POPULATION HEALTH MANAGEMENT
Volume 18, Number 6, 2015

DOI: 10.1089/pop.2014.0154

Automated Telephone Self-Management Support for Diabetes in a Low-Income Health Plan: A Health Care Utilization and Cost Analysis

Judy Quan, PhD,[1,2] Alexandra K. Lee, MSPH,[2] Margaret A. Handley, PhD, MPH,[1–3]
Neda Ratanawongsa, MD, MPH,[1,2] Urmimala Sarkar, MD,[1,2]
Samuel Tseng, PhD,[4] and Dean Schillinger, MD[1,2]

Abstract

The objective was to determine whether automated telephone self-management support (ATSM) for low-income, linguistically diverse health plan members with diabetes affects health care utilization or cost. A government-sponsored managed care plan for low-income patients implemented a demonstration project between 2009 and 2011 that involved a 6-month ATSM intervention for 362 English-, Spanish-, or Cantonese-speaking members with diabetes from 4 publicly funded clinics. Participants were randomized to immediate intervention or a wait-list. Medical and pharmacy claims used in this analysis were obtained from the managed care plan. Medical claims included hospitalizations, ambulance use, emergency department visits, and outpatient visits. In the 6-month period following enrollment, intervention participants generated half as many emergency department visits and hospitalizations (rate ratio 0.52, 95% CI 0.26, 1.04) compared to wait-listed participants, but these differences did not reach statistical significance ($P = 0.06$). With adjustment for prior year cost, intervention participants also had a nonsignificant reduction of $26.78 in total health care costs compared to wait-listed individuals ($P = 0.93$). The observed trends suggest that ATSM could yield potential health service benefits for health plans that provide coverage for chronic disease patients in safety net settings. ATSM should be further scaled up to determine whether it is associated with a greater reduction in health care utilization and costs. (*Population Health Management* 2015;18:412–420)

Introduction

HEALTH CARE COSTS FOR INDIVIDUALS with diabetes were estimated to be $176 billion in the United States in 2012.[1] Individuals who have diagnosed diabetes have 2.3 times higher health care costs than individuals who do not have diabetes. Health care costs for diabetes are expected to continue an upward trend as the prevalence of diabetes increases and newer, more expensive therapies come to the market.[2,3]

Diabetes disproportionately affects individuals of low socioeconomic status, lower levels of education, and minority race/ethnicity.[4] In these populations, limited health literacy (LHL) and limited English proficiency (LEP) often hinder individuals' access to and quality of care, resulting in poorer health outcomes.[5–10] With the expansion of Medicaid and the creation of low-cost health insurance exchanges, managed care plans will have an increased responsibility to provide culturally sensitive, language-concordant care to low-income people while controlling health care costs.[11–13] A recent paper from the Institute of Medicine describes how health systems need to experiment and invest in training, innovation, and personnel to transform their services to better accommodate the needs of populations with LHL.[14] Several studies have shown the positive impacts of diabetes self-management support among vulnerable populations, especially with regard to patient-centered outcomes such as health-related quality of life.[15–18] Automated telephone self-management support (ATSM) has been highlighted by the US Department of Health and Human Services as a potentially viable strategy to augment care for LHL and LEP populations with chronic conditions.[19]

[1]Division of General Internal Medicine at San Francisco General Hospital and Trauma Center, University of California, San Francisco, California.
[2]UCSF Center for Vulnerable Populations at San Francisco General Hospital and Trauma Center, University of California, San Francisco, California.
[3]Division of Preventive Medicine and Public Health, Department of Epidemiology and Biostatistics, University of California, San Francisco, California.
[4]Philip R. Lee Institute for Health Policy Studies, University of California, San Francisco, California.

However, few studies have rigorously evaluated the effects of diabetes self-management support on the health care costs among low-income populations.[20] One randomized controlled trial of telemedicine for Medicare beneficiaries with diabetes in a medically underserved area of New York State found no difference in health care costs over 5 years.[21] A randomized controlled trial at a federally qualified health center serving primarily Latinos in Denver, Colorado, aimed to lower low-density lipoprotein (LDL) among diabetes patients through nurse-run telephone-based outreach.[22] The authors reported significant reductions in inpatient costs and total health care costs, but the linear regression models used in the analysis did not adequately address the skewed distribution of the cost data.[23]

Another study, Project Dulce in San Diego, California, provided nurse care management and peer education via promotoras for low-income diabetes patients enrolled in County Medical Services.[24] Findings indicated that Project Dulce participants had significantly higher health care costs, which was attributed largely to nearly 2-fold higher pharmacy-related costs. Nonetheless, because of improvements in risk factor control, Project Dulce was found to be reasonably cost-effective using a cost-utility framework, in which costs per quality-adjusted life year (QALY) ranged from \$10,141 to \$69,587, depending on the type of insurance coverage.[25] However, this analysis used a historical cohort as a comparison group, and Project Dulce participants were likely to be much more motivated and engaged than a representative sample. Finally, the investigators previously performed a cost-effectiveness analysis of multilingual ATSM implemented in a public hospital system's clinics and found that the annual cost of the ATSM intervention per QALY gained, relative to a contemporaneous control group, was between \$29,402 and \$72,407.[26]

The Self-Management Automated and Real-Time Telephonic Support Study (SMARTSteps/Pasos Positivos/明智進步計劃) was a quasi-experimental study of language-concordant ATSM for low-income individuals with diabetes within an urban public health care system, carried out in collaboration with a low-income, government-sponsored health plan. The 27-week (6-month) intervention has previously been reported to improve patients' health-related quality of life and specific health behaviors, but was found to have no impact on cardiometabolic measures relative to wait-listed participants (NIH trial registration NCT00683020).[16] The purpose of the current study is to compare the health care utilization and costs of individuals in the ATSM intervention to those of wait-listed individuals during the 6-month period following randomization. This study took place within the University of California, San Francisco (UCSF) Collaborative Research Network (http://accelerate.ucsf.edu/community/sfbaycrn), a primary care practice-based research network in the Northern California area, and received approval from the UCSF Institutional Review Board.

Methods

Study design and participants

The SMARTSteps intervention, study design, and recruitment details have been reported in detail previously.[16,27] Briefly, participants were recruited from 4 clinics in the Community Health Network of San Francisco (CHNSF) from April 2009 to March 2011. Individuals had to have diabetes, be 18 years or older, be a covered member of the San Francisco Health Plan (SFHP), speak English, Spanish, or Cantonese, and have visited one of 4 CHNSF clinics in the past 24 months.

The SFHP is a health insurance plan that was created in 1994 and is operated by the San Francisco Health Authority, an agency established by the County of San Francisco. The SFHP's 3 programs—Medicaid, Healthy Workers (for in-home supportive services employees), and Healthy Kids—each have unique revenue sources and beneficiaries. Almost 47% of SFHP members are younger than 18 years of age; 36% are between 19 and 65 years of age, and 17% are older than 65 years of age. Only 39% of SFHP members identify English as their primary language: 33% speak Chinese, 18% are Spanish-speaking, and the remaining 9% speak other languages, including Russian and Vietnamese. Because SFHP wanted to improve its performance measures for diabetes care, the plan's leadership made a decision to carry out a demonstration project involving multilingual ATSM, given its promising results in similar patient populations with diabetes.[26,28,29]

SFHP members with diabetes who participated in SMARTSteps were randomized to one of 4 groups: SMARTSteps-ONLY, SMARTSteps-PLUS, or a wait-list for either intervention. The intervention focused on improving self-management related to behaviors such as taking medications appropriately, eating a healthy diet, exercising and being physically active, depressive symptoms, and checking one's blood sugar level and one's feet for wounds and sores. The SMARTSteps-ONLY intervention consisted of 27 weekly automated telephone calls in the participant's preferred language with rotating questions and health education regarding diabetes self-care. Participants with out-of-range responses also received a follow-up call from a SFHP-trained, lay health coach for behavioral action planning. Those randomized to SMARTSteps-PLUS also could receive additional callbacks if the participant had evidence of poor monthly adherence to cardiometabolic medications as indicated by SFHP pharmacy claims data. These additional callbacks were intended to promote self-disclosure of medication nonadherence and to troubleshoot barriers such as confusion about doses or frequency of medications, forgetfulness, concerns about side effects, or competing health beliefs. Telephone health coaches also encouraged participants in collaborative goal-setting and action planning to enhance medication regimens and adherence. Individuals who were wait-listed in the 2 arms began the intervention 6 months after randomization. The wait-list allowed for a rigorous evaluation with a randomized control group while ensuring that all participants eventually would receive the intervention. Active enrollment in the SFHP was a requirement for study participation because SFHP staff delivered the intervention. If individuals had a lapse in SFHP coverage that exceeded 1 month, the member was discontinued from the study, both for intervention and wait-list groups.

Outcomes

Because the investigators' prior research revealed similar benefits for SMARTSteps-ONLY and SMARTSteps-PLUS participants,[16] for the current analysis these groups were combined and compared to the combined wait-listed groups.

Baseline demographic and cardiometabolic characteristics were extracted from telephone surveys and the patients' electronic health record. Medical and pharmacy claims were obtained from the SFHP for each study participant for the year prior to study enrollment and the 6 months following randomization. The investigators examined 4 count-based measures of health care utilization: number of hospitalizations, days spent in hospital, number of emergency department visits, and number of outpatient visits.

Given that the SFHP is a managed care plan that maintains a fee schedule based on negotiated rates across health systems, health care costs for each medical encounter were estimated. To estimate outpatient, emergency department, and ambulance costs, the investigators linked the 2012 California Medicaid fee schedule to each claim by Current Procedural Terminology code.[30] Hospitalization costs were estimated at $2000 per diem based on average costs provided by the SFHP. Pharmacy claims contained the price paid by the SFHP for each prescription; however, this cost did not include any co-payments that might have been paid by the patient (these co-payments tended to be $5 or less, and often were zero). Pharmacy claims were present for 342 of 362 participants, and analyses followed the principle of intent-to-treat. However, individuals with Medicare insurance were deleted from analyses involving pharmacy data because these patients had alternative pharmacy benefits for which no cost information was available. Because information on health care utilization was contingent on enrollment in SFHP, health care utilization and costs were modeled as rates, with time enrolled in SFHP in the denominator.

Statistical analysis

Baseline characteristics of the active intervention and wait-listed groups were compared using *t* tests or Wilcoxon rank-sum tests for continuous variables and chi-square tests or Fisher Exact tests for categorical variables.

To compare health care utilization between the intervention and wait-listed participants, the investigators employed negative binomial regression with robust standard errors for each measure of health care utilization. Negative binomial regression is used for count data when the Poisson assumption that the mean is equal to the variance is violated.[31] Because of concerns that the intervention and wait-listed groups were different with respect to prior utilization, analyses were performed both without adjustment, as is standard for most randomized trials, and adjusted for the prior year's rate of utilization. Data cleaning, descriptive statistics, and negative binomial regression were performed in SAS, version 9.2 (SAS Institute Inc., Cary, NC).

A 2-part model was used to estimate the marginal effect of the intervention on costs incurred during the 6 months following randomization.[23,32] The 2-part model takes into account 2 salient characteristics of health care cost. First, health care cost is concentrated on zero because some patients incur no costs (ie, zero mass). Second, the cost distribution is quite skewed because a small portion of patients incur large costs. The marginal effect is defined as the change in cost attributable to the intervention. The investigators derived a closed-form expression for the point estimate of the marginal effect from the 2-part model. In both parts of the model, the independent variable was SMARTSteps status (intervention or wait-list); analyses were performed both unadjusted and adjusted for prior year cost. In the first part of the model, a logistic regression was used to estimate the probability of incurring any cost. In the second part of the model, the investigators estimated costs among participants who had costs greater than zero. Log-transformed costs were used to account for skewness. The investigators used the ordinary least squares regression model in estimation and employed the smearing estimate to adjust for the possible downward bias when transforming the resulting estimate back to a dollar amount.[33] However, there is no closed-form expression for the standard error of the marginal effect. Therefore, the investigators used bootstrapping to estimate the standard error of the marginal effect and then tested whether the marginal effect statistically differed from zero.[23] The 2-part model and bootstrapping were performed using STATA 12 (StataCorp LP, College Station, TX).

Results

Table 1 displays the baseline sociodemographic and medical characteristics of the SMARTSteps participants. At baseline, there were no significant differences in demographic characteristics, cardiometabolic measures, or health care utilization in the prior year between the intervention and wait-list groups. At the time of enrollment, nearly a third of participants had poor glycemic control (HbA1c $>8\%$). Intervention patients had more outpatient visits in the previous year compared to wait-listed patients ($P=0.05$), but both groups were high utilizers of the outpatient services. There were no statistically significant differences in hospitalizations and emergency department visits at baseline. The hospital costs in the prior year for the wait-listed patients were nearly double those of the intervention patients; however, this difference was not statistically significant ($P=0.08$). Costs from the emergency department, ambulance, outpatient, pharmacy, and total costs were similar between the 2 groups. More than 70% of participants were insured through Healthy Workers SF (a county-sponsored insurance program for low-income workers), and 23% through Medicaid, with similar payer distribution between intervention and wait-list groups.

The distribution of health care costs over the subsequent 6 months is shown in Table 2. More than 75% of participants incurred no hospital, ambulance, or emergency department costs during the 6-month study period. For all medical costs, the mean cost was far greater than the 75th percentile of cost, indicating a highly skewed distribution.

With respect to differences in health care utilization between the intervention and wait-list groups over the 6 months after enrollment (Table 3), the intervention group had half the rate of hospitalizations as the wait-list group, with a mean of 0.04 (range: 0–2) for the intervention group and 0.08 (range: 0–3) for the wait-list group. Similarly, the rate of emergency department visits among the intervention group was 0.51 times lower than the rate among the wait-listed group, with a mean of 0.14 (range: 0–4) for the intervention group and 0.26 (range: 0–4) for the wait-list group. However, neither of these differences were statistically significant ($P=0.23$ and 0.06, respectively), and the significance level was similar when these 2 outcomes were combined (rate ratio 0.52, $P=0.06$). Adjustment for prior

Table 1. Baseline Sociodemographic and Medical Characteristics of SMARTSteps Participants, n = 362

	Intervention (n = 182)	*Wait-list (n = 180)*	P *value*
Age, mean (SD)	55.5 (8.4)	54.1 (8.4)	0.12‡
Female, n (%)	138 (75.8)	120 (66.7)	0.05
Race/Ethnicity, n (%)			0.69†
Latino	45 (24.7)	36 (20.0)	
African American	10 (5.5)	15 (8.3)	
Asian/Pacific Islander	106 (58.2)	109 (60.6)	
White	18 (9.9)	16 (8.9)	
Other	3 (1.6)	4 (2.2)	
Language of Intervention, n (%)			0.98
English	60 (33.0)	61 (33.9)	
Cantonese	91 (50.0)	89 (49.4)	
Spanish	31 (17.0)	30 (16.7)	
Hemoglobin A1c >8.0%, n (%)	51 (29.0)	46 (26.7)	0.64
Hemoglobin A1c, mean (SD)	7.9 (1.7)	7.6 (1.4)	0.20‡
Systolic Blood Pressure, mean (SD)	128.5 (17.3)	128.8 (17.8)	0.87‡
Hospitalizations in year prior to study n (%)*			0.29
0	175 (96.1)	166 (92.2)	
1	5 (2.8)	9 (5)	
More than 1	2 (1.1)	5 (2.8)	
Emergency Dept visits in prior year n (%)*			0.57
0	158 (86.8)	150 (83.3)	
1	12 (6.6)	13 (7.2)	
More than 1	12 (6.6)	17 (9.4)	
Outpatient visits in prior year, mean (SD)*	16.6 (12.3)	14.2 (9.9)	0.05
Costs in prior year, $, mean (SD)			
Hospital	354.35 (1975)	680.68 (3041)	0.08‡
Emergency Department	79.03 (251)	107.84 (545)	0.44‡
Ambulance	6.00 (31)	9.89 (95)	0.58‡
Outpatient	1196.99 (2248)	1047.11 (1483)	0.16‡
Pharmacy	1458.39 (1569)	1242.09 (1011)	0.13‡
Total	3123.28 (4576)	3113.53 (4230)	0.98‡
Financial Class of Insurance n (%)			0.93†
Medicaid	42 (23.1)	41 (22.8)	
Healthy Workers SF	131 (72.0)	129 (71.7)	
Medicare	7 (3.8)	9 (5.0)	
Commercial/Uninsured	2 (1.1)	1 (0.6)	
Enrolled in San Francisco Health Plan during 6-month study period, n (%)	167 (91.8)	161 (89.4)	0.45

*Annualized rate based on eligibility in prior year

P values derived from chi-square tests or Fisher exact tests (the latter indicated with †) for categorical variables, *t* tests for interval variables if normally distributed, and Wilcoxon rank-sum tests if interval variables not normally distributed (as indicated with ‡).

SD, standard deviation

Table 2. Distribution of Health Care Costs (in Dollars) by Category During 6-Month Period Following SMARTSteps Enrollment, n = 362

		mean	*25th percentile*	*median*	*75th percentile*	*maximum*
Hospitalization	Intervention	398	0	0	0	40568
	Wait-list	1309	0	0	0	152501
Ambulance	Intervention	4	0	0	0	515
	Wait-list	10	0	0	0	391
Emergency Department	Intervention	40	0	0	0	2120
	Wait-list	64	0	0	0	3569
Outpatient	Intervention	1186	130	300	543	55284
	Wait-list	1011	139	288	633	55213
Pharmacy	Intervention	830	415	785	1021	9566
	Wait-list	678	287	629	967	3685
All costs combined	Intervention	2489	688	1137	1626	99173
	Wait-list	3136	578	1084	1630	156577

Table 3. Adjusted and Unadjusted Rate Ratios of Health Care Utilization in the 6 Months Following Randomization in SMARTSteps, Comparing Intervention to Wait-List, Using Negative Binomial Regression with Robust Standard Errors

	Unadjusted			*Adjusted for prior year utilization**		
	Rate Ratio	(95% Confidence Interval)	*P* value	Rate Ratio	(95% Confidence Interval)	*P* value
Hospitalizations (number of visits)	0.50	(0.16, 1.54)	0.23	0.55	(0.17, 1.54)	0.33
Days in Hospital	0.74	(0.12, 4.59)	0.75	0.19	(0.03, 1.40)	0.10
Emergency Department (number of visits)	0.51	(0.26, 1.02)	0.06	0.73	(0.37, 1.45)	0.37
Emergency Department and Hospitalizations	0.52	(0.26, 1.04)	0.06	0.60	(0.30, 1.17)	0.14
Outpatient Visits	0.98	(0.80, 1.21)	0.85	0.94	(0.79, 1.12)	0.48

*Hospitalizations, Days in Hospital, Emergency Department, and combined Emergency Department and Hospitalizations were adjusted with a binary variable (any vs. no visits/days in prior year); outpatient visits were adjusted using quartiles of visits in prior year

year's health care utilization, measured as visits, slightly attenuated both the rate of emergency department visits and hospitalizations, but the salutary effect of the intervention on number of hospital days was greatly amplified after adjustment for the prior year's number of hospital days. In contrast, the rate of outpatient visits was essentially the same between groups both before and after adjustment for prior visits.

The results of the 2-part model in general yielded estimates of lower costs among the intervention group compared to the wait-list group, although again these reductions did not reach statistical significance (Table 4). Participants in the intervention group incurred lower hospital costs in the unadjusted model and in the model adjusted for prior cost ($P=0.68$ and 0.73, respectively). There was no meaningful difference in either emergency department or ambulance costs ($P=0.49$ and 0.38, respectively). For outpatient care, individuals in the intervention incurred lower costs than those on the wait-list in the unadjusted model and in the adjusted model, but these reductions also were not statistically different ($P=0.80$ and 0.72, respectively). With respect to pharmacy costs, the unadjusted model found that pharmacy costs were higher among intervention participants compared to wait-listed participants ($P=0.03$). After adjustment for prior year pharmacy cost, this difference was slightly lower but was only marginally statistically significant ($P=0.05$). When examining all costs combined, participation in the SMARTSteps intervention was associated with $8.58 higher costs in the unadjusted model but $26.78 lower costs in the adjusted model, but neither of these was statistically significant ($P=0.98$ and 0.93, respectively).

Discussion

Diabetes is a rapidly growing problem; both the crude and age-adjusted prevalence continues to rise unabated, and it has been estimated that annual diabetes-related spending will increase from $113 billion in 2009 to $336 billion by 2034.[3] With the expansion of Medicaid in 2014 and the availability of health insurance plans for lower income people, medical care will be more accessible for millions of individuals who previously were uninsured. Multiple studies have examined the population that will be newly eligible for Medicaid to assess their potential health care utilization.[34–36] One study characterized the utilization patterns of a homeless population in Boston and found that the majority of these patients had mental illness, substance use disorders, and multiple comorbid conditions, such as diabetes.[34] These homeless

Table 4. Marginal Effect on Costs, in Dollars, Comparing Intervention to Wait-List, for the 6-Month Period Following Randomization in SMARTSteps, n = 362

	Unadjusted			*Adjusted for prior year costs**		
	Point Estimate ($)	(95% Confidence Interval)	*P* value	Point Estimate ($)	(95% Confidence Interval)	*P* value
Hospitalization	−12.48	(−72.41, 47.44)	0.68	−42.10	(−280.56, 196.36)	0.73
Ambulance	0.13	(−0.16, 0.43)	0.38	0.81	(−2.46, 4.09)	0.63
Emergency Department	1.41	(−2.57, 5.38)	0.49	0.67	(−6.50, 7.84)	0.85
Outpatient	−34.74	(−296.70, 227.21)	0.80	−46.52	(−301.32, 208.29)	0.72
Pharmacy	165.14	(21.23, 309.06)	0.03	162.93	(−2.54, 328.40)	0.05
All costs	8.58	(−640.02, 657.18)	0.98	−26.78	(−610.57, 557.01)	0.93

*Hospital, Ambulance, and Emergency Department costs were adjusted with a binary variable (any vs. no prior costs); Outpatient, Pharmacy, and All costs were adjusted with a categorical variable.

Note: The sum of the point estimates for all categories of cost is not equal to the point estimate for all costs because of the log-transformation used in the analysis.

individuals had 3.8 times higher medical expenditures than the average Medicaid recipient. Decker et al's analysis of the National Health and Nutrition Examination Survey 2007–2010 found that, compared to those enrolled in Medicaid, a smaller proportion of the uninsured had hypertension, hypercholesterolemia, or diabetes. Uninsured individuals with those conditions were less likely to be aware of them, and thus could require more complex medical care.[36]

These studies highlight the fact that the uninsured population is heterogeneous and individuals could enter Medicaid managed care plans with vastly different health care needs. It also has been well established that the prevalence of diabetes, diabetes complications, and mortality from diabetes are all higher among minority race and low-income populations, a burden largely borne by the Medicaid program.[4,37] These health disparities have the potential to be magnified by inadequate access to or quality of medical care among racial minorities.[38,39] Indeed, there have been few studies explicitly targeting diabetes interventions to vulnerable populations, and those interventions that have been done have not been evaluated for their effects on health care utilization and costs.[37] The current study is the first to use an appropriate study design with an evidence-based intervention in partnership with a low-income health plan to evaluate the effects on utilization and health care costs.

Although a great number of private-sector companies have developed technology-enabled diabetes self-management tools,[40] few, if any, have been evaluated in terms of costs or cost-benefit. The current study's methodology could serve as a model to feasibly study the cost aspect of diabetes self-management support interventions.[41]

A robust pattern of reductions in health care utilization and costs was observed for participants who received the SMARTSteps intervention compared to those who were wait-listed. The intervention group had half the rate of hospitalizations (rate ratio 0.50, 95% CI 0.16, 1.54) and half the rate of emergency department visits (rate ratio 0.51, 95% CI 0.26, 1.02) as the wait-list group. When prior year costs were controlled for, participation in the SMARTSteps intervention was associated with a $42.10 and $46.52 reduction in hospitalization and outpatient costs over 6 months, respectively. These meaningful results, although not statistically significant, suggest that the SMARTSteps program could yield a positive economic impact for Medicaid and low-income health plans, and that a larger-scale program is needed to generate more conclusive findings.

Few studies have explored utilization patterns and costs of care for patients with diabetes receiving self-management support. In a randomized study conducted in the Veterans Affairs, participants who received a 1-year intervention of automated telephone diabetes management support were more likely to utilize podiatry clinics and diabetes specialty clinics and to have a cholesterol test, suggesting that increasing patients' knowledge and ability to navigate the health care system may result in increased utilization. No other differences in utilization patterns or costs were reported.[42] Another study of telemedicine conducted among 1665 Medicare beneficiaries found no significant differences in health care costs despite significant reductions in hemoglobin A1c, LDL cholesterol, and blood pressure.[18,21] The average age of participants in that study was 71 years, so it is possible that other chronic conditions were driving their health care costs.[43] Project Dulce, a study of Latinos with diabetes in southern California, found a marginally nonsignificant lower cost of $688 for hospital and emergency department costs combined, no difference in outpatient costs, and $1539 higher pharmacy costs for program participants over an 18-month period compared to a historical (nonrandom) control group.[25] Finally, a recent study of a diabetes management program delivered via text message for members of the University of Chicago's health plan found significant reductions in health care costs; however, their comparison group was plan members who refused to participate in the intervention.[44] Although the current study observed very promising trends related to utilization and, to a lesser extent, costs, it is likely that this study was underpowered to detect small to moderate differences in utilization and costs, as more than 85% of SMARTSteps participants had no hospitalization or emergency department visit in the year prior to the study. The relative infrequency of such events may have hindered the ability to detect modest differences over a relatively short time period.

The primary strength of this study is the fact that it was carried out in a real-world setting, embedded in the operations of a health plan exploring the potential benefits of employing a communication innovation for its members with diabetes. This greatly enhances the external validity of the findings. Second, the use of a contemporaneous, randomly selected control group to test the effect of the intervention greatly enhances the internal validity of the findings. In addition, the economic analysis employed advanced statistical methods to account for unique distributions of health care utilization and cost data. The advantage of using the 2-part model for health care costs can be appreciated by comparing the difference of the mean total costs from Table 2 ($2,489 - $3,136 = −$647) to the estimate from the model ($8.58). This comparison suggests a simple subtraction of means between the intervention and control groups would have overestimated the impact of the SMARTSteps program on reducing total health care cost. Nevertheless, these results from the 2-part model were real from the perspective of the SFHP, even if they did not reach sufficient statistical significance to be scientifically valid. Finally, this utilization and cost analysis of ATSM for diabetes is, to the investigators' knowledge, the only study to rigorously examine the effects of a multilingual diabetes intervention.

There are several important limitations to this analysis. The first limitation, as mentioned, is that the study likely was underpowered for economic outcomes, as the sample size was generated to detect differences in patient-centered outcomes, not economic outcomes.[16] In their previous cost-effectiveness analysis involving a prior version of ATSM,[26] the investigators were able to focus on a range of values that met the threshold for cost-effectiveness. However, the current study did not evaluate cost-effectiveness, but differential costs and utilization. Because the literature does not support a single threshold for these domains, the investigators are unable to calculate a sample size for a future trial with any certainty.

Second, as is true for all utilization of care studies, the measures used in this study could not distinguish between inappropriate and appropriate utilizations. The one area of consensus regarding inappropriate utilization is in low-triage emergency room visits (eg, nonurgent visits). Although the

investigators have previously reported on this outcome,[45] the sample size was too small to assess the impact of the intervention on low-triage emergency room visits.

Third, this analysis relied on estimated costs using California's Medicaid fee schedule and a per diem rate for hospitalizations as determined by SFHP, a method that does not capture the intensity of hospital treatment. The investigators recognize that this method does not account for several factors that could impact the health plan's costs, such as whether providers were in or out of the health plan's preferred network.

Fourth, this study only examined health care costs and utilization during the 6 months following randomization. Because the investigators employed the wait-list variant of the stepped-wedge design to align with SFHP's service needs,[46] in which all participants eventually received the intervention, it was not possible to observe a randomized, unexposed control group for a longer period of time. Reductions in utilization and costs resulting from self-management support could accrue over a longer time frame than this study was able to capture. This was a necessary trade-off in carrying out this study with the health plan as a partner. Insofar as the intervention and study design involved an exposure time of only 6 months, the results likely underestimate the economic and health services benefits of self-management support, most of which accrue because of avoided long-term complications such as kidney failure, amputations, and cardiovascular disease. Although a prior manuscript from this study[16] reported on the behavioral and functional benefits of the intervention, the current study could not determine whether such improvements could offset economic burdens of diabetes in the future.

Fifth, the investigators were unable to obtain pharmacy costs for the few participants ($<5\%$) who had Medicare insurance. However, these participants were equally distributed between the wait-list and intervention groups and were excluded from analyses involving pharmacy cost.

Sixth, this study did not attempt to weigh the costs of the intervention against its cost offsets; such an analysis would be beyond the scope of the current paper. Finally, the generalizability of these results may be limited given the unique study population and setting. However, the investigators believe these findings are relevant to safety net health systems, as well as to Medicaid and low-income health plans, and possibly to chronic conditions beyond diabetes.

ATSM is a unique innovation to provide support to the growing population of linguistically diverse individuals with diabetes in Medicaid and other low-income health plans. Because it uses low-cost technology as well as trained health coaches as the main vehicles for support, rather than nurses or other clinicians, there is the potential for low maintenance costs from a health plan's perspective, once the ATSM program is established by a plan or health system. Controlling costs stemming from chronic diseases such as diabetes, while maintaining high quality and patient-centered care, will be crucial for Medicaid managed care plans and other insurance plans participating in the health care exchanges.

Although not conclusive, this randomized study adds to the literature on the impact of innovative, health information technology-based self-management support programs on utilization and cost outcomes. It is now well established that ATSM improves health-related quality of life and health promoting behaviors among low-income patients with diabetes.[16,29] The positive trends observed in the current study suggest that ATSM should be scaled up to include larger numbers of patients and a longer period of follow-up time to determine whether it also can affect health care utilization and reduce costs for linguistically-diverse, low-income individuals with diabetes.

Author Disclosure Statement

Drs. Quan, Handley, Ratanawongsa, Sarkar, Tseng, Schillinger, and Ms. Lee declared no conflicts of interest with respect to the research, authorship, and/or publication of this article.

The authors received the following financial support for the research, authorship, and/or publication of this article: This publication was supported by the Family Fund for Discovery and Education of the UCSF Diabetes Center, the Health Delivery Systems Center for Diabetes Translational Research (CDTR) funded through National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) grant P30-DK092924; the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH), through UCSF-CTSI Grant Number UL1 TR000004; Centers for Disease Control and Prevention (CDC) Grant Numbers 3U32DP922744-05W1 and 5U58DP002007-03; and the Agency for Healthcare Research and Quality (AHRQ) grants R18HS017261 and 1R03HS020684-01 (NIH trial registration NCT00683020). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of AHRQ, CDC, or the NIH.

References

1. American Diabetes Association. Economic costs of diabetes in the U.S. in 2012. Diabetes Care. 2013;36:1033–1046.
2. Boyle JP, Thompson TJ, Gregg EW, Barker LE, Williamson DF. Projection of the year 2050 burden of diabetes in the US adult population: dynamic modeling of incidence, mortality, and prediabetes prevalence. Popul Health Metr. 2010;8:29.
3. Huang ES, Basu A, O'Grady M, Capretta JC. Projecting the future diabetes population size and related costs for the U.S. Diabetes Care. 2009;32:2225–2229.
4. Beckles GL, Chou CF, Centers for Disease Control and Prevention (CDC). Diabetes - United States, 2006 and 2010. MMWR Surveill Summ. 2013;62(suppl 3):99–104.
5. Agency for Healthcare Research and Quality. 2010 National Healthcare Disparities Report. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2010.
6. Davis TC, Wolf MS, Bass PF 3rd, et al. Literacy and misunderstanding prescription drug labels. Ann Intern Med. 2006;145:887–894.
7. Fernandez A, Schillinger D, Warton EM, et al. Language barriers, physician-patient language concordance, and glycemic control among insured Latinos with diabetes: The Diabetes Study of Northern California (DISTANCE). J Gen Intern Med. 2011;26:170–176.
8. Sarkar U, Karter AJ, Liu JY, Moffet HH, Adler NE, Schillinger D. Hypoglycemia is more common among type 2 diabetes patients with limited health literacy: The Dia-

betes Study of Northern California (DISTANCE). J Gen Intern Med. 2010;25:962–968.
9. Schillinger D, Barton LR, Karter AJ, Wang F, Adler N. Does literacy mediate the relationship between education and health outcomes? A study of a low-income population with diabetes. Public Health Rep. 2006;121:245–254.
10. Schillinger D, Bindman A, Wang F, Stewart A, Piette J. Functional health literacy and the quality of physician-patient communication among diabetes patients. Patient Educ Couns. 2004;52:315–323.
11. Goldman LE, Handley M, Rundall TG, Schillinger D. Current and future directions in Medi-Cal chronic disease care management: a view from the top. Am J Manag Care. 2007;13:263–268.
12. Martin LT, Parker RM. Insurance expansion and health literacy. JAMA. 2011;306:874–875.
13. Rittenhouse DR, Robinson JC. Improving quality in Medicaid: the use of care management processes for chronic illness and preventive care. Med Care. 2006;44:47–54.
14. Brach C, Keller D, Hernandez LM, et al. Ten attributes of health literate health care organizations. Washington, DC: Institute of Medicine; 2012.
15. Philis-Tsimikas A, Walker C, Rivard L, et al. Improvement in diabetes care of underinsured patients enrolled in Project Dulce: a community-based, culturally appropriate, nurse case management and peer education diabetes care model. Diabetes Care. 2004;27:110–115.
16. Ratanawongsa N, Handley MA, Sarkar U, et al. Diabetes health information technology innovation to improve quality of life for health plan members in urban safety net. J Ambul Care Manage. 2014;37:127–137.
17. Rothman RL, DeWalt DA, Malone R, et al. Influence of patient literacy on the effectiveness of a primary care-based diabetes disease management program. JAMA. 2004;292: 1711–1716.
18. Shea S, Weinstock RS, Teresi JA, et al. A randomized trial comparing telemedicine case management with usual care in older, ethnically diverse, medically underserved patients with diabetes mellitus: 5 year results of the IDEATel study. J Am Med Inform Assoc. 2009;16:446–456.
19. Committee on Quality of Health Care in America. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academies Press; 2001.
20. Boren SA, Fitzner KA, Panhalkar PS, Specker JE. Costs and benefits associated with diabetes education: a review of the literature. Diabetes Educ. 2009;35:72–96.
21. Palmas W, Shea S, Starren J, et al. Medicare payments, healthcare service use, and telemedicine implementation costs in a randomized trial comparing telemedicine case management with usual care in medically underserved participants with diabetes mellitus (IDEATel). J Am Med Inform Assoc. 2010;17:196–202.
22. Fischer HH, Eisert SL, Everhart RM, et al. Nurse-run, telephone-based outreach to improve lipids in people with diabetes. Am J Manag Care. 2012;18:77–84.
23. Deb P, Manning W, Norton E. Preconference Course: Modeling Health Care Costs and Counts. Minneapolis, MN: American Society for Healthcare Engineering; 2012.
24. Gilmer TP, Philis-Tsimikas A, Walker C. Outcomes of Project Dulce: a culturally specific diabetes management program. Ann Pharmacother. 2005;39:817–822.
25. Gilmer TP, Roze S, Valentine WJ, et al. Cost-effectiveness of diabetes case management for low-income populations. Health Serv Res. 2007;42:1943–1959.
26. Handley MA, Shumway M, Schillinger D. Cost-effectiveness of automated telephone self-management support with nurse care management among patients with diabetes. Ann Fam Med. 2008;6:512–518.
27. Ratanawongsa N, Handley MA, Quan J, et al. Quasi-experimental trial of diabetes Self-Management Automated and Real-Time Telephonic Support (SMARTSteps) in a Medicaid managed care plan: study protocol. BMC Health Serv Res. 2012;12:22.
28. Schillinger D, Hammer H, Wang F, et al. Seeing in 3-D: Examining the reach of diabetes self-management support strategies in a public health care system. Health Educ Behav. 2008;35:664–682.
29. Schillinger D, Handley M, Wang F, Hammer H. Effects of self-management support on structure, process, and outcomes among vulnerable patients with diabetes: a three-arm practical clinical trial. Diabetes Care. 2009;32: 559–566.
30. Department of Health Care Services. Medi-Cal rates. http://files.medi-cal.ca.gov/pubsdoco/Rates/RatesHome.asp. Accessed July 1, 2012.
31. Cameron AC, Trivedi PK. Econometric models based on count data. Comparisons and applications of some estimators and tests. J Appl Econom. 1986;1:29–53.
32. Duan N, Manning WG, Morris CN, Newhouse JP. A comparison of alternative models for the demand for medical care. J Bus Econ Stat. 1983;1:115–126.
33. Duan N. Smearing estimate: s nonparametric retransformation method. J Am Stat Assoc. 1983;78:605–610.
34. Bharel M, Lin WC, Zhang J, O'Connell E, Taube R, Clark RE. Health care utilization patterns of homeless individuals in Boston: preparing for Medicaid expansion under the Affordable Care Act. Am J Public Health. 2013;103(suppl 2): S311–S317.
35. Chang T, Davis M. Potential adult Medicaid beneficiaries under the Patient Protection and Affordable Care Act compared with current adult Medicaid beneficiaries. Ann Fam Med. 2013;11:406–411.
36. Decker SL, Kostova D, Kenney GM, Long SK. Health status, risk factors, and medical conditions among persons enrolled in Medicaid vs uninsured low-income adults potentially eligible for Medicaid under the Affordable Care Act. JAMA. 2013;309:2579–2586.
37. Peek ME, Cargill A, Huang ES. Diabetes health disparities: a systematic review of health care interventions. Med Care Res Rev. 2007;64(suppl 5):101S–156S.
38. Gary TL, Narayan KM, Gregg EW, Beckles GL, Saaddine JB. Racial/ethnic differences in the healthcare experience (coverage, utilization, and satisfaction) of US adults with diabetes. Ethn Dis. 2003;13:47–54.
39. Heisler M, Smith DM, Hayward RA, Krein SL, Kerr EA. Racial disparities in diabetes care processes, outcomes, and treatment intensity. Med Care. 2003;41:1221–1232.
40. Chomutare T, Fernandez-Luque L, Arsand E, Hartvigsen G. Features of mobile diabetes applications: review of the literature and analysis of current applications compared against evidence-based guidelines. J Med Internet Res. 2011;13:e65.
41. Ritzwoller DP, Sukhanova AS, Glasgow RE, et al. Intervention costs and cost-effectiveness for a multiple-risk-factor diabetes self-management trial for Latinas: Economic analysis of inverted exclamation markViva Bien! Transl Behav Med 2011;1:427–435.

42. Piette JD, Weinberger M, Kraemer FB, McPhee SJ. Impact of automated calls with nurse follow-up on diabetes treatment outcomes in a Department of Veterans Affairs Health Care System: a randomized controlled trial. Diabetes Care. 2001;24:202–208.
43. Struijs JN, Baan CA, Schellevis FG, Westert GP, van den Bos GA. Comorbidity in patients with diabetes mellitus: impact on medical health care utilization. BMC Health Serv Res. 2006;6:84.
44. Nundy S, Dick JJ, Chou CH, Nocon RS, Chin MH, Peek ME. Mobile phone diabetes project led to improved glycemic control and net savings for Chicago plan participants. Health Aff (Millwood). 2014;33:265–272.
45. Schillinger D, Bibbins-Domingo K, Vranizan K, Bacchetti P, Luce JM, Bindman AB. Effects of primary care coordination on public hospital patients. J Gen Intern Med. 2000;15:329–336.
46. Handley MA, Schillinger D, Shiboski S. Quasi-experimental designs in practice-based research settings: design and implementation considerations. J Am Board Fam Med. 2011;24:589–596.

Address correspondence to:
Judy Quan, PhD
Division of General Internal Medicine
UCSF Center for Vulnerable Populations at San Francisco General Hospital and Trauma Center
University of California, San Francisco
1001 Potrero Avenue, Ward 13, Box 1364
San Francisco, CA 94110

E-mail: Judy.Quan@ucsf.edu