

## Effect of Cost-sharing Changes on Self-monitoring of Blood Glucose

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**Objective:** To study the effect of cost-sharing policy changes on utilization of test strips for self-monitoring of blood glucose.

**Study Design:** A legislative mandate (January 1, 2000) required California health plans to cover diabetes supplies, including those for self-monitoring of blood glucose. One health plan, Kaiser Permanente Northern California, initially waived established copayments and provided free test strips to members with diabetes mellitus for 2 years but later instituted a 20% coinsurance charge for a portion of their membership.

**Methods:** A retrospective cohort design was used to study pharmacy-based estimates of test strip utilization changes during this natural experiment. Analyses included 2 cohort investigations using pretest-posttest analysis with control subjects to study transitions from a copayment period to a free test strip period and from the free test strip period to a coinsurance period.

**Results:** During the copayment period, test strip utilization was inversely related to copayments for test strips. Offering free test strips did not increase utilization, even among those paying higher copayments before the policy change. Price-elastic patterns formed before and during the copayment period persisted, despite receiving free test strips for 2 years. The coinsurance, introduced after 2 years of receiving free test strips, resulted in statistically significant (but not clinically relevant) decreased utilization (approximately 1-3 fewer test strips/month). Change patterns did not differ by socioeconomic status.

**Conclusions:** Offering free test strips shifted costs from patient to health plan, without improving adherence. The introduced coinsurance slightly reduced utilization and adherence to recommendations about self-monitoring of blood glucose. Neither intervention had marked clinical effect. Cross-sectional analyses should not be used to predict utilization changes in the face of rapidly evolving benefit policies.

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For author information and disclosures, see end of text.

The Diabetes Control and Complications Trial<sup>1</sup> and the United Kingdom Prospective Diabetes Study<sup>2</sup> demonstrated the benefits of achieving tight glycemic control in patients with diabetes mellitus (DM) and led to a concomitant promotion of self-monitoring of blood glucose (SMBG) as an integral part of good diabetes care. However, SMBG is consistently practiced less than is recommended by commonly supported guidelines,<sup>3-5</sup> including those of the American Diabetes Association.<sup>6</sup> Test strips for SMBG are expensive, and SMBG practice is more sensitive to cost sharing<sup>3</sup> (ie, price-elastic demand) than many other health services (eg, dilated eye examinations).<sup>4</sup> However, current understanding regarding how financial barriers affect utilization is primarily based on cross-sectional analyses.

California Senate Bill 64 (SB64), implemented on January 1, 2000, mandated that California's health plans provide coverage for diabetes supplies, including those for SMBG. The bill was intended to eliminate a financial barrier to SMBG and to facilitate this self-care practice. In recent years, 37 other states have passed similar legislation. Following similar legislation, rates of SMBG utilization increased, and glycemic control improved after a New England health plan started providing free glucose monitors in 1993.<sup>7</sup> In the year before implementation of SB64 (hereafter referred to as the copayment period), a California health plan, Kaiser Permanente Northern California (KPNC), charged members with DM a \$0 to \$30 copayment for each prescription of test strips, depending on the member's type of benefit coverage. During the 2 years after SB64 was implemented (January 1, 2000, through December 31, 2001) (hereafter referred to as the free test strip period), test strips were provided free of charge to all KPNC members with DM. A second policy change occurred on January 1, 2002, after which approximately 35% of the commercial membership were charged a 20% coinsurance (approximately \$8-\$12 per prescription, depending on the brand of test strips) (hereafter referred to as the coinsurance period).

We studied the effects of these 2 benefit policy changes on SMBG practice (as measured by test strip utilization). We hypothesized an increase in individual-level test strip utilization after test strips were provided for free, with the greatest increase among those paying the largest copayments before the implementation of SB64. We assumed that poorer members would be more price

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sensitive and hypothesized that provision of free test strips would reduce socioeconomic disparities in utilization. We also hypothesized that, after receiving free test strips for 2 years, utilization would decrease after the coinsurance was introduced and that this decrease would be greatest among the poor and among those not treated with insulin.

## METHODS

### Study Setting

Kaiser Permanente Northern California is a group-model healthcare organization that provides comprehensive medical services to more than 3 million members (approximately 35% of the population in the surrounding geographic area) through 15 hospitals and 23 outpatient clinics. Study subjects were identified from the KPNC diabetes registry (approximately 132 000 in 2000).

Two cohorts were created to analyze the effect of the 2 separate policy changes. The first was created for the analysis of utilization before and after the introduction of free test strips (hereafter referred to as the free test strip cohort), and the second was created to assess utilization before and after institution of a coinsurance for test strips (hereafter referred to as the coinsurance cohort). For each cohort, we created a sampling frame that included subjects with continuous health plan membership and prescription drug benefits in the prepolicy and postpolicy periods who were also ongoing test strip users (defined as having at least 1 dispensing for test strips during each year of the study). We did not include members without prescription drug benefits and those with prescription drug caps, because they have little financial incentive to purchase SMBG supplies exclusively at KPNC pharmacies and we cannot ascertain utilization at non-KPNC pharmacies. Based on these inclusion criteria, we identified 33 596 subjects in the free test strip cohort and 27 810 subjects in the coinsurance cohort sampling frames. We then excluded 12 241 and 9841 noncommercial health plan members (ie, members in subsidized plans [eg, Medicare]) from the free test strip cohort and the coinsurance cohort, respectively, to reduce case mix, demographic, and socioeconomic heterogeneity in the cohort. Patients enrolled in Medicare received free test strips starting July 1, 1998; this age class would have dominated the reference group if included.

Pharmacy medication dispensing records were then used to classify subjects into the following 3 mutually exclusive treatment groups: patients who use any regimen that includes insulin (hereafter referred to as the insulin group), patients treated only with oral hypoglycemic agents (OHAs) (hereafter referred to as the OHA group), and patients receiving no

diabetes pharmacotherapy but receiving medical nutrition therapy (MNT) only (hereafter referred to as the MNT group). Healthcare providers generally encourage increases in SMBG frequency with the intensification of or the introduction of new pharmacotherapy; in these individuals, we would expect an increase in SMBG frequency during this time, independent of the change in the cost of test strips. Therefore, we excluded 2107 and 2323 additional subjects from the free test strip cohort and the coinsurance cohort, respectively, who switched type of diabetes therapy modalities (eg, adding insulin to regimens that previously included oral agents only) during the study period, although we could not exclude those with dosing changes or with additions of other therapies within the oral agent or insulin modality. The final free test strip cohort and coinsurance cohort on which this study was based included 19 248 and 15 646 subjects, respectively.

Because the 2 benefit changes in charges for test strips were not announced in writing to the KPNC membership, only ongoing users were aware of price changes (via the change in out-of-pocket charge for test strips). Therefore, for our main analyses of the individual-level effect of changes in out-of-pocket cost (eg, pre-post policy), we included only test strip users at baseline whom we assumed had experienced the changes in charges for test strips. However, although exclusion of individuals who were not prevalent users was appropriate for assessing individual-level changes, these cohorts are not well suited to study population-level patterns of utilization across levels of out-of-pocket cost because high cost may also lead to never initiating use or to discontinuing use. Therefore, we evaluated trends in SMBG practice and price sensitivity in a panel study of annual cohorts that included the individuals who were nonusers.

### Data Collection Methods

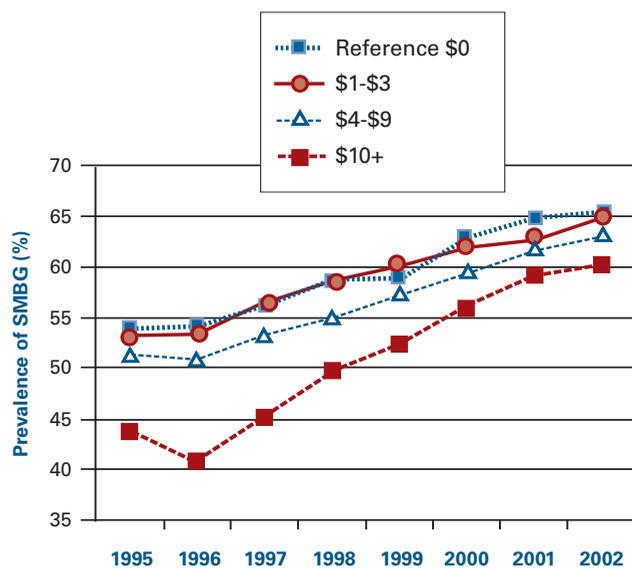
We assessed SMBG practice as indicated by test strip utilization (mean daily test strip utilization) recorded from pharmacy dispensing records. The use of pharmacy dispensing records to estimate utilization has been shown to be a valid measure for patients with a prescription benefit.<sup>3</sup> For each calendar year, the mean number of test strips used per day was calculated for each member by summing the cumulative number of test strips for the year and dividing by 365 days. We assumed that a patient possessed no stockpile of test strips at baseline. Test strip copayment amounts paid out-of-pocket were available through KPNC's benefits database. Copayment levels were collapsed into the following 4 categories: \$0 (reference group), \$1 to \$3, \$4 to \$9, and \$10 and higher to identify price-elastic patterns. Neighborhood-level socioeconomic status was characterized by geocoding each member's address

to its 2000 census block group and by creating variables for median household income in 1999 and for residence in an impoverished neighborhood (defined as  $\geq 20\%$  of the population with an income below the US poverty line).

### Statistical Analysis

We first detailed population-level 1995 to 2002 secular trends in SMBG (unadjusted), defined as a continuous measure (mean number of test strips used per day) and as a discrete measure (prevalent use vs nonuse). We then used a longitudinal retrospective cohort investigation in 2 separate cohorts to evaluate longitudinal changes in test strip utilization spanning a 4-year period across the following 2 thresholds: (1) transition from the copayment period to the free test strip period and then (2) transition from the free test strip to the coinsurance period. The outcome of interest was the change in the mean number of test strips used per day associated with the policy-based health plan-wide change in cost sharing. To control for selection bias and for intervening time factors (secular trends and aging), we used the difference-in-differences method (pretest-posttest analysis with control subjects).

■ **Figure.** Prevalence of Daily Test Strip Utilization Stratified by Prescription Drug Copayment Among Kaiser Permanente Northern California Diabetes Registry Members\*



\*Panel study of dynamic cohort, including active registry members as of January of the current year, with continuous membership and prescription drug benefits throughout the year. In 2000 to 2002, stratification is based on 1999 copayments (ie, the last year that copayments were charged). Members with prescription drug caps and those who were affiliated by Medicare, Medi-Cal, or subsidized programs were excluded from the analysis. SMBG indicates self-monitoring of blood glucose levels.

Hierarchical linear models (random coefficient models) were specified to determine the 1-year change in the mean daily test strip utilization following the introduction of 2 separate cost-sharing policies. All statistical analyses were conducted using SAS software (SAS Institute, Cary, NC); the multivariate models were run using PROC MIXED (SAS Institute). The reference group, the \$0 copayment group, received free test strips before and after each policy change and was used to account for the secular trend in SMBG in the absence of any price change. We expected that the levels of SMBG and the patterns of change in test strip utilization might cluster within the different medical facilities, which may have differed in their efforts to promote SMBG; therefore, we specified a random intercept for medical facility in our statistical models.

We assumed a priori whose effects would be modified by diabetes therapy, so we specified separate models for the insulin, OHA, and MNT groups. The exposures of interest (benefit-based changes in test strip copayment) were exogenous policy changes and were unlikely to be related to any individual-level factors. To be sure, we also specified adjusted models that controlled for potentially confounding individual-level prebaseline variables. These covariates included the mean daily test strip utilization during the year before the policy change, prepolicy prescription drug copayment (for the analysis of the first policy change only), prepolicy glycosylated hemoglobin level, age, missed appointment rate, sex, inpatient comorbidity score, total pharmacy cost in the prebaseline year, specialty visits, urgent care visits, primary care visits, residence in a predominantly working-class occupation neighborhood, residence in a predominantly undereducated neighborhood, block group median income (1999), oral medication refill adherence (OHA models only), and pharmacy-derived utilization of insulin syringes as a measure of daily insulin injection frequency (insulin models only). We found no substantive difference between unadjusted and adjusted models; therefore, we present only the unadjusted findings. In addition, we specified models with cross-product terms stratified by contextual measures of socioeconomic status, as we hypothesized that residence in an impoverished area might modify the degree of changes in SMBG after the implementation of each policy.

## RESULTS

### Price Elasticity and Population Secular Trends

We evaluated the population-level secular trends in SMBG as a discrete measure (prevalent use vs nonuse) (Figure) and as a continuous measure (mean number of test strips used per day) (data not shown) between 1995 and 2002

**Table 1.** Baseline (1999) Characteristics of 19 248 Patients With Diabetes Mellitus From the Kaiser Permanente Northern California Diabetes Registry Stratified by Prescription Drug Copayment Before Implementation of California Senate Bill 64\*

Baseline Characteristic	1999 Prescription Drug Copayment, \$				All Subjects	P <sup>†</sup>
	0 [Reference]	1-3	4-9	≥10		
<b>No. (%)</b>	1297 (6.7)	3956 (20.6)	12 147 (63.1)	1848 (9.6)	19 248 (100.0)	—
<b>Age at baseline, y</b>	49.9 ± 11.7	51.7 ± 11.8	51.2 ± 11.5	48.5 ± 12.4	50.9 ± 11.7	<.001
<b>Female sex, %</b>	45.7	51.8	49.5	45.2	49.3	.10
<b>Diabetes therapy, %</b>						.82
MNT group	5.7	5.6	5.4	5.5	5.4	
OHA group	51.8	52.6	52.0	53.3	52.2	
Insulin group	42.5	41.8	42.7	41.3	42.4	
<b>Test strips used per day</b>						
All subjects	1.25 ± 1.3	1.26 ± 1.2	1.21 ± 1.2	1.20 ± 1.2	1.22 ± 1.2	.02
MNT group	0.69 ± 0.5	0.75 ± 0.6	0.73 ± 0.6	0.77 ± 0.6	0.73 ± 0.6	.57
OHA group	0.74 ± 0.6	0.77 ± 0.6	0.74 ± 0.6	0.73 ± 0.6	0.75 ± 0.6	.15
Insulin group	1.95 ± 1.5	1.95 ± 1.5	1.84 ± 1.5	1.86 ± 1.5	1.87 ± 1.5	.01
<b>Median household income in 1999 based on block group 2000 census data, \$</b>	62 947 ± 22 438	61 613 ± 23 978	59 941 ± 24 009	62 328 ± 24 070	60 718 ± 23 926	.003
<b>Resides in a poverty area, %</b>	5.6	8.0	8.6	5.9	8.0	.39

\*Data are given as unadjusted mean ± SD unless otherwise indicated.  
<sup>†</sup>Mantel-Haenszel  $\chi^2$  test for categorical variables and Spearman rank correlation coefficient for continuous variables.  
MNT indicates medical nutrition therapy; OHA, oral hypoglycemic agents.

using the cohorts that did not exclude nonusers or inconsistent test strip users. There was a gradual trend toward higher prevalence of SMBG and more test strips used per day during the observation window. Consistent with price-elastic utilization, the mean daily test strip use and the prevalence of SMBG were consistently lower among those paying the higher out-of-pocket copayment at any point in time. Moreover, although the copayment charges that applied during the copayment period (1995-1999) were no longer in effect after 1999, the price-elastic patterns formed during the copayment period persisted.

**Baseline Characteristics of the Free Test Strip Cohort**

We identified 19 248 members with DM in the free test strip cohort who had pharmacy benefits, were test strip users during the year preceding the implementation of SB64, and did not change diabetes therapy type during the follow-up period. The reference group for the free test strip cohort comprised approximately 7% of the subjects who received test strips for free before the policy change (Table 1). The remain-

ing subjects were distributed across different levels of copayment. The free test strip cohort included the following 3 treatment strata: 8151 subjects in the insulin group, 10 049 subjects in the OHA group, and 1048 subjects in the MNT group. Given the large sample sizes, it is important to focus attention on clinically relevant differences, despite the several statistically significant differences across copayment groups. Diabetes therapy groups and the mean use of SMBG were similarly distributed across copayment groups.

**Test Strip Utilization Following the Introduction of Free Test Strips**

Parameter estimates for the 1-year change in the mean daily test strip utilization following the introduction of free test strips, after adjusting for secular trends observed in the reference group, were inconsistent with our study hypothesis (Table 2). We had hypothesized that SMBG would increase after the provision of free test strips following the policy change and that the degree of this increase would be proportional to the amount of out-of-pocket cost paid per test strip

■ **Table 2.** Parameter Estimates for the 1-Year Change in the Mean Daily Test Strip Utilization Following the Introduction of Free Test Strips Among 19 248 Patients\*

Prepolicy Copayment, \$	No. of Subjects	Estimate ± SE*	P†
<b>MNT Group (n = 1048)</b>			
0 [Reference]	74	—	.73
1-3	222	-0.001 ± 0.050	
4-9	651	0.03 ± 0.05	
≥10	101	0.04 ± 0.06	
<b>OHA Group (n = 10 049)</b>			
0 [Reference]	672	—	.24
1-3	2082	0.02 ± 0.02	
4-9	6311	0.03 ± 0.02	
≥10	984	0.03 ± 0.02	
<b>Insulin Group (n = 8151)</b>			
0 [Reference]	551	—	.03
1-3	1652	-0.08 ± 0.04	
4-9	5185	-0.0002 ± 0.0400	
≥10	763	-0.02 ± 0.05	

\*Adjusted for prepolicy self-monitoring of blood glucose.  
 †Type III test fixed effects.  
 MNT indicates medical nutrition therapy; OHA, oral hypoglycemic agents.

prescription during the year before this policy change. In the OHA and MNT groups, there were no substantive or statistically significant increases in SMBG relative to the control group. There was no evidence of price elasticity in response to the change in cost in either group. In the insulin group, providing free test strips was accompanied by a counterintuitive decrease, albeit small (range, <0.5-2.5 fewer test strips per month), in SMBG among all copayment groups relative to the reference group.

Although the change in cost sharing (ie, each member's preexisting copayment amount) should not be affected by individual-level variables, we ran adjusted models to rule out potential confounding. The parameter estimates did not change substantively with adjustment, so we present the results from the more parsimonious (unadjusted) models. Furthermore, there was no evidence that socioeconomic status modified our findings, as there were no statistically significant differences in price elasticity among those who lived in predominantly impoverished vs nonimpoverished neighborhoods.

**Test Strip Utilization Following the Introduction of a 20% Coinsurance**

There were 15 646 subjects in the coinsurance cohort: 4505 subjects in the insulin group, 9627 subjects in the OHA group, and 1514 subjects in the MNT group. Fifty-eight percent of the cohort continued to receive test strips for free after the policy change, and 42% were charged the coinsurance (\$8-\$12). Subject characteristics did not differ clinically among those who were exposed vs those who were unexposed to the second policy change (a 20% coinsurance per prescription), although many of the contrasts were statistically significant because of the large sample sizes (Table 3).

As in the previous analysis, we ran simple and adjusted models to determine the effect of this policy change on SMBG. Adjustment for individual-level covariates did not alter our results (ie, they were not confounders), so we report the results of models that adjust for prepolicy SMBG only. In the year following the policy change, subjects in the insulin, OHA, and MNT groups who were charged the coinsurance decreased their SMBG on average by 0.09 (P < .001), 0.06 (P < .001,) and 0.04 (P = .04) test strips per day, respectively, compared with those who continued to receive test strips for free. Although statistically significant, this decrease (approximately 2 test strips/month) is too small to be of clinical relevance.

In addition, there was no statistically significant difference in the SMBG discontinuation rates between those who were and those who were not charged the coinsurance. There was no statistically significant difference in the degree of the decline by socioeconomic status (ie, those living in vs those not living in impoverished neighborhoods) (data not shown).

**DISCUSSION**

This natural experiment provided a unique opportunity to evaluate the effect of changes in out-of-pocket costs on individual and population-level utilization of SMBG. We observed the effect of 2 policy-driven changes in cost sharing on SMBG (measured as test strip utilization) in a large managed care population with DM. As expected, we observed price-elastic demand in cross-sectional assessment of SMBG and out-of-pocket costs among prevalent SMBG users, suggesting the presence of a financial barrier to SMBG utilization. This graded utilization pattern was less marked when we restricted our analysis to the subset of patients with DM who were continuous SMBG users. This suggests that there may be a price threshold over which individuals choose to discontinue SMBG practice altogether, rather than to incrementally

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**Table 3.** Baseline (2001) Characteristics of 15 646 Patients With Diabetes Mellitus From the Kaiser Permanente Northern California Diabetes Registry Stratified by Whether Patients Were Charged the 2002 Coinsurance (\$8-\$12) for Test Strip Prescriptions\*

Baseline Characteristic	2002 Prescription Coinsurance			P <sup>†</sup>
	Free Test Strips [Reference]	Coinsurance	All Subjects	
<b>No. (%)</b>	9095 (58.1)	6551 (41.9)	15 646 (100.0)	—
<b>Age at baseline, y</b>	52.5 ± 9.7	52.0 ± 9.9	52.3 ± 9.8	.03
<b>Female sex, %</b>	48.5	48.2	48.4	.68
<b>Diabetes therapy, %</b>				.55
MNT group	9.8	9.5	9.7	
OHA group	61.6	61.5	61.5	
Insulin group	28.7	29.0	28.8	
<b>Test strips used per day</b>				
All subjects	1.0 ± 0.8	1.0 ± 0.8	1.0 ± 0.8	.39
MNT group	0.7 ± 0.5	0.7 ± 0.6	0.7 ± 0.6	
OHA group	0.8 ± 0.6	0.8 ± 0.6	0.8 ± 0.6	
Insulin group	1.4 ± 1.0	1.5 ± 1.0	1.4 ± 1.0	
<b>Prescription drug copayment, %</b>				<.001
0 [Reference], \$	8.7	4.8	7.1	
1-3	74.7	31.3	56.5	
4-9	16.1	62.3	35.5	
≥10	0.5	1.6	0.9	
<b>Median household income in 1999 based on block group 2000 census data, \$</b>	60 925 ± 23 353	60 689 ± 24 521	60 826 ± 23 842	.16
<b>Resides in a poverty area, %</b>	7.5	8.0	7.7	.31

\*Data are given as unadjusted mean ± SD unless otherwise indicated.

<sup>†</sup>Mantel-Haenszel  $\chi^2$  test for categorical variables and Spearman rank correlation coefficient for continuous variables.

MNT indicates medical nutrition therapy; OHA, oral hypoglycemic agents.

reduce test strip utilization (and SMBG frequency) in response to increasing test strip costs. Moreover, once a patient decides to initiate SMBG practice, he or she may be less price sensitive.

Our study findings are often counterintuitive and provide new insight into the effect of changes in healthcare policy, cost sharing, and provision of free services on this diabetes self-management practice. We expected that the elimination of the copayment would stimulate greater utilization, especially among those charged the most in the prepolicy period or among the poor. Paradoxically, the offering of free test strips following the implementation of SB64 did not increase SMBG above and beyond that expected by secular changes, despite historical evidence of price-elastic demand (based on the cross-sectional patterns). In fact, insulin users decreased test strip use slightly. Even economically disadvantaged patients and those

paying the most for test strips before the policy change did not take extra advantage of the free test strip offer.

The SMBG practice patterns formed during the copayment period (before the implementation of SB64) persisted, despite receiving free test strips for 2 years. These entrenched patterns suggest that monitoring frequency may be established at the initiation of SMBG practice, affected by cost and other previously demonstrated predictors such as socioeconomic status, inconvenience, physical discomfort associated with the fingersticks, disease severity, perceived health benefits, provider recommendations, and family support.<sup>8,9</sup> However, once individuals have habituated to a stable SMBG practice, it is likely to be less quickly altered by access to free test strips or by even slight increases in cost. It is important to note that the health economic concern that providing free test strips would lead to a spike in excessive utilization (eg,

multiple daily tests for oral agent only–treated patients) was unfounded; the prevalence of excessive use of SMBG continued to be dwarfed by the prevalence of underuse (<5% overutilized vs 40% did not practice at all in 2002 based on American Diabetes Association<sup>6</sup> clinical recommendations) after providing free test strips. Although the introduction of a small 20% coinsurance (\$8–\$12), the second policy change in the same population, resulted in a statistically significant decline in SMBG, it was too slight to be considered clinically relevant, and the decline did not differ by socioeconomic status.

Numerous cross-sectional studies have reported less frequent SMBG practice among patients lacking health insurance<sup>5,10–12</sup> and patients with an inability to pay.<sup>13</sup> The association with out-of-pocket costs (cost sharing) is also evident in studies<sup>4,7</sup> of fully insured managed care populations. Utilization of SMBG was shown to be more sensitive to out-of-pocket costs than other diabetes preventive services,<sup>4</sup> likely because demand is more price elastic when patients perceive a health service as optional.<sup>14</sup> There have been a few quasiexperimental or experimental studies. In one New England state, mandated policy change resulted in provision of free glucose meters, which was associated with increased SMBG use and with improved glycemic control,<sup>7</sup> although adherence to SMBG practice was of shorter duration among African Americans.<sup>15</sup> A study<sup>16</sup> of a policy change by Veterans Affairs guidelines that reduced the number of test strips provided free of charge reported an associated reduction in SMBG among oral agent–treated patients with DM but no change in glycemic control. Two randomized studies of Canadian reimbursement policies demonstrated that providing free test strips was associated with increased SMBG among insulin-treated patients<sup>17</sup> and among non–insulin-treated patients<sup>18</sup> but showed a significant improvement in glycemic control only in the former. Cost savings attributable to the receipt of free test strips differ substantially across studies, rendering the findings difficult to compare.

In a review of health insurance and healthcare utilization, Selby and Swain<sup>19</sup> noted that financial barriers negatively affect access among the poor. However, the evidence supporting higher price sensitivity for SMBG among the poor is inconsistent. A cross-sectional study<sup>3</sup> of SMBG in the KPNC population found significantly more price sensitivity among patients living in economically disadvantaged neighborhoods. However, the Translating Research Into Action for Diabetes study<sup>4</sup> of managed care across the United States failed to detect a significant interaction between income and copayment for test strips. The present study also failed to detect a differential response to increased or decreased cost sharing

among subjects with varying financial advantage; therefore, provision of free test strips did not reduce social disparities in SMBG utilization.

We hypothesized a “symmetric” price-elastic demand for test strips and predicted that the copayment elimination would lead to increased SMBG and that introduction of a similar-sized coinsurance would lead to a similar-sized decrease in practice. Instead, we observed no response to the introduction of free test strips but observed a statistically significant, albeit not clinically relevant, response to the introduction of coinsurance. Asymmetry in price-elastic demand may be explained by behavioral economic theory. Rabin<sup>20,21</sup> has described the behavioral economic theory of loss aversion as follows: “The displeasure from a monetary loss is greater than the pleasure from a same-sized gain.”<sup>21(p14)</sup> The elimination of the copayment (free test strips) and the subsequent out-of-pocket expense associated with the coinsurance may be viewed as a gain and as a subsequent loss. Statistically (albeit not clinically), our findings support Rabin’s theory, which would predict a greater response to the loss.

There are limitations of our study that need to be noted. This study relied on the number of dispensed test strips as a proxy for SMBG practice; while we can never know how test strips dispensed are actually used, this metric has been validated previously.<sup>22</sup> Also, because members were not notified of policy changes, we restricted the study of change to ongoing SMBG users who would have been exposed to the cost changes at the pharmacy checkout. Therefore, we could not study nonusers at baseline, who might have initiated test strip use when test strips became free. It is possible that the lack of increase in SMBG among prevalent users once test strips became free was due to a lack of awareness of the new policy. However, this is unlikely, because patients responded to the converse situation; they decreased SMBG when prices increased. The range in out-of-pocket charges for test strips was modest, and we cannot predict responses to greater policy-related cost changes. Our secondary analysis on the effect of free test strips on social disparities may have been somewhat limited by our exclusion of poor patients with federally subsidized benefits. However, we have a substantial number of patients with regular (ie, commercial) benefits who would be considered financially disadvantaged, so we should be able to address this issue. The true cost of test strips must include all costs, such as the discomfort of testing and inconvenience; the elimination of the copayment does not diminish the discomfort of testing, and the economic cost may be trivial relative to these other unmeasured costs. The practice of SMBG and the sensitivity to cost in this insured population might be different from

those observed in the general population. However, approximately one third of northern California's population receives its care from KPNC, and its membership's sociodemographic and self-reported health characteristics are consistent with those of the population in the surrounding geographic region.<sup>23-25</sup>

This study has several strengths worth noting. The longitudinal analysis of this natural experiment with control subjects who are unaffected by the policy change provides more reliable evidence regarding the effect of financial barriers (or their removal) than cross-sectional studies. Study findings are especially compelling because the exposure to policy change and to cost sharing was unrelated to individual characteristics (ie, exogenous), as it is applied uniformly to groups of members whose benefit coverage is determined by their employer group contract, and individuals cannot ordinarily choose their cost-sharing level. Given that most persons in the United States with DM have health insurance (approximately 93% of patients with DM<sup>26,27</sup>), the findings should be relevant to other insured populations. In addition, the uniform access to care in KPNC provides a unique setting to study the practice of SMBG relative to benefit structures, in contrast to population-based studies in which healthcare access and quality vary. Similar to the randomized Health Insurance Experiment,<sup>28</sup> we found less price elasticity than many cross-sectional investigations, likely because of uncontrolled adverse selection in the cross-sectional study designs and to timescale issues outlined herein.

## CONCLUSIONS

Given the need to control healthcare costs and to promote efforts to practice evidence-based medicine, SMBG guidelines and cost sharing are hotly debated in many managed care organizations and in countries with socialized medicine. Unexpectedly, providing free test strips did not lead to an unwanted spike in excessive utilization or even stimulate more guideline-adherent SMBG practice. This generous benefit cost the health plan in terms of lost cost-sharing revenues, without offset by measurable member health benefits or known downstream savings. The introduction of coinsurance shifted some of the economic burden back to the patient and slightly reduced demand (albeit unlikely causing clinical harm) in a population already underusing SMBG according to current clinical recommendations.<sup>3</sup> Utilization predictions are not always intuitive; we found entrenched copayment utilization patterns that persisted into the free test strip period and evidence suggestive of asymmetric price-elastic demand

### Take-away Points

We evaluated changes in utilization of test strips for self-monitoring of blood glucose levels across the following 2 cost-sharing thresholds: (1) from a period of copayments to a period of free strips and then (2) from the period of free strips to a period of coinsurance.

- Findings included slightly reduced utilization in response to increased cost sharing but unchanged utilization in response to free test strips.
- Price-elastic patterns formed before and during the period of copayments persisted, despite receiving free test strips for 2 years.
- Cross-sectional analyses should not be used to predict utilization changes in response to changes in benefit policies.

and loss aversion. In conclusion, cross-sectional relationships are likely not useful in forecasting utilization in the face of rapidly evolving benefit policies.

Convincing patients to adequately self-manage their DM is a daunting public health challenge. Cost sharing is implemented to minimize excessive utilization but is a blunt instrument, unintentionally also hindering recommended utilization. Because most patients underutilize and rarely overutilize SMBG (based on current clinical guidelines) even when receiving free test strips, the usefulness of creating additional financial barriers through cost sharing needs to be questioned. Future increases in cost sharing for medications may impose additional financial barriers that will further tip the balance, and patients may react more strongly to subsequent increases in out-of-pocket costs for SMBG. However, SMBG test strips pose a substantial cost to healthcare systems; therefore, future clinical guidelines need to carefully weigh the value of this practice against competing health expenditures.

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