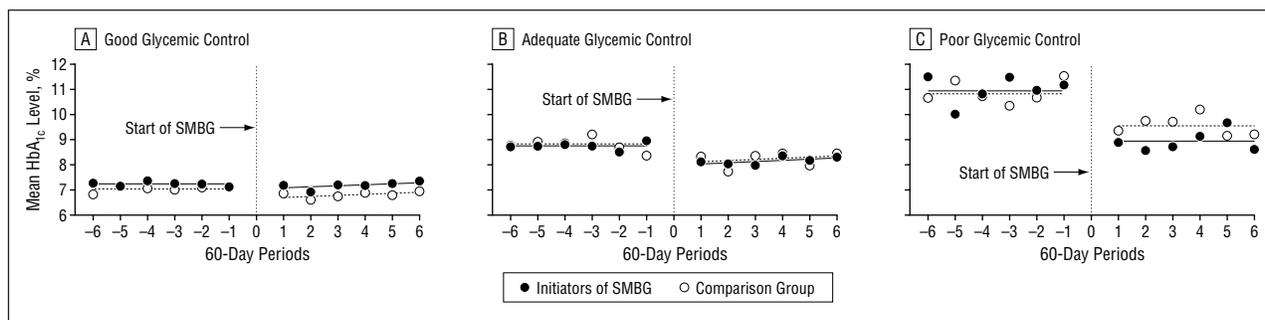


Figure 4. Temporal association between initiation of self-monitoring of blood glucose (SMBG) and hemoglobin A_{1c} (HbA_{1c}) levels among oral sulfonylurea-treated patients who initiated SMBG vs comparison group who never initiated SMBG, stratified by baseline HbA_{1c} levels (A, good glycemic control: $\leq 8.0\%$ [initiators, $n=123$; controls, $n=237$]; B, adequate glycemic control: $>8.0\%$ to ≤ 10.0 [initiators, $n=125$; controls, $n=107$]; and C, poor glycemic control: $>10.0\%$ [initiators, $n=90$; controls, $n=43$]). Zero point represents start of SMBG for each initiator. Zero point for a patient in the comparison group represents the start of policy (September 1, 1993). Solid and dashed lines represent fitted trend lines from segmented time-series regression.

those with adequate control, and 11.0% for those with poor control). Initiation of SMBG was not associated with improved HbA_{1c} levels in those with good or adequate baseline glycemic control (Figure 4A and B). However, among those with poor glycemic control, after controlling for baseline and comparison group trends, initiators of SMBG lowered their mean HbA_{1c} level by 0.63% compared with noninitiators (95% CI, -1.14% to -0.12% ; $P=.03$).

COMMENT

In efforts to improve health outcomes for patients with diabetes, 38 states now require MCOs and other insurers to cover self-monitoring equipment and supplies. However, to our knowledge, there are no published studies on the effects of such policies on self-care behavior, associated medication compliance, or glucose control. Such mandates represent population-wide natural experiments with unknown effects on quality of care. This longitudinal investigation among 3219 patients with diabetes in a large HMO with a diverse patient population indicates that a program including provision of free blood glucose monitors and training had significant effects on self-care behavior of oral sulfonylurea-treated patients, causing increases in new trials of SMBG and in the frequency of test strip use per patient. Among patients who initiated SMBG, there were significant improvements in

regularity of diabetes medication use and glucose control compared with noninitiators, particularly among those with low premonitoring rates of refill regularity or poor glycemic control. Decreases in HbA_{1c} similar to those found in this study have been associated with reduced risks of diabetic complications in type 2 diabetes.³¹

We hypothesized that we would observe changes in regularity of medication refills and glucose control because of increased sensitivity of patients to all aspects of self-management following initiation of home glucose monitoring. We hypothesized that free monitors would have similar effects as free drug samples, providing a “hook” to patients that stimulated monitoring and increased interactions with clinicians regarding desirable patterns of medication use.

Previous data linking SMBG in oral sulfonylurea-treated patients with improved glycemic control is sparse and has produced contradictory results.^{28,29,32-34} Using a cohort design, Karter and colleagues³² evaluated the effects of SMBG on glycemic control among 24 312 adult patients with diabetes from a large MCO. They concluded that more frequent SMBG was associated with clinically and statistically improved glycemic control regardless of drug treatment. These findings supported the conclusions of prior studies.³³ However, several other studies have reported that SMBG among oral sulfonylurea-treated patients has no effect on glycemic control.^{28,29,34} While further research is necessary to determine the ef-

fectiveness and optimal frequency of SMBG in patients with type 2 diabetes, we are not aware of any rigorous research that has observed whether coverage of blood glucose monitors is effective in increasing SMBG, achieving better glycemic control, and improving other self-care behaviors. To our knowledge, this study is the first to use a strong population-based, quasiexperimental method to examine the effects of coverage of home glucose monitors.

The sudden changes in the frequency of test strip use among oral sulfonylurea-treated patients are predictable and coincident with the start of coverage; these effects are unlikely to be explained by other threats to validity because of the suddenness of the changes in SMBG coinciding with the change in coverage. However, the associations between the start of SMBG and regularity of drug refills and blood glucose control must be interpreted more cautiously. Patients who initiate SMBG may also be more likely to increase other self-care activities independent of monitoring. For example, it is conceivable that declining health status and glucose control might prompt patients to begin SMBG as well as to improve drug regimen compliance. However, the similar demographic and clinical characteristics among initiators and noninitiators of SMBG, their identical baseline trends in regularity of refills and glucose control, and the immediate temporal change in these outcomes coincident with initiation of SMBG increases the plausibility of a direct relationship between SMBG and regularity of medication use and glucose control. Our finding that increased SMBG is associated with improved medication compliance is consistent with previous studies³² and may provide one explanation for the positive relationship between SMBG and glucose control. Nevertheless, we cannot separate out the effects of coverage of monitoring equipment per se from other aspects of the program (eg, education of clinicians and patients regarding self-monitoring and the importance of following up high blood glucose levels with appropriate self-care behaviors). In addition, this study examined the effect of adding coverage for monitoring equipment when test strips were already covered; thus, it does not assess the effects of coverage of more costly (over time) test strips.

What are the implications of this study for the substantial federal and state legislative activity during the last several years mandating coverage of monitoring equipment and supplies for all patients with diabetes? Given the observed improvement in self-care and the possible improved levels of glucose control, these data provide preliminary support for the effectiveness of state legislative activities promoting coverage of self-monitoring equipment and training. However, more data are needed from other settings to corroborate these findings.

In summary, this study provides clear evidence that the provision of free home glucose monitors improved rates of self-monitoring in this HMO population. Initiating SMBG was associated with increased regularity of use of medications and a reduction in high blood glucose levels that are associated with diabetes complications. These data provide preliminary support for efforts by HMOs and state legislators to cover home-testing equipment for this vulner-

able, high-cost population. More studies are needed on the health and quality-of-care effects of legislation promoting self-care practices in chronically ill patients.

Accepted for publication April 30, 2003.

This study was supported by grant HS10063 from the Agency for Healthcare Research and Quality, Rockville, Md, and by the Harvard Pilgrim Health Care Foundation, Wellesley, Mass.

An abstract of this study was presented at the 2002 Annual Meeting of the Academy for Health Services Research and Health Policy; June 23, 2002; Washington, DC.

We wish to thank Robert LeCates, MA, and Ann Payson, MA, of Harvard Medical School for their valuable technical and administrative support; James Meigs, MD, for his thoughtful comments on the manuscript; and the anonymous reviewers, for their valuable suggestions regarding additional analyses.

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Announcement

New Editor and New Address for Editorial Correspondence

Effective January 2004, Philip Greenland, MD, succeeded James E. Dalen, MD, MPH, as Editor of the ARCHIVES. Editorial correspondence should be sent to the new address: Philip Greenland, MD, Editor, *Archives of Internal Medicine*, 680 N Lake Shore Dr, Suite 1102, Chicago, IL 60611; phone: 312-503-5387; fax: 312-503-5388; e-mail: archinternmed@jama-archives.org. Manuscript submissions should be sent to Dr Greenland's attention via e-mail attachment to archinternmed@jama-archives.org.