

Application of a Diabetes Managed Care Program

The feasibility of using nurses and a computer system to provide effective care

ANNE L. PETERS, MD
MAYER B. DAVIDSON, MD

OBJECTIVE — Treatment of patients with diabetes often falls short of recommended process and outcome guidelines. To improve the quality of the provided diabetes care, a program (the Comprehensive Diabetes Care Service [CDCS]) using a computerizing tracking and recall system in conjunction with nurses following protocols was implemented in a managed care setting. The impact of this program was studied and compared to the care provided to patients in another managed care setting.

RESEARCH DESIGN AND METHODS — Patients followed in the CDCS who completed a diabetes education course were compared with patients followed in a group model health maintenance organization (GMH) who also completed a diabetes education course. CDCS patients received routine care in the program. GMH patients came to the CDCS yearly to have a diabetes evaluation. A chart review was also performed on their GMH outpatient records.

RESULTS — Initial HbA_{1c} levels were higher in the CDCS group than in the GMH group (median of 11.9 vs. 10.0%). In the CDCS patients, HbA_{1c} levels not only fell significantly but were also significantly lower ($P < 0.05$) than in the GMH patients during the 2nd and 3rd year of follow-up care. There were no significant changes in HbA_{1c} levels in the GMH patients. When CDCS patients were divided into compliant and noncompliant patients, the median HbA_{1c} levels in compliant patients was 8.2%, compared with 11.5% in the noncompliant group. The CDCS patients who needed treatment for hypercholesterolemia were more likely to have a lowering of their cholesterol levels than the GMH patients. All process measures, such as yearly measurement of HbA_{1c} levels, lipid levels, and foot and retinal exams, occurred much more frequently in the CDCS patients.

CONCLUSIONS — The system developed and implemented for managing diabetes improved both outcome and process measures. The comparison group, followed at another managed care setting, received the care consistent with the average (suboptimal) quality of care provided to patients with diabetes in the U.S. Therefore, by using innovative systems of management, the treatment of patients with diabetes can be greatly improved.

The treatment of diabetic patients in the U.S. is both expensive and often inadequate. In 1992, 14.2% of all direct health care expenditures were used to treat patients with confirmed diabetes,

who represent only 4.5% of the population (1). This expense represented a per capita expenditure of \$9,493 per diabetic patient, compared with \$2,604 in per patient medical costs for nondiabetic subjects.

In multiple studies, both in fee-for-service and in managed care environments, diabetes care falls far short of desired treatment goals (2). One recent survey evaluating the treatment of diabetic patients followed in a managed care organization at multiple sites in California (3) confirmed the poor quality of care provided. In 1 year, only 44% of the 353 patients studied had one or more HbA_{1c} levels measured (patients should have two to four measurements obtained per year based on the American Diabetes Association [ADA] recommendations for care [4]). Of those who had an HbA_{1c} level drawn, it was $\geq 10\%$ in 35% of the patients. Additionally, only 6% had a documented foot exam (this should occur at every regularly scheduled visit for diabetes), and $\sim 50\%$ had measurements of renal function and serum lipid levels performed (these should be obtained yearly). Therefore, much improvement is needed.

The Diabetes Control and Complications Trial (DCCT) (5) and the Kumamoto Study (6) have shown conclusively that the risk of developing microvascular (retinopathy and nephropathy) and neuropathic complications can be markedly decreased (and progression of early complications slowed) if near-normal blood glucose levels are maintained in patients with diabetes. This is true in patients with both type 1 (5) and type 2 diabetes (6). In both studies, an HbA_{1c} level of $\sim 7\%$ was found to be associated with a significant decrease in the development and progression of diabetic complications, compared with an HbA_{1c} level of $\sim 9.0\%$ in the control groups.

Since it is clearly beneficial to maintain near-normal blood glucose levels in patients with diabetes and since this goal is not being met in much of the population, we designed a system of diabetes management that provided consistent follow-up care using nurses who followed detailed protocols as the primary interface with the patient. This system was implemented to provide diabetes management to the patients followed in an independent practice association (IPA) affiliated with our

From the Department of Medicine (A.L.P.), UCLA School of Medicine, University of California, Los Angeles; and the Department of Diabetes, Endocrinology and Metabolism (M.B.D.), City of Hope National Medical Center, Duarte, California.

Address correspondence and reprint requests to Anne L. Peters, MD, UCLA Department of Medicine, 200 UCLA Medical Plaza, Suite 365, Los Angeles, CA 90095.

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Abbreviations: ADA, American Diabetes Association; CDCS, Comprehensive Diabetes Care Service; CSMC, Cedars Sinai Medical Center; DCCT, Diabetes Control and Complications Trial; GMH, group model health maintenance organization; IPA, independent practice association; SMBG, self-monitoring of blood glucose.

institution. To test whether or not this system improved care, it was compared with standard diabetic care provided to patients followed at another, local group model health maintenance organization.

RESEARCH DESIGN AND

METHODS — In 1987, the Comprehensive Diabetes Care Service (CDCS) was implemented at Cedars Sinai Medical Center (CSMC). In this program, nurses made clinical diabetes management decisions based on specific detailed protocols that provided step-by-step instructions for diabetes and lipid management (7). These protocols were designed based on appropriate clinical guidelines (e.g., ADA guidelines for diabetes issues [4], National Cholesterol Education Panel [NCEP][8], and ADA guidelines for lipid protocols) and published literature, when available. In addition to the hard copy protocols, a computer system was designed to maintain a database of the patients and their clinical information, to track patient appointments and required laboratory tests, and to interpret self-monitoring of blood glucose results entered into the computer system and then suggest insulin dose adjustments based on well-tested clinical principles (9). The system generated reminder cards to the patients for laboratory tests and appointments and continued to send out monthly “late” notices until the required event occurred. The computer system was a relational database designed in the mainframe computer system in use at CSMC at the time the program was implemented.

A total of 41 protocols were written for management of diabetes and lipid disorders. These protocols were modified as new diabetes medications were released or as new guidelines were adopted (although neither metformin, acarbose, nor troglitazone became available before the end of the study). Follow-up appointments were scheduled on a quarterly basis. Initial and annual laboratory panels were modeled after ADA guidelines and modified if a patient was on medication requiring additional laboratory testing (e.g., measurement of liver function tests for patients taking an HMG-CoA reductase inhibitor). HbA_{1c} levels (using affinity chromatography) were ordered every 2 months (with the goal of obtaining values on a quarterly basis, since most patients did not undergo their laboratory testing immediately upon receiving the card directing them to do so). Patients were referred to an ophthalmologist at least

Table 1—Patient demographics

Characteristic	CDCS	GMH	P value
<i>n</i>	97	67	
Men (%)	47.4	50.8	0.67
Age (years)	53.6 ± 1.4 (26–79)	58.6 ± 1.3 (23–78)	0.01
Years since diagnosis	6.3 ± 0.9	5.8 ± 0.9	0.70
New-onset* (%)	40.2	34.3	0.46
BMI (kg/m ²)	29.0 ± 0.65	29.1 ± 0.84	0.92
Type 2/type 1	88/9	64/3	0.34

Data are *n*, %, or means ± SEM (range). *Diagnosis of diabetes occurring within 6 months of entering into the study.

yearly and to a podiatrist as indicated by the protocols. At their initial and annual visits, patients were asked to complete an SF-36 quality-of-life questionnaire (10) with two additional questions related to diabetes. At the initial and annual visits, the patients underwent a diabetes-focused physical examination performed by the nurse and program physician. Data collected included measurement of weight and blood pressure and testing for protective sensation with a 5.07 monofilament (11). Urine protein was measured by dipstick. For patients with dipstick-negative urine, a spot albumin-to-creatinine ratio was measured to test for microalbuminuria. A ratio ≥30 µg/mg was considered positive for microalbuminuria.

Patients with diabetes enrolled in the IPA were referred by their physicians into the CDCS. Once enrolled in the CDCS, the patient underwent an individual diabetes evaluation, and all were given the option of attending a diabetes education course (at no additional cost). The subset of patients who had attended the diabetes education course from 1987 to 1992 were those followed in this study. Patients must have been continuously enrolled in the CDCS for 1 year after attending the course to be included in the analysis. The CDCS patients in this study received the same care as other CDCS patients, although they were asked to complete the SF-36 quality-of-life questionnaires at their annual visits. Since the care of these patients was no different from the care provided to other CDCS patients, they were not required to sign a consent form (CSMC Human Subjects Protection Committee exemption) and did not know they were in a study.

Patients who attended a diabetes education course at a local group model health maintenance organization (GMH) were recruited and compared with the patients

followed in the CDCS. Diabetes education courses at both institutions were comprehensive; one group meeting daily for 1 week (CDCS) and the other group meeting weekly for 4 weeks (GMH). The curriculum used in both courses was similar and followed ADA guidelines for diabetes education programs. A list of patients who attended this GMH monthly course was provided to the nurse coordinator of the CDCS program, and all patients were contacted and offered the opportunity to participate in the study. Those who agreed to participate came to the CDCS yearly for an evaluation that was identical to that received by the CDCS patients, although their laboratory values were often nonfasting. In addition to this follow-up care at the CDCS (the results of which were not given to the patient or to the patient's physician), the patient's GMH chart was reviewed at the end of the study for evaluation of the follow-up care they received at their primary site for medical care during the duration of the study. Because care was centralized at the GMH, all medical treatment that was provided (including primary care and specialist visits, hospitalizations, ophthalmologist examinations, laboratory values) was included in one patient chart.

Patients in the CDCS were divided into compliant and noncompliant groups and assessed at yearly intervals. Therefore, patient compliance is assessed from baseline to year 1, year 1 to year 2, and year 2 to year 3. To be considered compliant, a subject had to keep at least two routinely scheduled appointments each year, have at least one HbA_{1c} level obtained per year, and attempt to comply with medication changes suggested by the protocols. Noncompliant CDCS patients were considered those who kept none or only one appointment, did not have an HbA_{1c} level measured during the year, and had nurses note

Table 2—Diabetes and lipid-lowering therapies at baseline and study termination

Treatment	CDCS		GMH	
	Start	End	Start	End
Diabetes medication				
Diet alone	24.7	15.5	14.9	13.4
SA	54.6	42.3	50.7	47.8
Insulin	17.5	38.1	31.3	38.8
Insulin + SA	3.0	4.1	3.0	0
Lipid-lowering medication				
None/diet	92.8	68.0	92.5	92.5
Statin	2.1	21.6	3.0	4.5
Gemfibrozil	3.1	13.4	3.0	1.5
Resin	1.0	0	1.5	1.5
Resin + niacin	1.0	0	0	0
Statin + resin	0	1.0	0	0

Data are % of patients on each therapeutic modality. SA, sulfonylurea agent.

in their charts that they refused to change medications as advised. To be considered noncompliant, one or more of these parameters had to be missing (e.g., a patient who came in for four appointments and followed medication advice but had none of the ordered HbA_{1c} levels obtained would be considered noncompliant, as would a patient who missed all appointments, had no HbA_{1c} levels measured, and refused to follow medical advice about drug therapy). A patient's compliance was considered each year, and some patients were compliant for part of the study and noncompliant for other years. It was impossible for the GMH patients to be divided into similar categories of compliant and noncompliant since there was no standard follow-up care that was expected of patients, and therefore compliance with their care could not easily be measured.

Data analysis

To compare baseline characteristics of the CDCS and GMH groups, we used χ^2 tests for the categorical outcomes and *t* tests for continuous measures. Where applicable, data are presented as either means \pm SEM (evaluated by nonpaired *t* tests) or medians (evaluated by rank-sum tests). Statistical significance was declared for *P* values of <0.05 (two-tailed).

The profiles of repeated observations on individuals were compared using generalized estimating equations (12) as implemented in the "gee" function for Splus (V. Carey, Channing Laboratory, Harvard). The effect of time was parameterized as baseline versus average postintervention responses. The effects of subject-specific variables

(experimental group, recent onset, or compliance) were tested for interaction with the time contrast.

There are two caveats owing to the experimental design. One is that intervention at an institution (i.e., group randomization) confounds institution-specific temporal changes with treatment. The other is that data may not be missing completely at random. However, the change from baseline to the 1st year involves few missing data.

RESULTS—Table 1 lists the patient demographics from each group. The patients in the GMH group were slightly older, but otherwise the groups were similar. Approximately 40% were Caucasian,

40% African-American, 15% Asian, and 5% Hispanic in each group. Although socioeconomic data on subjects were not collected, both patient groups were drawn from working-class populations in Los Angeles. In the CDCS patients, the average follow-up care was 2.3 ± 0.1 years, with 18 patients having only 1 year of follow-up care, 27 patients completing 2 years of follow-up care, and 47 patients completing 3 years of follow-up care. The average follow-up care was 2.2 ± 0.1 years among the GMH patients, 16 completing 1 year of follow-up care, 19 completing 2 years, and 32 completing 3 years. A total of 27 patients (17 CDCS; 10 GMH) did not complete 1 year of follow-up care. These patients were not included in the results and had similar demographic characteristics (age, sex, proportion with total cholesterol levels >240 mg/dl, and proportion with new-onset diabetes) and identical baseline median HbA_{1c} levels (11.2 vs. 11.2%), compared with those patients who completed at least 1 year of follow-up care.

The diabetes treatments in the two groups are shown in Table 2. The number of CDCS patients initially taking insulin was lower than that of the patients followed in the GMH; however, by the end of the study, the proportion of patients on insulin were similar in the two groups. Lipid-lowering medication use is described in Table 2 and was much more commonly prescribed in the CDCS patients.

Figure 1 shows the change in HbA_{1c} levels in the CDCS and GMH patients. The initial median HbA_{1c} level in the CDCS

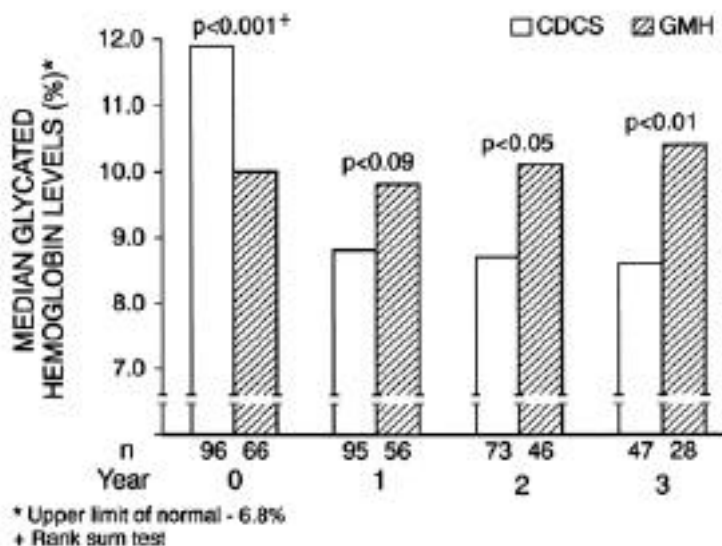


Figure 1—Median HbA_{1c} levels in CDCS patients compared with GMH patients.

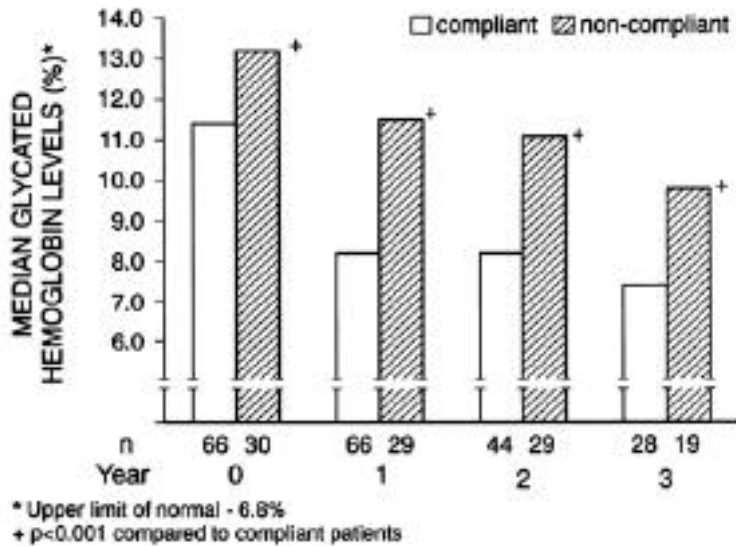


Figure 2—Median HbA_{1c} levels in compliant versus noncompliant CDCS patients.

patient was higher than that in the GMH patient (11.9 vs. 10.0%; $P < 0.005$). The median HbA_{1c} level fell in the CDCS patients from 11.9 to 8.8% at year 1, and this lowering was maintained for the 3 years of the study. The HbA_{1c} level did not fall in the GMH patients, and the median value was statistically higher than that in the CDCS patients during the 2nd and 3rd years of the study. Fig. 2 shows the difference in HbA_{1c} levels between compliant and noncompliant CDCS patients.

Fasting lipid values were not available in the GMH patients. Therefore, only total cholesterol levels were analyzed. Overall cholesterol levels did not change between the two groups, but if analyzed in subsets of patients who might need lipid-lowering therapy (i.e., patients with a total cholesterol level of >6.2 mmol/l [>240 mg/dl]), total cholesterol levels fell significantly in the CDCS patients but did not change in the GMH patients (Fig. 3).

Serum creatinine levels and the presence or absence of proteinuria or microalbuminuria (in patients whose urine dipstick was negative at baseline) were not different at baseline or throughout the course of the study. Similarly, there were no differences in the baseline blood pressure levels (CDCS = 136/82 mmHg; GMH = 137/80 mmHg) or mean levels throughout the study. At baseline, 7% of CDCS patients and 14% of GMH patients had peripheral neuropathy ($P = 0.17$) based on 5.07 monofilament testing; neuropathy was con-

sidered present if a patient could not feel the monofilament on all three sites in a region (the foot was divided into three regions, each region with three testing sites: region one, the bottom of the great toe, third toe, and fifth toe; region two, three points across the ball of the foot; region three, one point in the middle of the foot plus two sites on the heel).

Process measures, such as the number of HbA_{1c} levels and lipid panels obtained per year and the number of documented foot exams, were performed much more frequently in the CDCS patients. The fre-

quency of testing is compared to the ADA standards of care (4) and is shown in Table 3. Frequency of HbA_{1c} testing met these standards if it was performed ≥ 2 times/year in patients not taking insulin and ≥ 4 times/year in patients taking insulin. Lipid panel frequency should be at least yearly and foot exams should be carried out ≥ 2 times/year. Ophthalmology referral rates were also much higher in the CDCS patients (overall 95% referred to an ophthalmologist each year compared with 21% in the GMH patients). Additionally, all patients without known retinopathy in the CDCS had non-mydratric retinal photographs taken at the time of their initial and annual visits and were referred immediately to the ophthalmologist if evidence of macular edema or moderate to severe retinopathy was found.

Among the CDCS patients, there were no hospitalizations for acute diabetes-related metabolic problems. There were three hospitalizations among the GMH patients (one each for hypoglycemia, diabetic ketoacidosis, and diabetes out of control).

Quality-of-life indexes, as measured by the standard SF-36 form, showed no differences in nondiabetes-related parameters. However, two specific diabetes-related questions did show differences (APPENDIX; R. Hayes, personal communication of diabetes-specific questionnaire). These diabetes-specific questions were designed to find differences that were due to diabetes per se, rather than a patient's overall health status. Because these diabetes-specific questions were not used previously, it is difficult to assign statistical significance to the

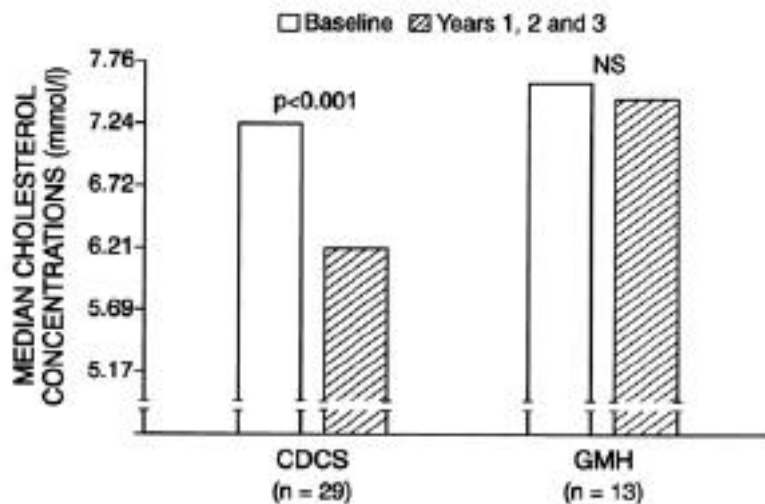


Figure 3—Total median cholesterol concentrations in patients with an initial total cholesterol level >6.2 mmol/l (>240 mg/dl) in CDCS versus GMH patients. Baseline values are compared with the mean value for all 3 years in each patient.

Table 3—Compliance with ADA guidelines

	Year 1		Year 2		Year 3	
	CDCS	GMH	CDCS	GMH	CDCS	GMH
<i>n</i>	98	64	74	55	42	42
HbA _{1c} levels	87	24	69	14	71	11
Lipid panels	100	36	92	39	93	49
Foot exams	100	11	96	9	93	9
Ophthalmology referrals	99	19	92	24	95	19

Data are %.

results, but they are used here descriptively to reflect how patients felt with regards to their diabetes during the study. CDCS patients had a lower score (felt worse) for their overall diabetes-related quality of life at baseline than did the GMH patients. The overall diabetes-related score improved over the course of the study in CDCS patients (Table 4). The GMH patients had a higher overall diabetes-related score (i.e., they felt better at baseline), and this sense of well-being did not change over the course of the study.

CONCLUSIONS — This study shows that physician-supervised nurses, following protocols, aided by a computer recall system, can substantially improve the quality of diabetes care in a managed care setting. Although the CDCS patients initially had poorer glycemic control, their HbA_{1c} levels fell below those levels seen in the GMH patients, and this improvement was maintained for the next 3 years. When subsets of CDCS patients were analyzed, it was clear that those who complied with the recommendations of the program had far better outcomes than those who did not. Although most health care providers intuitively feel that outcomes are poorer in noncompliant patients, this is the first demonstration (to our knowledge) that this assumption is true.

Although initially more GMH patients were taking insulin than CDCS patients, by the end of the study the treatments for diabetes were similar (with an increase in the number of CDCS patients taking insulin from 17.5 to 38.1%). This study was performed before the release of metformin, troglitazone, or acarbose, which might allow for improvements in glycemic control without starting insulin. The other striking treatment change was in the number of patients in the CDCS taking an HMG-CoA reductase inhibitor (2.1% at baseline compared with 21.6% at the end of the study). At baseline, only 3% of GMH patients were taking an HMG-CoA reductase inhibitor, which did not change over the course of the study (4.5% at the end of the study). This finding was consistent with the significant fall in cholesterol levels found in the CDCS patients and the lack of change in the GMH patients. To separate changes in glycemic control from changes in lipid levels, initial glycemic control was compared in the hypercholesterolemic patients in both groups and did not differ. Moreover, there was no relationship between the fall in cholesterol levels and the change in HbA_{1c} levels in the CDCS patients (data not shown).

The improvements seen in glycemic control are similar to those found with other systems of diabetes management

(14,15), although improvements in process measures (laboratory testing, foot exams, and ophthalmology referrals) were better (16). This likely was due to the persistence of the computer system in tracking patients and sending reminder cards for laboratory tests and patient appointments. The system would continue to send cards monthly until the patient either complied with the recommendation or the number of ignored reminders triggered a telephone call.

The issue of noncompliance was a significant problem, as it is in all systems of diabetes management (17). We were unable to analyze why patients did not comply with the recommendations of the system, since it was not due to a lack of education or persistence of follow-up care. Some patients consciously did not wish to achieve near euglycemia (although still came in for visits), and others chose to avoid dealing with the program altogether. A total of 14 patients met the criteria for compliance during some years of the study but were noncompliant during other years. Since the system never “gave up” on a patient once enrolled, some patients would finally return after an absence of a year or more and become compliant with their diabetes management.

Unfortunately, the data set in this study is incomplete. In the CDCS patients, this primarily was due to patients changing their insurance provider (34%) or the fact that the study ended before 3 years of follow-up care could be completed (52%). The data from the GMH patients were incomplete primarily because of the difficulties in scheduling and following the GMH patients who were not entered into the routine follow-up system. Although all diabetic patients referred to the CDCS or seen by a GMH primary care physician were given the opportunity to attend a diabetes education course, data are not avail-

Table 4—Diabetes-related quality-of-life results

	Year 0	Year 1	Year 2	Year 3	Years 1–3	<i>P</i> value
GMH						
Negative aspects of diabetes	68.8* ± 2.6	67.4 ± 3.3	72.1 ± 3.1	70.5 ± 3.5	69.6 ± 1.9	NS
Overall diabetes rating	71.4† ± 3.5	63.9 ± 4.7	75.8 ± 4.6	66.4 ± 6.9	68.3 ± 3.0	NS
CDCS						
Negative aspects of diabetes	59.4* ± 3.9	74.6 ± 2.7	74.2 ± 4.4	73.5 ± 7.0	74.3 ± 2.2	<0.001
Overall diabetes rating	59.7† ± 5.5	75.2 ± 4.1	69.2 ± 6.5	74.8 ± 8.4	73.2 ± 3.2	0.025

Years 1–3 represent weighted mean. *P* values represent baseline versus weighted mean of years 1–3. **P* < 0.025 GMH versus CDCS Year 0 values; †*P* = 0.03 GMH versus CDCS Year 0 values.

able on how many attended or on the differences between those who attended and those who did not. All GMH patients had full coverage for durable medical equipment, while CDCS patients had variable coverage, depending on their insurance plan. Finally, although GMH patients could have received their diabetes care through another provider (and thus data would not be available in their GMH chart), each patient was queried at their yearly evaluation to be sure they were still followed primarily in the GMH facility. Those who changed or had dual insurance policies were excluded from the study. And in spite of these limitations, the data still suggest improvement in patients followed in the CDCS. Moreover, implementing the program at a nonacademic site also showed improved outcomes (18), suggesting that the CDCS system is effective.

The duration of this study was too short to show any improvement in chronic complications, although based on data from the DCCT (5) and Kumamoto Study (6), maintaining near-normal blood glucose levels over many years should eventually lower the rates of progression and development of the microvascular and neuropathic complications of diabetes. In addition, the improvement of lipid levels through use of diet and HMG-CoA reductase inhibitors should lower the risk of macrovascular disease (19,20). Interestingly, as found in other studies (3), blood pressure levels were similar between the two groups, suggesting that the implementation of guidelines on the diagnosis and treatment of hypertension (21) has been effective in managed care settings.

In conclusion, diabetes care, as assessed by both process and outcome measures, can be greatly enhanced by the implementation of a coordinated system of care using a computer program, protocols, and physician-supervised nurses. This study found that the care provided to the control group of patients (GMH) was similar to the care received by diabetic patients in most settings (2). Compared with the control group, patients in the CDCS fared much better. However, the overall fall in HbA_{1c} levels was not as great as it could have been because of the noncompliant patients followed in the program. The issue of compliance is one of great importance and necessary to consider when physicians become evaluated for the quality of their diabetic outcomes. Since our computer system and nurses never "gave up" on the patients, chances for compliance were probably enhanced in this setting com-

pared with a system of care in which a busy physician provides diabetes management. No doubt there are many patients whose compliance would improve if their interaction with a system of care was increased. It is for this reason that systems for tracking patients and implementation of clinically practical protocols are important tools for the improvement of the quality of diabetes care in the U.S. This may be especially true in a managed care setting where the goal is to deliver diabetes care on a population basis rather than on an individual one.

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APPENDIX — The diabetes-specific questions included the following (R. Hayes, personal communication).

Negative aspects of diabetes and overall diabetes rating

1. During the past month how much did your diabetes cause a problem with each of the following?
 - Doing things on the spur-of-the moment.
 - The amount of time or inconvenience involved in treating your diabetes.
 - Maintaining a diet and preparing food.
 - Having a large appetite for food.
 - Feeling embarrassed in public while managing your diabetes.
 - Taking a trip or going on vacation.
 - Pain or discomfort involved in taking care of your diabetes.
 - Doing things socially with friends/relatives.
 - Planning meals or eating out with others.

Your family life, getting along with others.

Having to plan things differently to take care of your diabetes.

Lack of interest in sex or enjoyment of sex.

2. Overall, how much of a problem is it to live a normal life and take care of your diabetes?

(Responses were given a discrete score as listed. The higher the score, the more positive the answer.)

- Very much a problem (0)
- Somewhat of a problem (33)
- A little bit of a problem (66)
- Not a problem (100)
- Not applicable (NA)

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