Effectiveness Of A Disease Management Program For Patients With Diabetes

Testing the impact on health care quality, use, and spending shows that disease management has many positive effects.

by Victor G. Villagra and Tamim Ahmed

ABSTRACT: Diabetes disease management programs (DDMPs) are proliferating, but their effectiveness in improving quality and mitigating health care spending has been difficult to measure. Using two quasi-experimental methods, this study analyzed the first-year results of a multistate DDMP for people with diabetes sponsored by a national managed care organization. In both analyses, overall cost of care were significantly lower in DDMP sites, and the payer saved more than it spent. Pharmacy costs showed mixed results. Quality scores in the DDMP sites were significantly better than in sites without the program.

DIABETES IS A SERIOUS AND COSTLY DISEASE affecting eighteen million Americans.[1] Yearly direct and indirect costs associated with diabetes care were estimated at $132 billion in 2002.[2] The steady rise in the incidence of diabetes and its risk factors, including inactivity, obesity, and changing demographics, raises concerns about an even greater burden of illness in years to come.[3]

In spite of the widespread availability of evidence-supported information about effective treatments, many patients are not benefiting from them.[4] Multiple studies have demonstrated that gaps in quality of care can be narrowed through comprehensive, multidisciplinary disease management programs (DMPs).[5] Some programs can result in short-term decreases in use of acute care services and lower overall health care costs.[6] Attracted by the positive impact on quality, use of services, medical costs, and worksite productivity, many employers, managed care organizations (MCOs), and insurance companies have adopted DMPs.[7] Previous studies focused on economic outcomes and quality have included relatively few patients, have been confined to a single site or region, and therefore have limited generalizability.[8] This paper evaluates the impact of a national MCO's diabetes disease management program (DDMP) on quality of care, use of services, and costs in ten U.S. urban areas across twelve states.

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Study Data And Methods

■ **Study sites.** We defined each study site as a unique administrative business unit of the sponsoring MCO under the jurisdiction of one or more health plans. The ten sites were Nashville, Tennessee; Florida; Denver, Colorado; the mid-Atlantic (Baltimore; Washington, D.C.; Philadelphia; Delaware; and southern New Jersey); Dallas, Texas; Houston, Texas; Chicago, Illinois; Kansas; Ohio; and Tri-State (New York metropolitan area, northern New Jersey, and Connecticut). The same DMP was delivered in all study sites. Site selection and implementation sequence were nonrandom, based on practical considerations such as customer request, stable staffing, and noninterference with previously scheduled National Committee for Quality Assurance (NCQA) accreditation activities. Program implementation was phased in over three years (Exhibit 1).

■ **Study population and eligibility.** All members enrolled in fully insured health maintenance organizations (HMOs) and point-of-service (POS) plans whose self-insured employers elected to cover the DDMP were eligible for the program. Members with the diagnosis of diabetes mellitus were identified through claims using a centralized national data warehouse. Non-claims-based identification was done through direct physician referral or self-referral. Participation was voluntary; members could opt out of the program or change their level of participation at any time.

EXHIBIT 1
Implementation Of Diabetes Disease Management Program In Ten Sites

Pre-post

Study sites	Baseline period	Intervention period
Chicago	03/1999–02/2000	03/2000–02/2001
Kansas	09/1997–08/1998	09/1998–08/1999
Dallas	03/1998–02/1999	03/1999–02/2000
Houston	04/1997–03/1998	04/1998–03/1999
Denver	06/1999–05/2000	06/2000–05/2001
Mid-Atlantic	06/1998–05/1999	06/1999–05/2000
Nashville	05/1999–04/2000	05/2000–04/2001
Florida	05/1998–04/1999	05/1999–04/2000
Ohio	03/1999–02/2000	03/2000–02/2001
Tri-State	02/1998–01/1999	02/1999–01/2000

Parallel group

Study sites[a]	Intervention period	Control period
Kansas/Chicago	08/1998–07/1999	03/1999–02/2000
Houston/Dallas	04/1998–03/1999	03/1998–02/1999
Mid-Atlantic/Denver	06/1999–05/2000	06/1999–05/2000
Florida/Nashville	05/1999–04/2000	05/1999–04/2000
Tri-State/Ohio	02/1999–01/2000	03/1999–02/2000

SOURCE: CIGNA HealthCare, Network/POS and Network/HMO.
[a] Pairs are in the order of intervention/control. See text for details.

The selection protocol favored identification of patients with diabetes (true positives) over all possible patients with the disease. The initial query identified most eligible members. Subsequent monthly queries added new members and removed those no longer covered by the plan.

■ **Program description.** The DDMP was implemented as part of the general operation of a multisite MCO under usual business conditions rather than as a controlled experiment. Patients received assistance with self-care for diabetes and all common comorbidities such as cardiovascular and respiratory diseases. All educational contents were based on reputable national guidelines.[9]

All participants received graduated frequency and intensity of interventions according to a four-level severity stratification, with level four being those in need of most support and often the sickest. Stratification took place upon the first telephone contact with a nurse but was allowed to move up or down according to the patient's health status and need for assistance at each subsequent assessment.

■ **Interventions.** For the purposes of this study, the first day of the one-year intervention period began two weeks after the first group of patients were mailed their "welcome package." The program consisted of repeated telephone outreach by trained nurses, dietitians, or health educators; Web-based education; remote monitoring devices; and reminders and educational mailings throughout the year. Physicians caring for participating members received information about the program prior to any contact with their patients and were notified of their progress by mail, fax, or telephone periodically thereafter. During the first nurse telephone call, patients underwent a structured interview that included a detailed lifestyle inventory and an assessment of the patient's understanding of his or her disease(s) and adherence to prescribed drug treatments. Specific behavioral and cognitive goals were set for each patient and monitored regularly. Subsequent phone calls emphasized patients' understanding of the American Diabetes Association (ADA) standards of care and other guidelines, adherence to their doctor's treatment plans, motivation to adopt healthful lifestyle changes, and support to achieve those goals.

Because of the complex, multimodal nature of patient outreach activities, the intervention was deemed complete only after members had been exposed to the program for a minimum of ten months. This period, established a priori, was also considered necessary to give patients enough time to assimilate all of the information and modify their self-care behavior. In contrast, members with any length of program exposure (minimum of one month) are referred to as "all participants."

■ **Data analyses.** We conducted two separate analyses. The first analysis evaluated the program's impact on quality, cost, and use among "full participants" (those enrolled in the first two months of the intervention period who remained in the program until the completion of the first year). All results were based on members' entire one-year claim experience, with a three-month lag. The second analysis was based on "all participants" to approximate an intention-to-treat analysis.

■ **Intervention and control groups.** The three-year phased implementation

schedule created "natural experiments" that allowed two sets of comparisons. The first was a sequential pre-post comparison in which each of the ten sites served as its own historical control. The "baseline" period was the year preceding the DDMP, and the "intervention" year corresponded to the first year of program operation. A second, parallel group comparison was also assembled by matching five DDMP (intervention) sites with a concurrent site in which no DDMP (control) was yet in place. When possible, sites were paired by geographic proximity.

■ **Cost and use.** The medical cost analysis counted each study member's entire one-year claims experience regardless of the underlying diagnosis associated with each claim. In-network and out-of-network costs and use were counted. Encounters (services paid through capitation) were imputed with a local site fee-for-service equivalent value. Pharmacy costs were included, although some members had that benefit carved out. The proportion of such members remained stable throughout the study period. Claim caps and stop-loss rules were not applied. The costs of the DDMP itself are not reported because of the confidential nature of the contract between the MCO and the DDMP vendor, but we report the relative costs of the program against the results observed, as dollars per diabetic member per month.

■ **Pre-post analysis.** Several factors other than a DDMP influence year-over-year cost and use of services, and each site has unique market dynamics. These factors include provider contracts; changes in benefits; and unit price increases of drugs, devices, and other goods and services. These are usually not disease-specific and therefore tend to affect all medical costs. Adjustments for year-to-year overall medical inflation were made using each site's cost trends. The reference population was the entire plan membership minus patients with diabetes. To account for possible shifts in demographics and comorbidity profiles related to member turnover, an age-sex and comorbidity adjustment was made using a multivariate member-month weighted regression method.[10]

■ **Parallel group analysis.** A similar case-mix adjustment was used when comparing concurrent intervention and control sites. In this case, the pre-post variable was switched to a control-intervention variable. Since three of the five site pairs were slightly off phase, an additional trend adjustment was made, so that intervention and control pairs were temporally aligned.[11]

■ **Quality of care.** Quality was quantified using six indicators: dilated retinal exam, lipid testing, hemoglobin A1c (HbA1c) testing, microalbumin testing, prescribed angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs), and tobacco use. The first four metrics were calculated according to the NCQA's Health Plan Employer Data and Information Set (HEDIS) methodology.[12] Use of tobacco was based on patients' self-reports during telephone visits. The metric represents the proportion of patients using tobacco regularly among all patients undergoing care by telephone. Assessment of the proportion of diabetic patients receiving a prescription for ACE inhibitors or ARBs was based on administrative data. Only the results among "full participants" are reported.

Study Results

■ **Participation.** A total of 55,439 members with diabetes were identified. Because a subset of companies opted not to cover the DDMP, 10,062 members (18.1 percent) were not eligible for the study. Another 1,885 eligible members (3.4 percent) opted out voluntarily or were falsely identified as diabetics, were not included in the program, and were not followed further. Of the remaining 43,492 members, 27,876 were included in the "full participant" pre-post analysis and 27,548 in the parallel group analysis. All 43,492 members were included in the "all participants" pre-post analysis, and 39,292 in the parallel group analysis. Exhibit 2 presents demographic characteristics, unadjusted baseline utilization patterns, and costs for both full participants and members excluded from the full participant analysis (n = 15,616, including patients who changed insurance carriers or died).

■ **Patient education and support.** The DDMP distributed 677,940 educational mailings to participants. This was complemented by 186,088 telephone interactions lasting an average of 13.6 minutes. An average of 8.77 telephone interactions per year were done with patients in the highest severity category. Only 0.01 percent of participants could not be reached at all. A small proportion (0.08 percent) declined telephone contact but accepted mailings.

■ **Physician feedback.** All physicians were notified of their patients' eligibility for the DDMP. Following initial patient contact by the DDMP staff, physicians received periodic updates of their patients' progress. Although physicians' input or feedback was sought, they rarely responded as intended in the program protocol. Because of this, few data were accrued regarding the impact of physician-DDMP-patient interaction on outcomes.

■ **Cost and use, parallel group comparison.** Results from all five site pairs were aggregated into intervention and control groups. Overall cost per diabetic member per month in the "full participants" intervention group was $417, compared with $554 in control sites (24.7 percent lower, $p < .0001$). Pharmacy costs in the intervention sites were $9.02 lower (−7.6 percent, $p < .0002$). Inpatient costs in the intervention sites were $17 (−11.4 percent) lower than in control sites ($p < .08$). There were 30 percent fewer admissions to the hospital ($p < .0001$) per 1,000 members in intervention sites than in control sites. Length-of-stay was 0.61 days higher in the intervention sites (11.6 percent, $p < .0007$). Results in the "all participants" analysis also showed an overall cost reduction (Exhibit 3).

■ **Cost and use, pre-post comparison.** Average cost in the intervention period was 8.1 percent less than in the baseline period ($p < .01$). Costs rose in the pharmacy and "other" categories (which includes durable medical equipment, oxygen therapy, radiology, physical/occupational therapy, home health, and other nonclassified costs). Overall cost reductions of $26 were also seen in the "all participants" analysis (Exhibit 4). The cost of delivering the program was lower than the cost reduction observed among full and all participants by either the pre-post or parallel group method in DDMP sites. This holds true even after the cost of the program is prorated

EXHIBIT 2
Baseline Demographics And Unadjusted Mean Cost And Use Profile of Members Included And Excluded In the "Full Participants" Analysis, 1997–2001

Characteristic	10 months or more in DDMP (N = 27,876)	Less than 10 months in DDMP (N = 15,616)	*P* value
Demographic			
Male			
0–17	1.1%	1.2%	NS
18–24	0.6	1.2	NS
25–34	2.6	4.4	NS
35–44	8.5	10.7	<.02
45–54	18.8	17.3	NS
55–64	20.9	15.7	<.001
65+	4.5	4.5	NS
Female			
0–17	1.1	1.0	NS
18–24	0.6	1.3	NS
25–34	2.9	5.0	<.03
35–44	7.3	9.1	NS
45–54	14.7	13.8	NS
55–64	14.0	12.0	<.04
65+	2.7	3.0	NS
Cost			
Total cost	$485	$519	NS
Inpatient	156	182	NS
Outpatient	81	74	NS
Professional services	122	119	NS
Other	39	39	NS
Rx drugs	111	108	
Use			
Days[a]	1,127.23	1,161.21	NS
Emergency room[a]	255.69	309.53	NS
Visits[b]	6.71	6.02	<.01
Admissions[a]	203.07	185.6	NS

SOURCE: CIGNA HealthCare, Network/POS and Network/HMO.

NOTES: "Full participants" were in the diabetes disease management program (DDMP) ten or more months and were part of the study group for the entire year-long observation period. See text for details. NS is not significant. Cost is measured per diabetic member per month. Overall cost is less than the sum of components because weighted averages by eligibility were used.

[a] Measured as per 1,000 members per year.

[b] All primary care and specialist visits per member per year.

to match the ten-month evaluation period and the 3.4 percent voluntary opt-outs are counted.

■ **Quality outcomes.** Quality indicators in the intervention sites in both analyses showed higher scores than in the control or baseline sites (Exhibits 5 and 6). Differences reached statistical significance for dilated retinal exam, microalbumin testing, lipid testing, and tobacco use. A positive trend was observed in HbA1c testing and prescriptions for ACE inhibitors or ARBs.

EXHIBIT 3
Adjusted Mean Cost And Utilization Of "Full Participants" And "All Participants" In The Parallel Group Comparison, 1987–2001

	Full participants			All participants		
	No DDMP (n = 9,977)	DDMP (n = 17,571)	Percent difference	No DDMP (n = 12,104)	DDMP (n = 27,188)	Percent difference
Cost						
Overall[a]	$554	$417	−24.7****	$551	$431	−21.8****
Inpatient	151	134	−11.4	147	145	−1.9*
Outpatient	116	58	−49.8****	118	58	−50.5****
Pharmacy	118	109	−7.6****	118	106	−10.6****
Professional	138	94	−31.7****	137	97	−29.1****
Other	48	44	−8.1	47	45	−5.9*
Utilization[b]						
Bed days	1,077	843	−21.7****	1,061	938	−11.6**
Admissions	205	143	−30.2****	206	157	−23.8****
ER visits	303	234	−22.8%****	307	263	−14.3****
ALOS (days)	5.27	5.88	11.6****	5.2	6.0	16.0****
Office visits	6.91	6.44	−6.8****	6.93	6.56	−5.3****

SOURCE: CIGNA HealthCare, Network/POS and Network/HMO.

NOTES: "Full participants" were in the diabetes disease management program (DDMP) ten or more months and were part of the study group for the entire year-long observation period; "all participants" were in the DDMP at any time during the study period for at least one month. See text for details. Intervention sites' significantly larger membership is explained almost entirely by the differences between the Florida/Nashville and Tri-State/Ohio pairs. Cost is measured per diabetic member per month. ALOS is average length-of-stay.

[a] Overall cost is less than the sum of components because the pharmacy regression model included fewer member-months (because of carve-outs) than other cost components.

[b] Bed days, admissions, and emergency room (ER) visits represent use per 1,000 diabetic members per month. Office visits represent the average per diabetic member per year.

*$p < .10$ **$p < .01$ ****$p < .001$

Discussion

This study adds to previous reports concerning DMPs. It evaluates results of a multistate program reaching many more patients than previous studies. Consistent case definition, severity stratification, interventions, and a centralized data source allowed comparisons across geographic locations and over time. The program was evaluated in the context of usual health plan operations, and it is still in place today, which demonstrates its sustainability and long-term viability. Finally, this study reports results using two complementary quasi-experimental methods, both of which produced concordant results.

■ **Cost of care.** The presence of the DDMP in any site was associated with significantly lower overall costs of care within one year. The most important source of savings was a 22–30 percent decrease in hospitalization. Savings measured using any length of program exposure were most likely lower because program effect was not measured at its mature performance point.

In the pre-post analysis, pharmacy costs were higher with the DDMP in place. This is not surprising, since the program actively promoted use of appropriate drugs and adherence to pharmacologic regimens. In the parallel group analysis, pharmacy costs were lower in the intervention group. The differences between

EXHIBIT 4
Adjusted Mean Cost And Utilization Of "Full Participants" And "All Participants" In The Pre-Post Analysis, 1997–2001

	Full participants			All participants		
	Pre (n = 27,380)	Post (n = 27,876)	Percent change	Pre (n = 32,267)	Post (n = 43,492)	Percent change
Cost						
Overall[a]	$485	$446	−8.1****	$490	$464	−5.3***
Inpatient	156	126	−19.0****	156	137	−12.3***
Outpatient	80	76	−5.8***	82	77	−5.6**
Pharmacy	111	114	3.1**	112	112	0.0
Professional	121	106	−12.6****	122	111	−9.4****
Other	39	44	13.6	39	46	16.3**
Utilization[b]						
Bed days	1,119	878	−21.5****	1,133	955	−15.7****
Admissions	202	158	−21.8****	206	172	−16.5****
ER visits	255.2	257.5	0.9	262	286	9.2****
ALOS (days)	5.53	5.55	0.4	5.5	5.6	1.0**
Office visits	6.7	6.47	−3.4****	6.75	6.63	−1.8***

SOURCE: CIGNA HealthCare, Network/POS and Network/HMO.

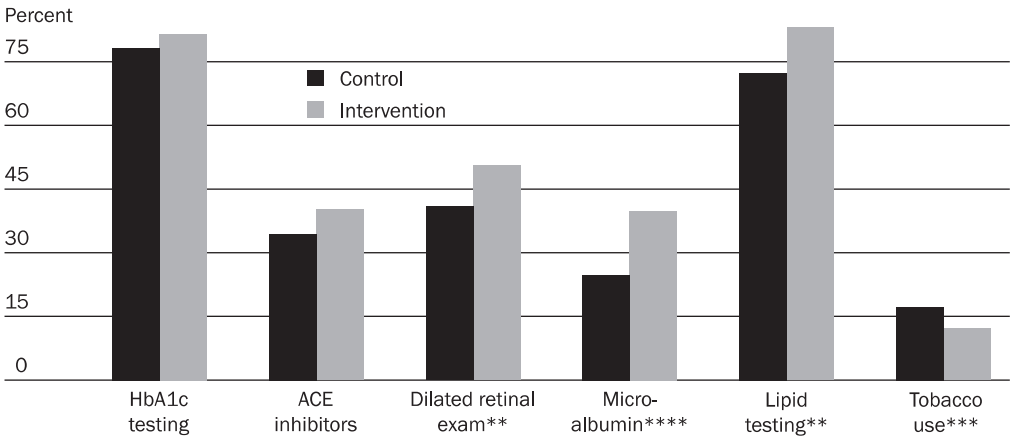
NOTES: "Full participants" were in the diabetes disease management program (DDMP) ten or more months and were part of the study group for the entire year-long observation period; "all participants" were in the DDMP for any length of time during the study period for at least one month. See text for details. "Pre" is the baseline period; "post" is the intervention period. Cost is measured per diabetic member per month. ALOS is average length-of-stay.

[a] Overall cost is less than the sum of components because the pharmacy regression model included fewer member-months because of carve-outs) than other cost components.

[b] Bed days, admissions, and emergency room (ER) visits represent use per 1,000 diabetic members per month. Office visits represent the average per diabetic member per year.

*p < .10 **p < .01 ***p < .001 ****p < .0001

EXHIBIT 5
Quality Indicators, Full Participants In The Parallel Group Analysis Of A Diabetes Disease Management Program (DDMP), 1997–2001

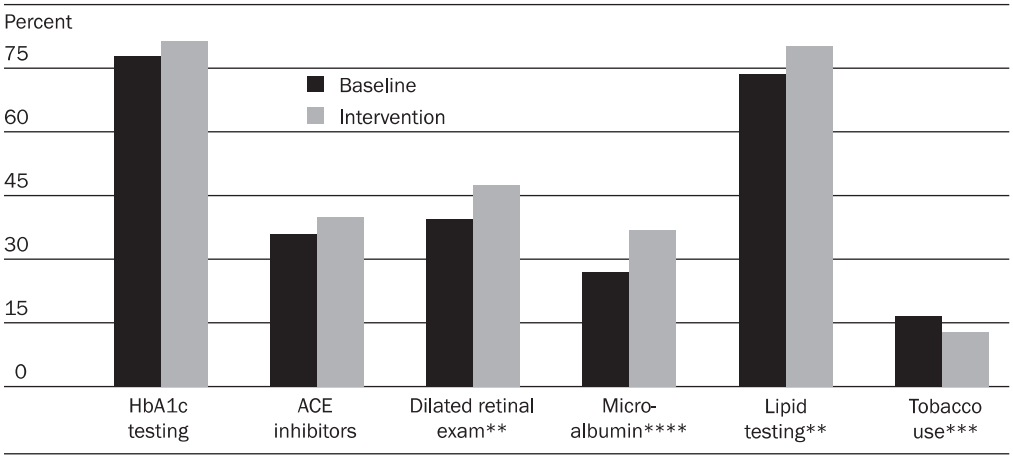


SOURCES: For all but tobacco use, CIGNA HealthCare, Network/POS and Network/HMO. For tobacco use, American Healthways.

NOTES: "Full participants" were in the DDMP ten or more months and were part of the study group for the entire year-long observation period. See text for details. ACE is angiotensin-converting enzyme.

**p < .05 ***p < .01 ****p < .001

EXHIBIT 6
Quality Indicators, Full Participants In The Pre-Post Analysis Of A Diabetes Disease Management Program (DDMP), 1997–2001



SOURCES: For all but tobacco use, CIGNA HealthCare, Network/POS and Network/HMO. For tobacco use, American Healthways.
NOTES: "Full participants" were in the DDMP ten or more months and were part of the study group for the entire year-long observation period. See text for details. ACE is angiotensin-converting enzyme.
$^{**}p < .05$ $^{***}p < .01$ $^{****}p < .001$

these analytical approaches deserves further evaluation. The study was not designed to establish a direct cause-and-effect relationship between drug use and overall costs, but attempts have been made to establish such a link.[13]

■ **Study limitations.** The study's reliance on quasi-experimental evaluation methods may elicit criticisms that the observations are subject to biases and confounders that could invalidate its conclusions. This is a fair criticism, but the cost and logistical challenge of a randomized controlled trial involving this many sites and patients would be formidable. However, the results of such trials often lack external validity, which could deprive patients of the benefits of effective therapies.[14] Efforts were made to mitigate the most often cited objections to the quasi-experimental approach.[15] All participants in the DDMP were taken into consideration regardless of level of disease severity. Excluding patients based on length of participation was a determination made before rather than a retrospectively applied criterion. Demographics and cost-and-use patterns did not differ significantly between the two groups. The pre-post analysis conferred some degree of intrasite stability. The analysis was strengthened by adjustment for age, sex, and comorbidity. This should mitigate concerns about year-to-year member turnover that could lead to shifts in case-mix between the baseline and intervention periods and imbalance between intervention and control sites in the parallel group analysis.

The use of redundant claims in case-finding queries to avoid false positives could lead to the selection of a sicker diabetic population than the total population with the disease. If that were the case, the reduction in cost in the pre-post analysis could be attributable to regression to the mean rather than program ef-

fect. Although this study design cannot fully eliminate regression to the mean, including patients of all severity levels in the analysis diminishes that concern. Furthermore, such a criticism would be valid only in the pre-post analysis but not in the parallel group analysis, where similar patient selection criteria applied to control and intervention sites. Another limitation of the study is the exclusion of voluntary opt-outs because data on these members were incomplete or missing.

Analysis of "all participants" approximates an intention-to-treat approach. This analysis does not reflect the actual conditions chosen for internal program evaluation because the program did not end at one year but continued beyond the end of the observation period of this study.

■ **Impact on use.** The impact of disease management on use of health services is of interest because disease management is driven entirely by patients' and providers' behavior changes, not by utilization controls. This is an attractive medical management model because of the backlash against utilization management tactics such as prior authorization for referral and hospital admissions. Recent evidence suggests that utilization control is, in fact, yielding to disease management as the preferred medical management strategy in a managed care setting.[16] In this study, both analyses showed a decline in admission rates, increases in average length-of-stay, a net decline in bed days, and a slight decline in physician visits when a DDMP was in place. Lower admission rates and higher length-of-stay in intervention sites suggest more effective disease control in the nonhospital setting (including telephonic and other remote interactions between patients and caregivers). These results are similar to previous studies demonstrating decreases in hospital admissions associated with a DDMP.[17]

There was no a priori expectation of the DDMP's impact on the number of outpatient visits. Both analyses showed fewer outpatient visits when the program was in place. These results are similar to those of previous studies.[18] The explanation for decreased visits in our study is not readily apparent, but repeated telephonic and written communications between care managers and patients may have reduced patients' need or desire to see a physician as often as they did before. In contrast to in-person visits, telephone contacts remove barriers stemming from lack of transportation, lack of time, payment of an office copayment, or having to take time off work. The use of care manager–initiated outbound calls also decreases the need to rely on patients to call in with problems. This is particularly important if patients choose not to "bother" their physician with seemingly unimportant concerns. Many potentially serious complications could be averted in the course of "routine" disease management interactions. On a population basis, this study shows no apparent adverse impact from this observed change in the number of office visits. If this observation is confirmed in other studies, the implications could be significant and may influence reimbursement policy for telephone, Internet, or other remote patient-provider interactions. Physicians could then increase same-day access for patients who really need it without any additional in-

vestment by physician practices. These implications would be important for the Medicare population in light of passage of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, which includes a provision for disease management.[19] Additional research is needed to confirm our observations and to understand the root causes and trade-offs between more remote supportive care and on-site care on the quality and use of various health services.

■ **Patients' acceptance of the DDMP.** The ability through a DDMP to reach large numbers of patients quickly and cost-effectively has the potential to change the public health profile and cost of care for patients with diabetes at a level commensurate with its epidemic proportion. Rapid patient identification and engagement provided multiple opportunities for patient interactions. The incentive for rapid program deployment was driven in part by a contract between the MCO and the DDMP vendor that formalized program performance evaluation in one-year blocs. Typically, program installation was completed within three months.[20] Speedy implementation creates additional value in the quest for better quality and economic performance in heath services, a factor that is seldom considered in large-scale initiatives.

■ **Impact on quality of care.** HEDIS indicators are widely accepted as valid quality measures. In this study diabetes-related HEDIS and non-HEDIS metrics improved when a DDMP was in place. Improved HEDIS scores noted in the pre-post analysis could be interpreted as being secular changes related to "other" health plan activities aimed specifically at improving HEDIS scores instead of being attributed to the DDMP's specific effects. Higher scores in DDMP sites in the parallel group analysis, however, could not be interpreted as such, because both intervention and control health plans had HEDIS improvement initiatives in place.

In summary, the DDMP resulted in improved quality of care, reduced use of hospital beds, and overall reduction in the total cost of care. If others obtain similar findings, the disease management model could have profound effects on the organization of care for people with chronic illnesses.

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NOTES

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