Diabetes Management in a Health Maintenance Organization

Efficacy of care management using cluster visits

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OBJECTIVE — To evaluate the effectiveness of a cluster visit model led by a diabetes nurse educator for delivering outpatient care management to adult patients with poorly controlled diabetes.

RESEARCH DESIGN AND METHODS — This study involved a randomized controlled trial among patients of Kaiser Permanente's Pleasanton, CA, center who were aged 16–75 years and had either poor glycemic control (HbA_{1c} >8.5%) or no HbA_{1c} test performed during the previous year. Intervention subjects received multidisciplinary outpatient diabetes care management delivered by a diabetes nurse educator, a psychologist, a nutritionist, and a pharmacist in cluster visit settings of 10–18 patients/month for 6 months. Outcomes included change (from baseline) in HbA_{1c} levels; self-reported changes in self-care practices, self-efficacy, and satisfaction; and utilization of inpatient and outpatient health care.

RESULTS — After the intervention, HbA_{1c} levels declined by 1.3% in the intervention subjects versus 0.2% in the control subjects ($P < 0.0001$). Several self-care practices and several measures of self-efficacy improved significantly in the intervention group. Satisfaction with the program was high. Both hospital ($P = 0.04$) and outpatient ($P < 0.01$) utilization were significantly lower for intervention subjects after the program.

CONCLUSIONS — A 6-month cluster visit group model of care for adults with diabetes improved glycemic control, self-efficacy, and patient satisfaction and resulted in a reduction in health care utilization after the program.

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The American Diabetes Association's (ADA) clinical practice guidelines recommend "treatment aimed at lowering blood glucose levels to or near normal in all patients" to avoid acute decompensation, reduce symptoms, diminish the chance of developing long-term complications, and improve the atherogenic lipid panel (1). This recommendation has been based primarily on studies conducted in patients with type 1 diabetes (2,3). However, evidence now shows that good glycemic control is likewise important in reducing long-term sequelae in type 2 diabetic patients (4–7). The accomplishments of the Diabetes Control and Complications Trial required a team approach to care that included dietitians, psychologists, and nurses as well as physicians. A multidisciplinary approach may be even more critical for achieving normoglycemia in type 2 diabetes, given the greater need for behavioral change and self-management in this disorder.

Growing numbers of diabetic patients are involved in managed care. In an era of more tightly controlled health care resources, health maintenance organizations (HMOs) are challenged to identify cost-effective programs that can accomplish the prevention aims set forth by the ADA. One-on-one patient–physician encounters are both time consuming and costly and appear to be suboptimal for achieving glycemic control and other prevention goals. The use of nurse case management for adult patients with diabetes has recently been shown to lead to improved glycemic control and quality of care (8–10) and to enhanced health status (11) in managed care settings. Improved glycemic control has also been shown to result in prompt health economic benefits for diabetic patients (11). However, these studies did not examine the net effects of intensive interventions on health care utilization and direct costs of care.

In this randomized study, we compared a multidisciplinary, nurse-led team providing comprehensive medical care for diabetic patients in a cluster visit setting with usual diabetes care provided by primary care physicians in an HMO setting. In addition to the primary end points of glycemic control and patient satisfaction, we also studied the effects of the intervention on health care utilization and cost of care.

RESEARCH DESIGN AND METHODS

Study setting, eligibility, recruitment, and baseline assessment

This randomized trial was conducted with patients served by the Pleasanton facility of the Kaiser Permanente Medical Care Program, Northern California. The study was supported by the HMO's Innovations Pro-

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Abbreviations: ADA, American Diabetes Association; DCCC, Diabetes Cooperative Care Clinic; HMO, health maintenance organization.

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

gram, an internal peer-reviewed funding mechanism, and was approved by the Institutional Review Board of the Kaiser Foundation Health Plan.

Eligible diabetic patients were initially identified from the program's diabetes registry (12), a population-based database estimated at the time to have a sensitivity of ~96%. To be eligible, a patient must have been between 16 and 75 years of age and either have had a recent HbA_{1c} concentration >8.5% or not had an HbA_{1c} concentration measured during the previous year. Both type 1 and type 2 diabetic patients were included in the study. Approximately 57% of all diabetic Kaiser members in this age range met these criteria in 1995. After initial identification from the registry, the research assistant or a registered nurse contacted potential subjects by telephone to invite them to participate in a randomized evaluation of the Diabetes Cooperative Care Clinic (DCCC), a cluster visit model of care management. Several additional exclusion criteria were applied at the first telephone contact, including current pregnancy, dementia, inability to speak English, or inability to attend monthly meetings.

Overall, 70% of the eligible subjects who were contacted agreed to participate in the study. Identifying information was not collected for patients who refused to participate. However, compared with all eligible nonparticipants in the registry who lived in the same service area, participants were slightly older (mean age 56 vs. 53 years), were equally likely to be female (42% of each group), had been enrolled in the HMO slightly longer (11 vs. 10 years), and were more likely to have used insulin (with or without oral hypoglycemic agents) during the preceding year (46 vs. 29%).

Once a group of ~30 willing and eligible participants was identified, a baseline group visit was scheduled. At this visit, informed consent was obtained, and subjects completed questionnaires that included assessment of demographics, questions on several self-care practices, eight 10-valued items on self-efficacy for aspects of diabetes self-management (with the range from not at all confident to extremely confident), and six five-choice items concerning level of satisfaction with aspects of general medical care and with care specific to diabetes. Group members were then randomized to the DCCC or to usual care with the primary physician by using a coin-toss method by a research assistant who had no previous contact with the subjects. Seven groups were recruited (and the participants randomized) between September 1995 and June 1996. In the first group, the number of patients was so small that all were assigned to the intervention group. For this reason, the final number of intervention subjects is somewhat larger (n = 97) than the number of control subjects (n = 88).

Description of the study intervention

The DCCC is a multidisciplinary diabetes care team that includes a dietitian, a behaviorist, and a pharmacist and is led by a diabetes nurse educator who is supported by two diabetologists. Most services are delivered in monthly 2-h cluster visits that involve 10–18 patients. A total of seven groups of members were randomized to the DCCC during a 10-month period. After the 6-month intervention, care transitioned back to the primary care physician.

The diabetes nurse educator reviewed baseline questionnaires of intervention subjects for the presence of certain complications (e.g., angina pectoris), for symptoms of significant hypoglycemia, and for difficulties in managing diet, alcohol intake, and tobacco use. Referrals to the behaviorist, smoking cessation or drug and alcohol rehabilitation programs, or the patient's primary care physician were made as appropriate. Patients not already monitoring blood glucose were quickly targeted for meter education. Between meetings, the diabetes nurse educator reviewed diabetes management by telephone from twice monthly to every 3 days, depending on the patient's needs. The team dietitian conferred individually with ~50% of the patients at the patient's request or based on a referral from the nurse for one of the following criteria: no dietitian visit for >2 years, poor food choices as indicated by the food logs, or patient interest in intensive insulin management. The team behaviorist conducted from one to four individual sessions with a total of 13 patients after either patient self-referral or referral initiated by the nurse or dietitian. The team pharmacist reviewed computer-based medication profiles, contacted patients to verify the medications, and alerted patients to any potential drug interactions or adverse effects on blood glucose. The medical assistant measured blood pressure and provided clerical support.

The DCCC team polled patients at the outset of the 6-month course for the information they wanted presented beyond the core education material. Depending on the requests of the individual cluster group, patients arranged sessions concerning diabetes complications, sexual dysfunction, exercise, and stress and emotional aspects of diabetes. Every group opted to schedule a cluster session with the podiatrist, who lectured and screened all patients with a foot examination. Patients requiring individual therapy were scheduled for visits in the podiatry clinic. Two groups requested an interactive session with the pharmacist. Patients requiring ophthalmology screening had examinations scheduled by the team.

The project's physician coinvestigators (W.C.J., C.N.S.) met regularly with the two diabetes nurse educators to review each patient's progress during the preceding 1–4 weeks, depending on the case management need. Topics included medication dosage changes, review of laboratory results, and triage for medical care outside of the clinic. Rarely, one of the physician coinvestigators was called to examine a patient during the clinic. The clinic provided all patients' primary care physicians with copies of the progress notes that went into the medical record.

Near the end of the 6-month intervention, the diabetes nurse educator and the behaviorist discussed transitioning diabetes care back to the primary care physician. Physicians were notified by mail regarding their patient's completion of the project. The clinic also sent a review letter to the patient with details of the diabetes care plan, including medication specifics, diet, exercise, and suggested monitoring frequency. The diabetes nurse educator and patients together arranged for collection of follow-up data, including an HbA_{1c} measurement and the mailed follow-up questionnaire at 6 months after randomization.

Subjects assigned to the usual care group continued to receive all diabetes care from their primary care physicians throughout the 6-month study period. At 6 months after randomization, the team mailed these control subjects a follow-up questionnaire and a request for repeat laboratory testing. At 12 months after randomization, both intervention and control group participants received a second letter again requesting that they have laboratory tests performed. Because of limited resources, study personnel could not aggressively follow patients in either group who failed to comply with initial requests.

Study outcomes

The outcomes available for the study included postintervention HbA_{1c} levels;

self-reported measures of self-care practices, self-efficacy, and satisfaction with general medical care and with diabetes-specific care; measures of utilization of inpatient and outpatient services before, during, and after the 6-month intervention through the end of 1997; and total costs of care for the same periods. Questionnaire items were adapted from items used previously in health plan surveys. HbA_{1c} values were obtained from the HMO's automated clinical laboratory database. For each patient, the first value recorded more than 5 months after randomization (i.e., near the completion of the intervention) was used as the 6-month value. Values were available for 100% of subjects in each study group at baseline and for 85% (82) of subjects in the intervention group and 84% (74) of subjects in the control group at 6 months of follow-up. All subjects in each group completed the baseline questionnaire; however, baseline data from the instrument concerning satisfaction with care are available for only 30 intervention and 30 control members. A total of 80 intervention subjects (82%) and 62 (70%) control subjects completed the postintervention questionnaire.

HMO databases provided information on utilization of services. These data were therefore available for all subjects. Inpatient utilization was tabulated for the 12 months before randomization and for an average of 18 months after randomization. Outpatient utilization was categorized as visits to the Department of Medicine (separately for visits to physicians and nonphysicians), Urgent Care Clinic, Emergency Department, Department of Ophthalmology, and Department of Optometry. Outpatient utilization was examined separately for a 6-month period before randomization, for the period of the intervention (the first 6 months after randomization), and for the period after intervention (~12 months).

Statistical methods

Unpaired *t* tests for continuous variables and χ^2 analyses for proportions were used to compare the baseline values for intervention and control subjects. The *t* tests for the differences from baseline to the postintervention values formed the basis for the continuous variable comparisons. Mantel-Haenszel χ^2 statistics compared dichotomous postintervention responses after stratifying on baseline responses. Calculations for visit rates used person-months denominators. Data analyses censored patients if they died ($n = 2$) or left the health plan ($n = 11$) by the end of follow-up. The average postrandomization follow-up time (through December 1997) was 18.4 months for the intervention group and 17 months for control subjects. This difference was due to the early start of the first intervention group. Poisson regression methods examined counts of visits for the statistical testing of visit rate comparisons after adjusting for the modest baseline differences in utilization. To account for the variable length of follow-up, the available number of person-months of observation was treated as the offset term in Poisson models.

Table 1—*Intervention and control group subjects at baseline*

	Intervention group ($n = 97$)	Control group ($n = 88$)	*P* value
Mean age (years)	55.7 ± 9.1	56.4 ± 9.1	0.64
Mean age at onset (years)	44.4 ± 14.8	43.9 ± 14.9	0.84
Female (%)	41.2	44.3	0.67
Education (six-point scale)	4.1 ± 1.2	4.4 ± 1.1	0.17
Race/ethnicity (%)			0.41
African-American	5.0	4.8	
Asian	6.3	8.1	
Hispanic	15.0	4.8	
White	71.2	79.0	
Other	2.5	3.3	
HbA_{1c} (%)	9.7 ± 1.8	9.6 ± 1.5	0.73
Current treatment (%)			
Insulin	25.8	28.4	0.69
Sulfonylureas	30.0	31.0	
Metformin	4.1	6.8	

Data are means ± SD or %.

Laboratory methods

Kaiser Permanente's regional laboratory performed all laboratory tests. HbA_{1c} assays used turbidimetric immunoinhibition of hemolyzed whole blood samples (Boehringer Mannheim, Indianapolis, IN).

RESULTS

Baseline comparisons

Intervention ($n = 97$) and control ($n = 88$) subjects were comparable regarding age, sex, and education level (Table 1). Although the intervention group had a somewhat higher percentage of minority patients (29 vs. 21%), the difference was not statistically significant ($P = 0.41$).

Before randomization, intervention and control groups did not differ regarding HbA_{1c} level (9.7 vs. 9.6%). Similar percentages of subjects used insulin and oral hypoglycemic agents, including metformin (Fig. 1).

Postintervention data

Glycemic control. For the 85% of patients with HbA_{1c} levels available at 6 months postrandomization or beyond (Table 2), levels declined by 1.3% from baseline for the intervention group but by only 0.22% for the control group ($P < 0.0001$ for the difference in change between the two groups). Values were found at 12 months postrandomization or beyond for 65 intervention and 61 control subjects. The average HbA_{1c} level remained well below baseline for the intervention patients (8.5 ± 1.9%), but, surprisingly, mean levels for control subjects fell to 8.4 ± 1.9%. Of these 61 subjects, 8 began cluster visits by the 12-month point. The mean HbA_{1c} of these eight subjects at 12 months was 7.0 ± 0.9%, whereas subjects who did not attend cluster visits had a mean HbA_{1c} at 12 months of 8.6 ± 2.0%. Control subjects who began cluster visits after the intervention ended had higher HbA_{1c} levels than subjects who did not at both baseline (10.0 vs. 9.4%) and at 6 months (9.5 vs. 9.0%).

Pharmacotherapy, as determined for all subjects from the health plan's pharmacy database, intensified during the program for the intervention group. The percentage of patients taking insulin increased from 26% at baseline to 35%, the percentage of patients taking sulfonylureas increased from 30 to 38%, and the percentage of patients taking metformin increased from

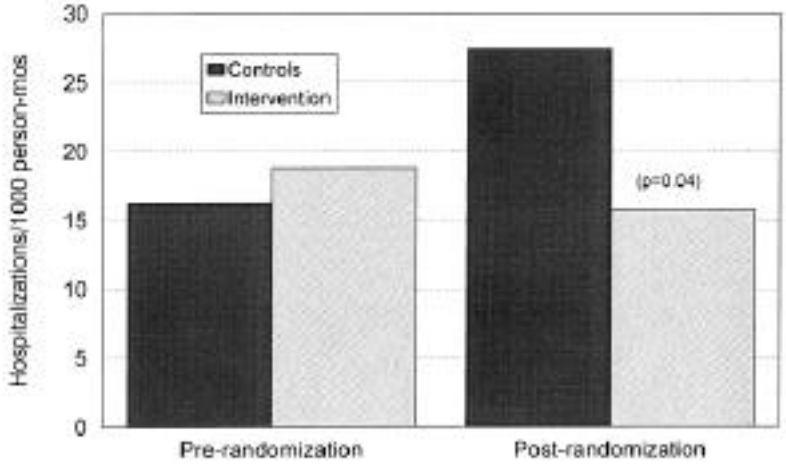

Figure 1—*Hospital admission rates for the 12 months before randomization and the postrandomization period (~18 months) for intervention and control groups. Postrandomization rate comparisons are based on a total of 69 hospitalizations. P values are obtained from Poisson regression models that adjust for prerandomization rates.*

4 to 32% ($P < 0.001$ vs. the control group). The control group demonstrated only minimal changes.

Self-reported processes and outcomes. For the 80% of intervention subjects and the 72% of control subjects who completed follow-up questionnaires, several self-care practices improved significantly in the intervention group (Table 3). The percentage of patients consulting a nutritionist during the past 2 years increased in the study population compared with the control group. The proportion who practiced home blood glucose monitoring was high in both groups at baseline but increased slightly more in the intervention group after the 6-month intervention. Intervention subjects also increased the number of times they checked their blood glucose daily; they reported finding controlling their glucose levels easier; and, consistent with findings for HbA_{1c}, they had lower average blood glucose levels after completing the DCCC.

Seven of the eight measures of self-efficacy improved at least slightly in the intervention group compared with four of eight measures improving in the control group. Intervention group changes were significantly greater than those of control subjects for three measures, including confidence in balancing one's diet to control blood glucose, the ability to recognize and treat low blood glucose, and maintaining blood glucose control when ill.

Satisfaction with three aspects of general medical care did not differ between intervention and control groups after the intervention. Baseline satisfaction with each aspect of general medical care was also comparable between groups in the small number of patients with available baseline satisfaction data. For care related to diabetes, postintervention satisfaction with each of three aspects of care was substantially and significantly higher in the intervention group. For the subgroup with baseline data, the change from baseline was also significantly greater in the intervention group ($P < 0.0001$ for each aspect of diabetes care).

Use of health care services. Hospital discharge rates were similar for the intervention and control subjects during the 12 months before randomization (Fig. 1). However, during the 17 to 18 months after randomization, discharge rates were significantly higher in the control group. After adjusting for baseline rates, hospitalizations were 80% more frequent in control subjects after randomization ($P = 0.04$). Of the 41 postrandomization hospitalizations for control subjects, 14 had diabetes-related principal discharge diagnoses (*International Classification of Diseases, Ninth Revision,* code 250.xx), and 13 had cardiovascular disease-related diagnoses. For the 28 hospitalizations of intervention subjects, only 6 involved diabetes-related diagnoses, and 10 involved cardiovascular disease.

Outpatient visit rates to the Department of Medicine were slightly but not significantly higher for control subjects than for intervention subjects for both physician and nonphysician visits before randomization (Fig. 2*A* and *B*). During the 6-month intervention, visits by intervention subjects to physicians decreased by 17%, but, as expected, visits to nonphysicians increased eightfold. Control subjects experienced no change in physician visits and a small increase in nonphysician visits during this period. After the intervention, both physician and nonphysician visit rates were lower in the intervention group. After adjusting for baseline utilization rates, the postintervention difference was statistically significant for nonphysician visits ($P = 0.0002$) and nearly so for physician visits ($P = 0.06$). Visits to the Urgent Care Clinic, the Emergency Department, the Department of Ophthalmology, and the Department of Optometry did not differ significantly either before or after the intervention.

CONCLUSIONS — The effectiveness of disease management strategies that use extended care nurses with appropriate training, protocols, and supervision to improve the intensity and quality of care for patients with diabetes and other chronic illnesses has been documented in several previous studies (8–11,13,14). The cost implications of such strategies in managed care settings are less clearly understood. The unique aspect of the current approach is the provision of intensive multidisciplinary care in a group visit setting. This strategy was patterned after a similar model that showed enhanced patient satisfaction

Table 2—*Mean HbA_{1c} levels before and after the intervention for subjects with follow-up values available 5 months or more after randomization*

	Intervention group ($n = 82$)	Control group ($n = 74$)	*P* value*
Baseline value	9.48	9.55	0.79
Postintervention	8.18	9.33	<0.0001
Change in HbA_{1c}	−1.30	−0.22	<0.001

*Postintervention comparisons are adjusted with analysis of covariance for baseline values.

Table 3—*Self-reported health practices, self-efficacy, and satisfaction measures before and after the DCCC intervention*

	Intervention (n = 80)		Control (n = 62)		
	Before	After	Before	After	P value*
Health practices					
Saw a nutritionist during the past 2 years (%)	50	85	40	39	<0.001
Monitor blood glucose at home (%)	90.0	97.5	93.4	93.6	0.24
Home blood glucose monitoring (number of times/day)	1.6	2.6	2.0	1.9	<0.0001
Ease of maintaining an acceptable blood glucose level (from 1 [easy] to 6 [impossible])	3.8	3.1	3.7	3.4	0.11
Average home blood glucose level during the past 4 weeks (mg/dl)	162	133	155	157	0.01
Frequency of self-examining the feet (number of times/week)	5.1	6.6	5.5	5.7	0.23
Exercise (min/week)	89	106	107	111	0.50
Self-efficacy (10-point scale)†					
Follow a low-fat diet	6.6	6.7	6.7	6.4	0.55
Exercise regularly	7.3	7.0	6.8	6.5	0.41
Monitor blood glucose regularly	8.3	8.8	8.0	8.1	0.17
Balance your diet to keep your blood glucose in control	6.3	7.1	6.0	6.0	0.003
Recognize and treat low blood glucose	7.4	8.6	8.0	8.1	0.03
Keep your blood glucose in control when you are sick	6.4	7.3	6.4	6.2	0.001
Talk to your physician about your concerns	8.2	8.8	7.7	8.5	0.81
Express your feelings about having diabetes to family and friends	7.9	8.5	7.8	8.0	0.12
Satisfaction (%)‡					
Satisfaction with general medical care					
Quality of care	84.3		83.6		0.92
Personal and responsive service	84.3		82.0		0.72
Convenient and easy access	85.5		77.0		0.22
Satisfaction with diabetes care					
Quality of care	94.2		75.4		0.002
Personal and responsive service	91.4		73.3		0.006
Convenient and easy access	91.4		69.5		0.001

*P values for comparison of postintervention health practice and self-efficacy values are adjusted for the preintervention value. P values for comparison of postintervention satisfaction scores are based on χ^2 tests. †Self-efficacy was assessed by using a 10-point response to the question "How confident are you that you can..." (from 1 [not at all confident] to 10 [totally confident]); ‡preintervention satisfaction scores were not available for most participants. Postintervention responses shown are the percentage of participants reporting either of the two highest responses on a five-point satisfaction scale response from "very good" or "excellent."

and reduced excess utilization in older patients with various chronic illnesses (15).

Various types of patient groups for individuals with diabetes have been evaluated extensively. Support groups may improve patients' subjective feelings but may not improve glycemic control (16,17). Both physicians and certified diabetes educators can provide a group with psychosocial support (18). Group sessions also help to empower diabetic patients (19,20). Both young (21) and geriatric (17) patients and Hispanic (22) and African-American (23) patients respond favorably to the group settings. Nurse-coordinated telephone contacts can also enhance glycemic control when used as part of usual outpatient care for type 2 diabetic patients (13), and multidisciplinary teams have been shown to be effective in lowering HbA_{1c} levels (24) and in decreasing the risk of limb amputation (25).

In the present study, participants who received their ambulatory diabetes management care in a cluster visit setting for a 6-month period showed a marked improvement in glycemic control at the end of the intervention, much higher levels of satisfaction with diabetes care, and significant improvements in three of eight measures of self-efficacy and in three of seven health practices compared with control subjects. Most of the improvement in glycemic control persisted 6 months after the intervention ended, although further observation will be important to determine whether the benefits persist in the absence of continuing programs. Somewhat surprisingly, among the ~70% of control group members for whom we could find HbA_{1c} levels drawn 12 months or more after randomization, HbA_{1c} levels had declined and were comparable with those in the intervention group. This was due in part to a dramatic drop in HbA_{1c} levels in eight control subjects who had enrolled in cluster visits at the end of the intervention. However, the remaining control subjects also reduced their HbA_{1c} levels moderately. Whether these subjects were motivated by participation in the study to improve their glycemic control cannot be determined. HbA_{1c} levels also declined moderately in the entire Kaiser Permanente diabetes registry population during this period in part because of the increasing use of metformin (26).

Importantly, and consistent with the Cooperative Health Care Clinic experiment (15), this study achieved improved outcomes without evidence of a long-term increase in utilization of services. Although intervention group patients had somewhat higher ambulatory care utilization and more intensive pharmaceutical management than control subjects during the 6-month intervention, this excess utilization was offset by fewer hospital admissions after the intervention. Lower utilization persisted for both inpatient and outpatient care during the months after the end of the intervention.

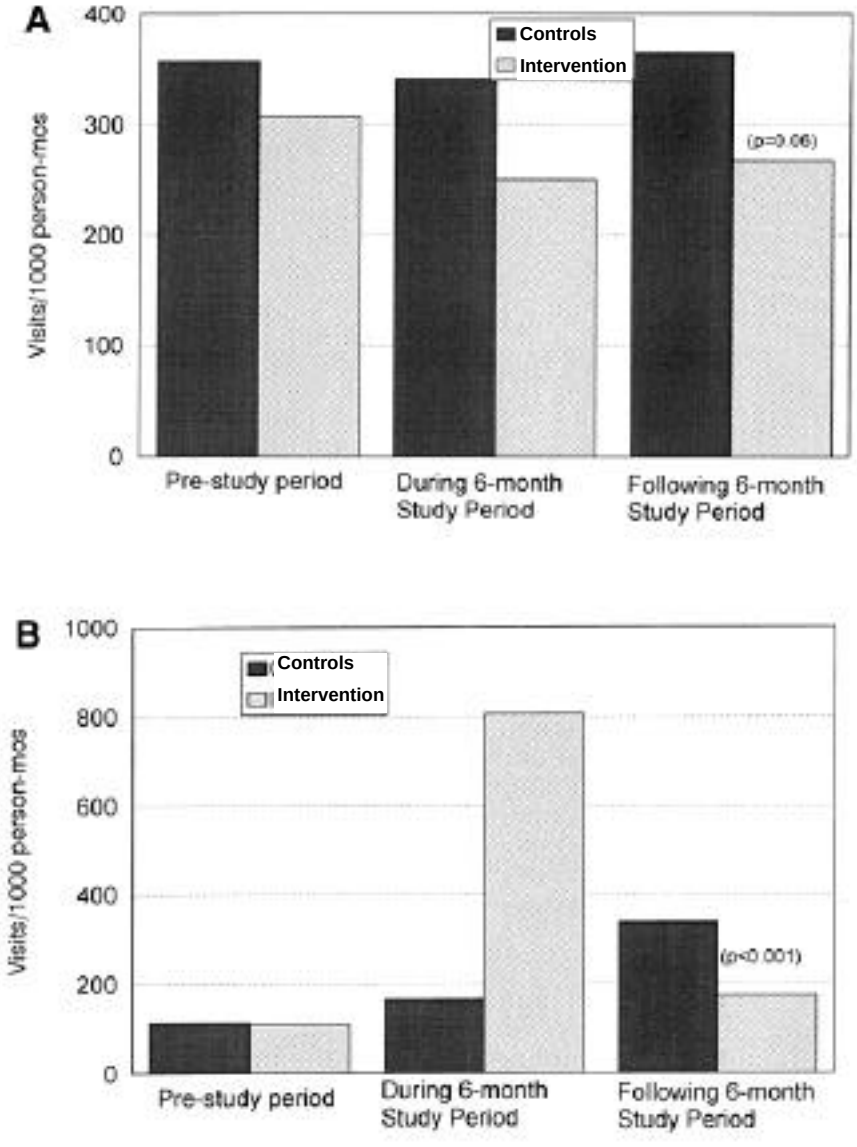

Figure 2—*Outpatient visit rates to the Department of Medicine for physician visits (A) and non-physician visits (B) during the 6 months before randomization, the 6-month intervention period, and ~12 months of postintervention follow-up. The* P *values for comparison of postrandomization rates are obtained from Poisson regression models that adjust for prerandomization visit rates.*

The lower hospitalization rates in the intervention group are of particular interest because of the dominant effect of hospitalizations on cost of care. A sizeable portion of the difference in hospitalization rates was attributable to hospitalizations for conditions directly related to diabetes. Cost-effectiveness models (27) of intensive diabetes management have assumed, based on findings from the Diabetes Control and Complications Trial, that little benefit will occur until ≥5 years after treatment initiation. Thereafter, reductions in complications begin to offset program expenditures such as hospitalizations for complications. Under these assumptions, intensive diabetes management represents a long-term investment. This investment cost, multiplied by the large numbers of patients to be served, can present a major barrier to program implementation in managed care settings and elsewhere.

However, our study suggests that improved glycemic control may lead to an earlier reduction in health care utilization, which would offset costs of the intervention promptly. Another recent study suggested that improved glycemic control can produce a prompt improvement in symptom status and reduced days lost from work (11). If these two reports are confirmed, an economic as well as a clinical rationale exists for offering intensive management programs. Beyond this short-term cost neutrality are, of course, the dollars ultimately saved as the incidence of long-term diabetes complications decreases.

A total of 70% of patients contacted were willing to join these cluster visits, a level of interest much higher than for standard health education classes in the same HMO (N.M., personal communication). Many patients were persuaded to be randomized only because of the eventual (if not immediate) opportunity to participate in the group program. At 12 months after the intervention, 21 control members had enrolled in cluster visits. The greater interest may reflect patient knowledge that these visits offered specialized diabetes care in addition to education. Nevertheless, cluster visits were not for everyone. Some patients unwilling to participate cited scheduling difficulties that precluded monthly visits, even to evening meetings. Small numbers flatly refused to participate in any group meeting.

This "intensive" program did not rely excessively on switching type 2 diabetic patients to insulin therapy or on increasing the frequency of injections for subjects taking insulin. The most notable change in pharmacotherapy was much greater use of metformin in the intervention group. However, the improvement in HbA_{1c} was equivalent for patients who took metformin and patients who did not, which suggests that other components of the program were essential to its success.

Limitations of the study include failure to obtain follow-up HbA_{1c} levels and questionnaires on approximately 16 and 25% of subjects, respectively. A comparison of subjects with and without follow-up questionnaires found that patients completing the questionnaire were slightly older (mean difference 1.5 years) but did not differ by sex, baseline HbA_{1c} level, or postrandomization hospitalization rates. A second limitation is the absence of baseline information on patient satisfaction for most subjects (nearly 70%). This was apparently because of the loss of a large set of completed questionnaires rather than because of patient unwillingness to complete the questionnaire. The differences in satisfaction with diabetes care observed after the intervention were equally apparent in the small group with baseline questionnaires and in the larger group that

had postintervention questionnaires only. A third limitation is the absence of information on the cost of the intervention itself. Although the HMO maintains a cost management information system, this system does not compute the costs of innovative programs such as the DCCC. Directly estimating these costs is difficult because of the time spent by the clinical staff members in research activities such as study planning and data collection. However, clearly some efficiencies are involved with the cluster visit approach. Three providers saw 12–18 patients for a 2-h session monthly, a somewhat higher number of patients than these same providers would see in one-on-one sessions during the same 2 h. Our findings also suggest that a modest reduction in visits to physicians during the intervention period would also help to offset the costs of the intervention. Thus, compared with other methods that systems may use to address poor control in diabetes (e.g., referrals to nurse educators, nutritionists, or behaviorists or more frequent visits with the primary care physician), the cluster visit program does not appear to be more costly.

Because of the poor outcomes and high cost of care for patients with diabetes (7), managed care organizations are actively developing new approaches to care for this large group of members. This study suggests that innovative approaches may be cost neutral in the short term, an observation that, if replicated, would remove a key barrier in adopting and implementing these effective innovations in treatment.

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