

A Systematic Approach to Risk Stratification and Intervention Within a Managed Care Environment Improves Diabetes Outcomes and Patient Satisfaction

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OBJECTIVE — To determine whether a comprehensive diabetes management program that included risk stratification and social marketing would improve clinical outcomes and patient satisfaction within a managed care organization (MCO).

RESEARCH DESIGN AND METHODS — The 12-month prospective trial was conducted at primary care clinics within a MCO and involved 370 adults with diabetes. Measurements included 1) the frequency of dilated eye and foot examinations, microalbuminuria assessment, blood pressure measurement, lipid profile, and HbA_{1c} measurement; 2) changes in blood pressure, lipid levels, and HbA_{1c} levels; and 3) changes in patient satisfaction.

RESULTS — Complete data are reported for the 193 patients who had been enrolled for 12 months; life table analysis is reported for all patients who remained enrolled at the study's end as well as for a comparative control group of 623 patients. For the 193 patients for whom 12-month data were available, the number of patients in the low-risk category (HbA_{1c} <7%) increased by 51.1%. A total of 97.4% of patients with an HbA_{1c} >8% at baseline had a change in treatment regimen. Patients at the highest risk for coronary heart disease (LDL >130 mg/dl) decreased from 25.4% at baseline to 20.2%. Patients with a blood pressure <130/85 mmHg increased from 23.8 to 44.6%. Of these patients, 63.0% had changes in medication. Patients and providers expressed significant increases in satisfaction with the program.

CONCLUSIONS — The program was successful in initiating the recommended changes in the diabetic therapeutic regimen, resulting in improved glycemic control, increased monitoring/management of diabetic complications, and greater patient and provider satisfaction. These results should have great significance in the design of future programs in MCOs aimed at improving the care of people with diabetes and other chronic diseases.

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Abbreviations: ADA, American Diabetes Association; DQIP, Diabetes Quality Improvement Project; HEDIS, Health Plan Employer Data and Information Set; HMO, health maintenance organization; MAU, microalbumin; MCO, managed care organization; PAID, Problem Areas In Diabetes; SMBG, self-monitoring of blood glucose.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Studies have shown that control of glycemia, hypertension, and hyperlipidemia significantly reduces the risk of microvascular and cardiovascular complications in patients with diabetes (1–4). Nevertheless, diabetes remains poorly controlled in the U.S., with <2% of adult diabetic patients receiving optimal quality of care as defined by the Clinical Practice Recommendations of the American Diabetes Association (ADA) (5,6).

This study incorporated the findings of several previous studies suggesting that to improve patient outcomes, it is necessary for the patient to interact with a practice team prepared with the appropriate information, skills, and resources (7–11). The comprehensive approach used was based on processes of social marketing to influence physician behaviors (12–19) (Table 1). The study was predicated on the utilization of previously agreed-upon protocols that could be acted on as a result of the patient interview and the data obtained.

The purpose of this study was to determine whether improvements could be made in clinical outcomes, patient/provider compliance, and patient/provider satisfaction within a managed care organization (MCO) through an assessment and intervention initiative. The program addressed the needs of diabetes care within the primary care setting, bringing together a team with the patient as a central and empowered participant. An enhanced data management system was devised to facilitate communication and practice-initiated follow-up. Outputs allowed for both risk stratification to identify patients in the greatest need of medical intervention and reports that prompted providers with suggested interventions and care plans. They also allowed for the systematic allocation of personnel resources (i.e., primary care

Table 1—Changing practitioner behavior: what works?

Intervention	Description/Findings
Audit and feedback	Particularly effective for prescribing and diagnostic testing
Reminders	Prompts the provider to perform clinical action
Outreach visits	Meetings with providers in practice settings to provide information and feedback
Patient-mediated interventions	Educating and informing patients – particularly useful when combined with outreach Visits
Opinion leaders	Providers explicitly nominated by their colleagues to be “educationally influential”
Conferences	Need to be explicit and related to the practice environment
Marketing	Use of interviews, focus groups, or surveys to identify barriers
Multifaceted	The use of a variety of interventions is most effective

Summary: there must be agreement that there is a problem and that the solution agreed-upon is the solution to the problem, combined with a system of information and feedback necessary to resolve the problem.

physicians, extenders, diabetes educators, and administrative staff) to optimize the function and value of each provider. The objectives of the study were to: 1) improve compliance with Health Plan Employer Data and Information Set (HEDIS) 1999 Diabetes Quality Improvement Project (DQIP) measures (20) (i.e., following defined guidelines for frequency of dilated eye examinations, foot examinations, urinary microalbumin [MAU] assessment, blood pressure measurement, lipid profile, and HbA_{1c} measurement); 2) improve patient outcomes as measured by HbA_{1c} levels, blood pressure, and lipid levels; 3) improve patient satisfaction with the services provided; 4) improve patient understanding and compliance with therapeutic regimens; and 5) improve provider satisfaction.

This study was conducted at an MCO based in Las Vegas, Nevada. This report describes study objectives, protocol, and 12-month results for 193 patients who participated in the program.

RESEARCH DESIGN AND METHODS

Clinical setting

The MCO studied has >180,000 health maintenance organization (HMO) members. Most (~70%) of the HMO members obtain primary care services at the MCO-owned clinics, with the balance of members receiving care at network clinics. The MCO has >8,500 members with diabetes. A majority of these members are Medicare Risk enrollees.

The two clinics studied were staff-model primary care clinics. Each provider had his/her own panel of patients. Clinic 1 had nine providers. Clinic 2 had seven providers. Data from 623 members

at a third clinic were analyzed to identify secular trends over the 12-month study period.

Participants

Patient selection. Using a computerized database from the MCO, 1,121 subjects were identified. Letters were sent to all 1,121 subjects, inviting them to participate in the study. We then randomly selected 655 patients for telephone follow-up; we were able to contact 555 (85%) patients. Of the 555 patients contacted, 431 met the study criteria. The study excluded members who were <21 or >75 years of age; had end-stage renal disease; were on dialysis; had cancer, blindness, drug or alcohol addiction, or stage III or IV congestive heart failure; were in another clinical trial; had gestational diabetes or were pregnant; or were institutionalized or unable to provide self-care.

Of the 431 eligible patients, 370 (86%) were included in the study. At the study's end, 315 patients remained enrolled. This represents 85% of the patients who were initially enrolled in the study. We have 12-month data for 193 subjects, which are herein reported. An overview of the selection and enrollment process is presented in Fig. 1.

Although no data are available regarding the reasons for patient withdrawal (14.9%), it should be noted that the annual patient turnover rate within the MCO studied averaged ~26%.

Patient demographics. The average age of the subjects enrolled was 64.0 years; the average duration of diabetes was 10.7 years. Of the patients enrolled, 76% were Caucasian, 14% were African-American, 7% were Hispanic, and 2% were Asian. Median annual income was \$10,000–20,000; 70% had a median an-

nual income of <\$40,000. There were no significant differences between the control and study groups with regard to age, duration of diabetes, race, or income.

Treatment modalities. At baseline, subjects controlled their diabetes with an insulin–oral therapy combination (11.4%),

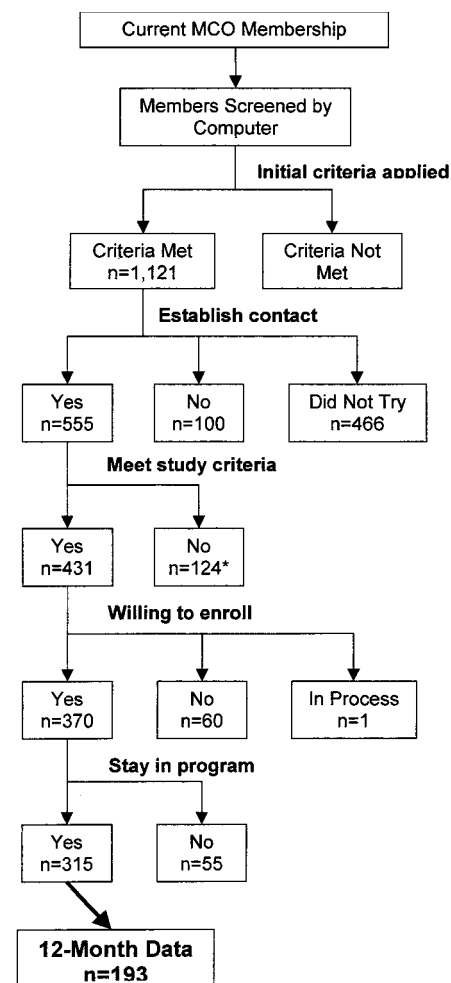


Figure 1—Enrollment process.

insulin (14.0%), oral medications (59.6%), or diet and exercise (15.0%). The control group used similar treatment modalities.

Comorbidities. At baseline, 1.0% subjects self-reported having kidney disease; the subjects also reported having diabetic foot disease (12.8%), diabetic eye disease (15.1%), heart disease (31.6%), and diabetic neuropathy (35.4%). High blood pressure and high cholesterol occurred in 67.2 and 57.8% of the subjects, respectively. Comorbidities were similar in the control group.

Protocol

The program was implemented in the following phases: 1) enrollment; 2) initial encounter; 3) risk stratification and action planning; 4) intervention; 5) patient education; 6) interim visits; and 7) follow-up visits. Program personnel included a team care coordinator, who was responsible for administrative tasks, maintaining contact with patients, data management, and scheduling. Program personnel also included a team care leader, who was a registered nurse who implemented the orders and assumed responsibilities for care as directed by the patients' primary care providers. In addition to these individuals, each clinic had available diabetes educators, nutritionists, advanced practice nurses, and physician assistants; these people, with the physicians, comprised the health care team.

Enrollment. Potential subjects were identified by diagnosis (ICD-9 250.xx) through patient records, and their data were downloaded into the software. Patients were eligible if they were continuously enrolled in the health plan for at least 2 years and had at least two clinical encounters coded specifically for diabetes procedure/diagnostic codes. Patients received letters of invitation from their provider. Patients were asked to complete a questionnaire enclosed with the letter, obtain necessary lab tests, and call the team care coordinator to schedule an initial visit. The questionnaire (administered pre- and postintervention) solicited demographic information, self-reported comorbidities, current healthcare practices and medical therapies, self-assessment of current status of diabetes control, and overall satisfaction with the healthcare plan, healthcare staff, and level of knowledge about diabetes care. Patients were instructed to bring the completed ques-

tionnaire to the first clinic visit, along with their current blood glucose meter and medications. An overview of the enrollment process is presented in Fig. 1.

Initial encounter. At the first visit, the team care coordinator measured blood pressure, height, and weight; conducted a foot examination (pedal pulses, deformities, 10 gm monofilament test); and measured microalbuminuria using the Micral test (Roche Diagnostics, Indianapolis, IN). Patients were also instructed in the self-monitoring of blood glucose (SMBG) and were provided with a blood glucose meter (Roche Diagnostics) and supplies.

Risk stratification and action planning. Laboratory tests and data from completed patient questionnaires were entered into the software. Risk profiles were generated using stratification algorithms and clinical intervention guidelines based on the ADA Clinical Practice Recommendations. Patients were stratified into high-, moderate-, or low-risk groups in seven categories: 1) glycemic control, 2) cardiovascular disease, 3) nephropathy, 4) retinopathy, 5) hyper/hypoglycemia, 6) amputation, and 7) psychosocial disorders.

Interventions. Interventions were based on previously agreed-upon standing orders (protocols) after approval from the primary care physician. The team care coordinator printed risk profile reports (physician and patient versions) and entered data elements into patient trending flowcharts. The team care coordinator and team care leader met to review the reports and develop action plans. The team care leader then met with primary care providers to review risk stratification reports and approve action plans. The appropriate follow-up action was determined by the healthcare team based on the degree of medical intervention deemed necessary. For example, if follow-up was needed, the team care coordinator scheduled the patient for nurse consultation and/or a provider visit. If no immediate follow-up was needed, a telephone call to the patient may have been sufficient to update the patient on his/her status or to make a minor medication change, followed by a mailing of the patient's report. The patient reports contained information about the patient's level of risk in each category and provided self-care recommendations for improving his/her diabetes (Fig. 2).

Patient education. All patients attended three educational programs (2 h each) and received educational materials. Educational programs focused on adult learning principles and actively engaged the patients in their care. As a result, when patients presented for physician office visits, they were knowledgeable about their risk status and what actions would be necessary. Patients also were invited to attend optional support groups.

Interim visits. Interim visits were scheduled at 3 and 6 months after the initial encounter. The team care coordinator verified that patients were performing SMBG at least twice per day and recording test-strip usage. If patients were not performing SMBG at the minimal frequency, the team care coordinator worked with patients to identify barriers and propose solutions. Other potential self-care barriers related to meal-planning adherence, exercise, smoking cessation, medication administration, and so forth were identified, and solutions were explored with the patient. At these visits, patients completed an interim survey regarding their health care utilization.

Follow-up visits. The team care coordinator reviewed patient records monthly (via an internet application) to monitor patient compliance; this was facilitated by an automated reminder function provided by the software. The team care coordinator made reminder telephone calls to patients, answered questions, and referred patients to the team care leader when appropriate.

Statistical and analytical methods

Methods/technologies used to assess complications.

The patients' blood work was performed by a local certified laboratory contracted by the MCO. HbA_{1c} determinations were performed using a high-performance liquid chromatography method. Foot examinations included the use of the Semmes-Weinstein 5.07 monofilament (21) to test cutaneous sensitivity. Eye examinations were obtained by referral to optometrists supervised by ophthalmologists at several MCO practice locations. Lipid panels included a calculated LDL cholesterol. Random urine dipsticks using Micral were used to obtain a MAU result. MAU results >100 mg/l were sent to a local laboratory for quantitative evaluation.

Design/validity of questionnaires used to assess patient satisfaction and statis-

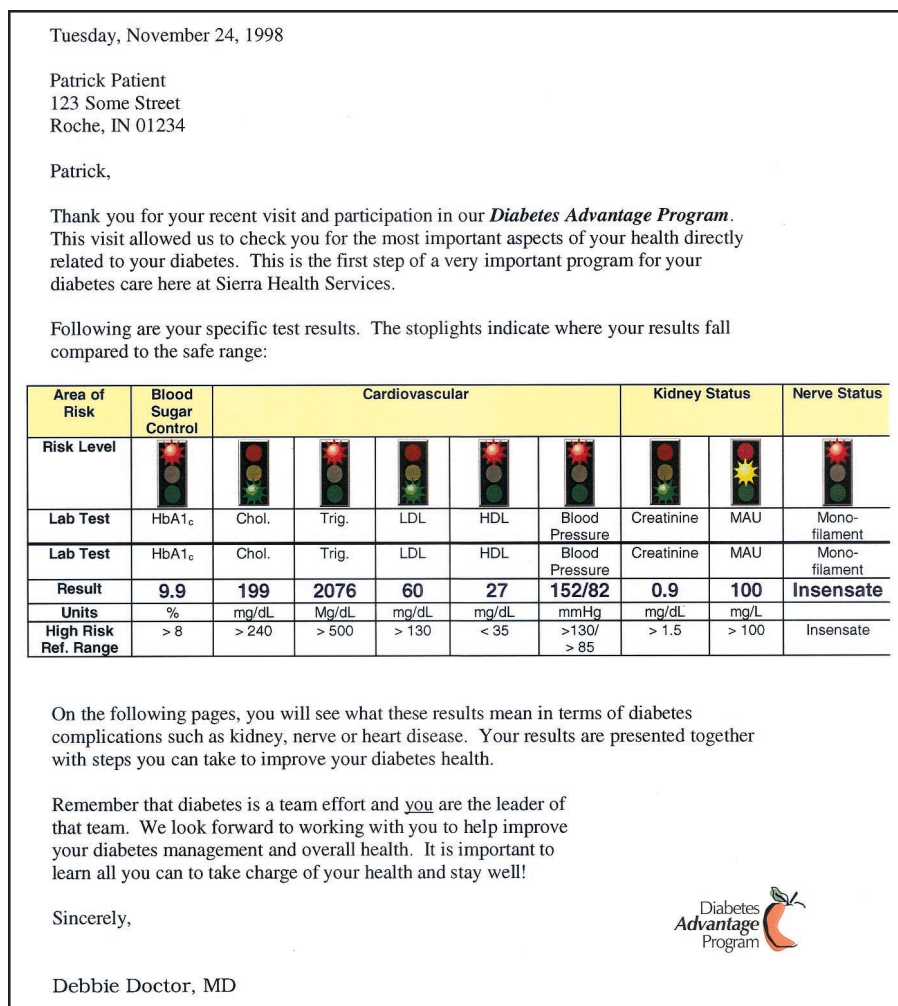


Figure 2—Example of a risk stratification report generated from the application server.

tical analysis of all data. Metabolic, clinical lab, and patient survey response data were extracted from the database based on a priori hypotheses established for the statistical analyses. For DQIP (20) analysis, measures (e.g., lab HbA_{1c} or metabolic blood pressure group values) were categorized by DQIP criteria; changes over time were tested for statistical significance using McNemar's test (22).

The diabetes-specific patient satisfaction survey tool, which incorporates a five-point Likert-response scale, was developed by a research group at the Office of Health Policy and Clinical Outcomes, Thomas Jefferson University (Philadelphia, PA). Changes over time for the satisfaction multiple-response items were tested using Agresti's test of marginal homogeneity for ordinal data (23). This statistical significance test is based on the generalization of the McNemar test; it ap-

plies for more than two response categories and takes advantage of the ordered responses of the questions. All analyses were performed using SAS software, version 6.12 for MacIntosh (SAS Institute, Cary, NC).

RESULTS — At 12 months, data from 193 patients were available to assess metabolic outcomes, which were evaluated by changes in HbA_{1c}, blood pressure, and lipids. Additionally, an assessment was made of provider adherence to care guidelines with regard to frequency of HbA_{1c} measurements, blood pressure readings, lipid panel utilization, foot examinations, and dilated eye examinations (Table 2). Assessments were also made regarding the number of patients who received diabetes self-management education, nutrition counseling, and smoking cessation counseling. Patient satisfaction with the health care services

provided and patient understanding and compliance with the therapeutic regimen were evaluated by questionnaire.

Data showed a significant improvement in glycemic control as measured by HbA_{1c} (Fig. 3). During the 12-month period, the number of patients in the low-risk category (HbA_{1c} <7%) increased by 51.1%, from 47 members at baseline to 71 after 12 months. The number of patients in the moderate category (7 to <8%) increased 2.5%. The number of patients in the high-risk category (≥8.0%) decreased by 58.3%, from 76 to 48 participants. Furthermore, of those patients with HbA_{1c} levels ≥8% at baseline, 97.4% had a change in treatment regimen during the 12 months in the program.

In addition to analyzing the HbA_{1c} data for the 193 patients for whom 12-month data were available, we also analyzed the time course of 356 patients from the experimental group (which included

Table 2—Summary of changes in clinical outcomes and provider adherence at 12 months

	Baseline	12 Months
Clinical outcome measures		
High-risk glycohemoglobin, HbA _{1c} >9.5%	10.9	3.1
Members with drop in HbA _{1c} ≥0.5%	—	45.6
Blood pressure <140/90 mmHg	38.9	66.8
Provider adherence measures		
Lipid profile testing within the last 2 years	66	100
Microalbuminuria within the last year	17	100
Retinal eye exam within the last year	53.9	80.3
Foot exam with monofilament test within the last year	N/A	100

Data are %.

data from the 315 patients who were still enrolled and the 41 patients who had dropped out of the study) and 623 patients from the control group. These data are summarized in Fig. 4. The control group remained essentially unchanged, whereas significant decreases in HbA_{1c} in the experimental group were seen at the first interval at which it was measured. The change remained constant throughout the remainder of the study.

A reduction in hypertension was also seen at 12 months. The percentage of patients with blood pressure readings <140/90 mmHg, an accountability measure for HEDIS accreditation, increased from 38.9% at baseline to 66.8% at 12 months (Fig. 5). The percentage of patients with blood pressure readings <130/85 mmHg (our pilot clinical decision threshold for hypertension) increased from 23.8 to 44.6%. Of those patients with blood pressure readings >130/85 mmHg at baseline, 63.0% had a change in medication within 12 months in the program.

The percentage of patients receiving lipid profile tests increased from 66% at baseline to 100% at 12 months, and microalbuminuria testing increased from 17 to 100%, respectively (Table 2). The percentage of patients at the highest risk for coronary heart disease (LDL >130 mg/dl) decreased from 25.4% at baseline to 20.2% at 12 months. Of those patients identified at the highest risk for nephropathy, 76.7% had a change in medication within the 12 months of program participation after the initial visit. In addition, at the end of 12 months, the percentage of patients who had received a dilated eye examination increased from 53.9 to 80.3%, and documented foot examinations increased from 0 to 100%.

Improvements were also observed in patient and provider satisfaction scores (Table 3 and Fig. 6). Patients expressed a significant increase in satisfaction with the program and staff performance. Of the 70% of providers that responded to the survey, 100% indicated that they were “very satisfied” with the program, 100% believed that their patients’ diabetes was better controlled as a result of the diabetes management program, and 93% believed the program saved them time on patient visits. In addition, 100% of the providers said they would recommend the use of this program to other physicians.

CONCLUSIONS— In our program, it was necessary to convert the ADA’s Clinical Practice Recommendations into concrete actions that could be carried out by the care team, supported by a interrelated set of practice enhancements. The

most significant of these enhancements was to translate the protocols into a data system that stratified each patient into risk categories based on his/her data. Therapeutic recommendations were then generated in an easy-to-follow format that could be quickly reviewed and signed by the provider and then implemented with guidance from the team care leader.

The provider and the patient received an illustrated summary of the data and the resultant recommendations, allowing a productive discussion at the time of the patient visit on how to act upon the data. Based on data from the provider survey, this process resulted in more efficient visits and improved use of both the provider’s and the patient’s time. The patient survey data showed that in combination with the educational programs, it also resulted in improved patient satisfaction because the patient understood a priori the changes necessary and the rationale.

Whereas the program is simple to describe, it was complex to initiate for several reasons. First, the providers had to be involved from the start to assure that the standards and their recommended actions were consistent with the practitioners’ views. Perhaps even more important than creating provider buy-in to this program was creating awareness that there were significant gaps in performance. In several instances, this involved interactive discussion with the practitioners as well as nonpunitive provider-specific feedback on prior performance. This feedback was provided by the authors (C.M.C. and

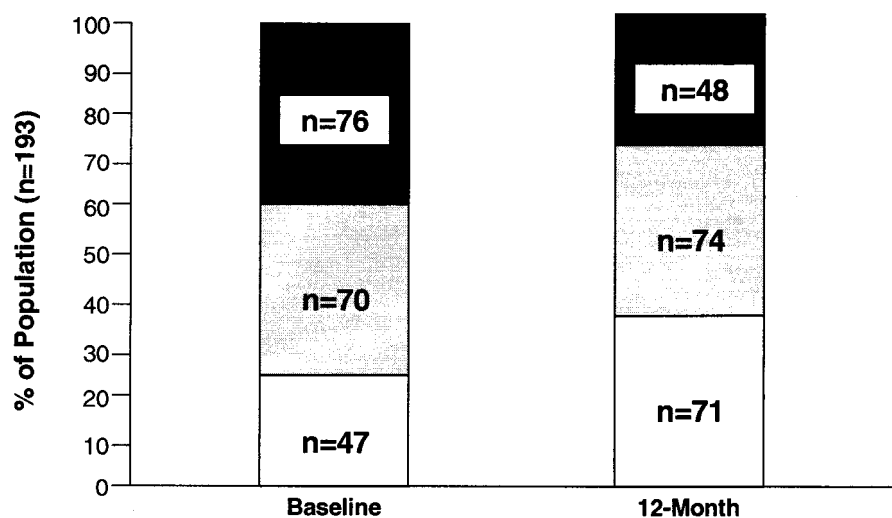


Figure 3—Change in glycemic control risk (% HbA_{1c}) for the treatment cohort. □, Low (HbA_{1c} <7.0%); ▨, moderate (HbA_{1c} 7–8%); ■, high (HbA_{1c} >8.0%).

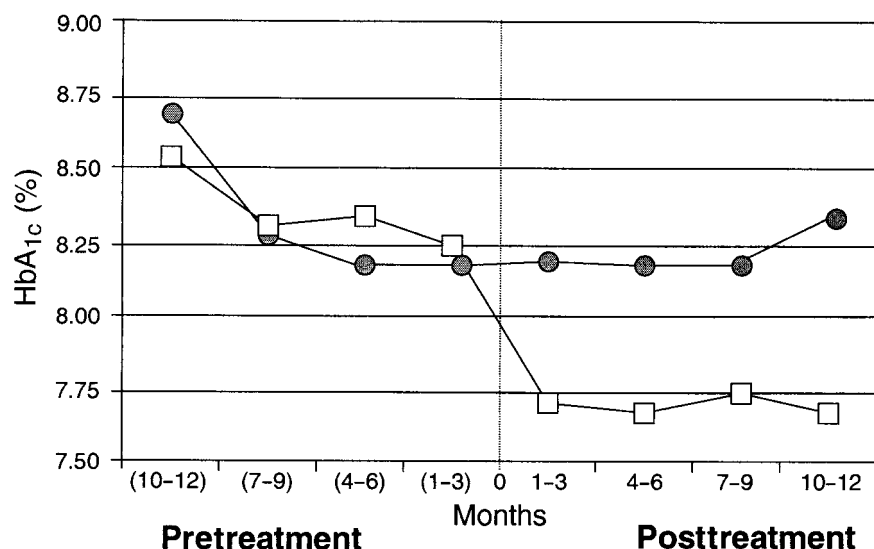


Figure 4—Time trend in average HbA_{1c} value for Diabetes Advantage Program treatment and control groups. Average HbA_{1c} is shown at 3-month intervals for the 12-month periods before and after enrollment. Note that the treatment group includes patients who dropped out of the program. ●, Control (n = 623); □, treatment (n = 356).

J.W.S.) reviewing the scientific basis for both the recommendation and the acceptance of the need for change in the approach to diabetes care.

These educational sessions and the presentation of data on prior performance were viewed as critical links in the process of prompting the recognition that a change in the way care is delivered could have positive consequences. However, it was also critical to devise a process that included the necessary support and resources to enable providers to achieve results without being overburdened. Although the clinic structure was left intact, patient flow was altered, and tasks were delegated to the team care coordinator and team care leader. The team care coordinator and leader assured that the data were available before the patient's visit with the provider and that the appropriate patient education occurred before that visit. The patients were involved in education programs from the start of the program and received a printout (in condensed form) of their data and risk status (Fig. 2). Thus, they were prepared for the visit and the discussion about how they might improve their health-risk status. The providers saw this process as improving effectiveness and productivity, which greatly facilitated ongoing participation and support of the program within their clinics.

Another enhancement in the program

was the initiation at the onset of a psychosocial evaluation using the Problem Areas In Diabetes (PAID) questionnaire developed and validated by Polonsky et al. (24). This was viewed as an important part of the initial assessment because a large percentage of adult patients with diabetes have significant psychological comorbidities, usually depression or anxiety disorders (25,26). Patients with abnormal PAID scores were identified to the practitioners for appropriate action. Educational courses by the clinic psychologist were conducted with all providers to assist them in managing such patients. Thus, before recommendations were

made for changes in therapy, it was necessary to address those comorbidities.

Finally, it was necessary to develop a system that collated the data and presented it in a format that was immediately understandable by (and useful to) the patient and the provider. Thus, the data needed to be summarized in such a fashion as to be clear and accurate, yet of sufficient brevity that it could be the basis of discussion by the patient and provider. The system developed also had two additional important features. First, it generated a set of orders for the clinicians to review and initiate, making the recommended changes easy, yet permitting individualization as needed. Visual graphic and analytical reporting components were shared between the patient and provider report formats, facilitating the communication between the patient and the healthcare team. Second, it generated a reminder list for the team care coordinator, providing a fail-safe system to ensure that recommended actions were not overlooked or omitted. For example, if an eye exam was recommended, the system would repeatedly remind the team care coordinator until the exam took place.

The success of the program in initiating the recommended changes in the diabetes therapeutic regimen was the most striking; 95.8% of the patients outside of the recommended therapeutic range had a prescribed change in therapy. These data suggest that the program was successful in convincing both patients and providers that the goals were of value and that changes were necessary to reach those goals. As the number of therapeutic choices available to treat diabetes ex-

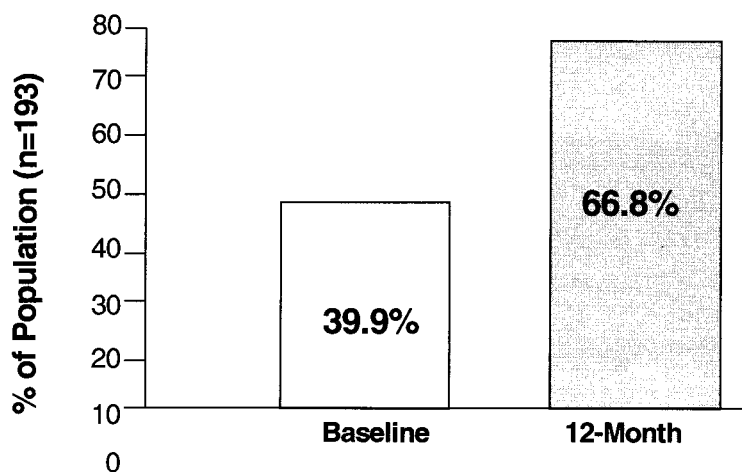


Figure 5—Reduction in hypertension risk for treatment cohort.

Table 3—Results from patient satisfaction survey

Category/question	Responses	
	Baseline	12 months
Knowledge and information		
“In the past 3 months, how satisfied have you been with your knowledge of your diabetes?”	49.2	81.3
“How helpful is the information that you received from your health plan about taking care of your diabetes?”	82.4	96.9
Program staff		
“How satisfied are you with the way the staff in the diabetes program treated you?”	63.8	97.4
“How satisfied are you with the number of times that the diabetes program staff talked with you?”	51.3	96.9
Program recommendation		
“Overall, how satisfied are you with your health plan’s diabetes program?”	57.5	94.3
“How likely are you to recommend your health plan’s diabetes program to someone else who has your kind of diabetes?”	56.4	94.8

Data are %. Responses column refers to the percentage of patients responding “very” and “slightly” satisfied, “helpful,” or “likely” to the questions on the survey.

pands, the metabolic success of the program should increase. It is also important to note that based on provider surveys at the completion of the study, the program did not add work to the already “overburdened” physician. In fact, the program served to improve workflow efficiencies for both providers and staff. The noted improvements demonstrated that excellent diabetes care can be achieved through enhancements in the primary care setting and that “carve-outs,” or separate systems of care involving mass referrals of patients with diabetes to specialty clinics, are not necessary.

In addition, the success of the program in initiating new therapies and improving patient outcomes did not come at the expense of patient satisfaction. Quite the contrary, the most striking finding of the study was the improvement in patient satisfaction that accompanied the program.

Whereas the striking results of the study could have been attributable to some unique features of the patients selected, there are several reasons why we do not feel this is the case. Although only 193 of the patients had complete 12-month data at the completion of the study, >85% of the patients entered into the study remained in the study at its end. The data over time for the complete cohort revealed a significant fall in HbA_{1c} by 3 months that persisted throughout the study, whereas the HbA_{1c} levels

of a comparative control group remained constant.

We believe the program was successful because it effectively capitalized on an array of interventions based on social marketing that have been shown to change physician behavior. Our overall strategy was to provide necessary information regarding diabetes management to care providers while removing obstacles that have traditionally inhibited the delivery of quality diabetes care. To this end, we developed interventions to ad-

dress each of the areas previously demonstrated to influence physician behaviors, as summarized in Table 1. For example, with regard to audit and feedback, explicit standards were agreed upon by the practitioners, and feedback was provided. Furthermore, once these standards were inputted into the system, they were implemented automatically; there was no deviation or partial compliance with the established protocols. With regard to the “opinion leader” involvement, both primary care leadership and endocrine leadership were enthusiastic and supportive of the program. Additionally, an automatic system of risk stratification and reminders was put into place. Through these interventions and others previously described, we created an environment that was supportive of comprehensive diabetes management.

Regarding the economic benefits of the intervention, this study did not address the financial implications of improved diabetes control. However, two recent publications suggest that there are significant and immediate economic advantages to improving glycemic control and treatment of diabetes risk factors (27,28).

The intervention studied was comprehensive, and we are unable to tease out the relative role of the various interventions. Additionally, the study was conducted in a staff-model MCO and may not be applicable to other types of delivery systems. Despite these limitations, we feel that the results provide a sound basis for

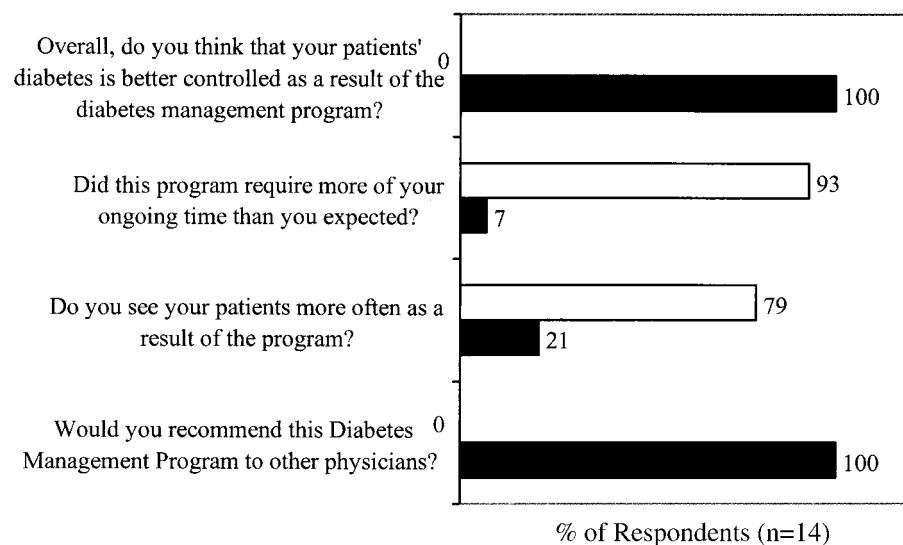


Figure 6—Staff provider responses to satisfaction survey. ■, Yes; □, no.

the design of future programs within MCOs directed at improving the care of patients with diabetes and other chronic diseases. To determine whether these protocols can be adapted to other care settings, we have developed a CD-ROM-based continuing medical education program that targets primary care physicians; we are now in the process of evaluating this program (29).

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