Improving Diabetes Processes of Care in Managed Care

Liza L. Ilag, MD, MS
Catherine L. Martin, RN, MS
Bahman P. Tabaei, MPH
Deanna J. M. Isaman, MAS
Ray Burke, MA
Douglas A. Greene, MD
William H. Herman, MD, MPH

OBJECTIVE — To evaluate the impact of systematic patient evaluation and patient and provider feedback on the processes and intermediate outcomes of diabetes care in Independent Practice Association model internal medicine practices.

RESEARCH DESIGN AND METHODS — Nine practices providing care to managed care patients were randomly assigned as intervention or comparison sites. Intervention-site subjects had Annual Diabetes Assessment Program (ADAP) assessments (HbA_{1c}, blood pressure, lipids, smoking, retinal photos, urine microalbumin, and foot examination) at years 1 and 2. Comparison-site subjects had ADAP assessments at year 2. At Intervention sites, year 1 ADAP results were reviewed with subjects, mailed to providers, and incorporated into electronic medical records with guideline-generated suggestions for treatment and follow-up. Medical records were evaluated for both groups for the year before both the year 1 and year 2 ADAP assessments. Processes and intermediate outcomes were compared using linear and logistic mixed hierarchical models.

RESULTS — Of 284 eligible subjects, 103 of 173 (60%) at the Intervention sites and 71 of 111 (64%) at the comparison sites participated; 83 of 103 (81%) of the intervention-site subjects returned for follow-up at year 2. Performance of the six recommended assessments improved in intervention-site subjects at year 2 compared with year 1 (5.8 vs. 4.3, $P = 0.0001$) and compared with comparison-site subjects at year 2 (4.2, $P = 0.014$). No significant changes were noted in intermediate outcomes.

CONCLUSIONS — The ADAP significantly improved processes of care but not intermediate outcomes. Additional interventions are needed to improve intermediate outcomes.

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Clinical trials have demonstrated the efficacy of interventions to prevent or delay the development of diabetic complications and to reduce their sequelae (1–14). Recognizing the wealth of evidence supporting prevention and treatment in diabetes, professional organizations have developed standards of care for people with diabetes (15,16). Unfortunately, numerous studies have demonstrated that treatment of patients with diabetes does not adhere to recommended standards of care (17–22).

Shortcomings in self-management support, clinical information systems, and decision support contribute to suboptimal diabetes care in primary care (23). The Annual Diabetes Assessment Program (ADAP) was designed as a population-based program of evaluation and feedback to support diabetes clinical practice guidelines (24,25). During a 1-h focused encounter with nonphysician providers within the primary care setting, key diabetes and cardiovascular health parameters were measured and discussed with the patient by a certified diabetes educator. A tailored report with guideline-driven recommendations for care (25) was then sent to the patient's primary care provider (PCP) and incorporated into the electronic medical record. We hypothesized that implementing the ADAP would improve processes and intermediate outcomes of diabetes care.

To rigorously assess whether the ADAP would improve measures of diabetes care, we conducted a randomized, controlled clinical trial.

RESEARCH DESIGN AND METHODS

Clinical setting

Nine university-affiliated primary care internal medicine (IM) practices affiliated with a managed care organization (MCO) were paired by size and type and then randomly assigned as intervention or comparison sites. One unpaired practice was assigned as an intervention site. Most of the PCPs in the practices were working full-time and there were no residents in the practices.

Participants

Diabetic members of the MCO who were aged ≥18 years and had been members for at least 1 year were identified at the nine selected sites using the MCO Diabetes Registry. This registry uses claims data to identify members with diabetes based on the Health Plan Employer Data and Information Set definition (26). Classification of type 1 versus type 2 diabetes is based on an algorithm that considers age at diagnosis, age at initiation of insulin therapy, and duration of insulin therapy. The registry is updated quarterly.

Up to 75 members per site were randomly selected using a random draw. The 43 PCPs reviewed member lists for study eligibility. Individuals who did not have diabetes, were no longer being followed by the PCP, or were judged by the PCP to be unsuitable candidates for the study

From the Division of Endocrinology and Metabolism, Department of Internal Medicine, University of Michigan and the Michigan Diabetes Research and Training Center, Ann Arbor, Michigan.

Address correspondence and reprint requests to Liza L. Ilag, MD, MS, 3920 Taubman Center, Ann Arbor, MI 48109-0354. E-mail: lilag@umich.edu.

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Abbreviations: ADAP, Annual Diabetes Assessment Program; ARB, angiotensin receptor blocker; IM, internal medicine; MCO, managed care organization; PCP, primary care provider.

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

were excluded. A letter and brochure were then mailed to all eligible members, inviting them to participate in the study.

Methods

The study was approved by the MCO Research Review Committee and by the Institutional Review Board at the University of Michigan. All participants provided written informed consent. Subjects at intervention sites had two ADAP visits: at year 1 and at year 2. Year 1 ADAP visits at intervention sites were conducted between October 1999 and September 2000. Subjects at comparison sites had one ADAP visit at the time intervention subjects were having their second ADAP visits (year 2), from October 2000 to September 2001. Medical records were reviewed in parallel for subjects at paired intervention and comparison sites for the 12 months preceding the year 1 and year 2 ADAP visits. This design allowed comparison of medical care measures at years 1 and 2 at the intervention sites and between intervention-site subjects and comparison-site subjects at year 2. Through the medical record review, we determined whether recommended assessments were being performed and determined the results of these assessments.

During ADAP visits, participants completed a questionnaire that assessed tobacco and aspirin use and underwent a series of assessments. These assessments included measurement of blood pressure; capillary blood tests for cholesterol, triglycerides, HDL and LDL cholesterol (Cholestec, Hayward, CA), and HbA_{1c} (DCA-2000, Bayer Healthcare, Tarrytown, NJ); and ration of urine microalbumin to creatinine (DCA-2000). Foot examinations were performed using the Michigan Neuropathy Screening Instrument (27). In participants without known diabetic retinopathy or other eye disease requiring ophthalmologic follow-up (e.g., glaucoma, cataracts, or macular degeneration), nonmydriatic fundus photographs were taken using a Topcon NW3 Polaroid retinal camera (Topcon America, Paramus, NJ). The results of these assessments were recorded in an informational booklet that was given to the participant and reviewed with a Registered Nurse/Certified Diabetes Educator at the end of the ADAP visit. The test results and diabetes care recommendations (based on the provider group and MCO diabetes guideline) (25) were also mailed to the participant's PCP and entered into the electronic medical record. Participant satisfaction and PCP satisfaction were assessed at the end of each ADAP visit and at the end of the study period, respectively. The survey included statements rated on a five-point Likert scale ranging from "strongly agree" to "strongly disagree."

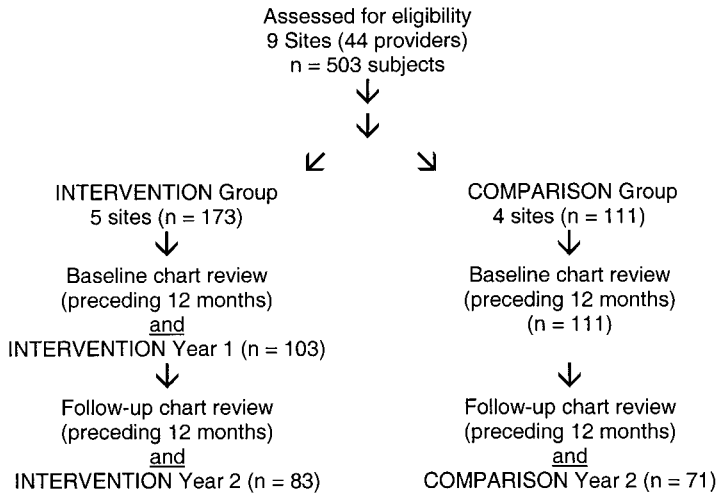

Figure 1—*Study enrollment and progress.*

Diabetes care measures included process measures (frequency of dilated retinal examinations, urine microalbumin measurements, foot examinations, and blood pressure, HbA_{1c}, and LDL cholesterol measurements as obtained from medical chart review) and intermediate outcomes (levels of HbA_{1c}, blood pressure, and LDL cholesterol and current tobacco and aspirin use, as obtained from the ADAP evaluations). We also determined whether intervention-site subjects identified from the year 1 ADAP evaluation as candidates for ACE inhibitor/angiotensin receptor blocker (ARB) therapy (urine microalbumin/creatinine ≥30 mg/dl), statin therapy (LDL ≥100 mg/dl), or aspirin therapy (≥50 years of age) were receiving recommended therapy at the year 2 ADAP evaluation.

Power calculations and statistical analyses

The study was a randomized, controlled clinical trial. Data were analyzed for all intervention-site subjects completing both the year 1 and year 2 visits and for comparison-site subjects completing the year 2 visit. Intervention-site and comparison-site subjects who did not return for the year 2 visit were excluded to avoid within-group and between-group bias. It was estimated that if observations were independent, with a total of 160 subjects (80 at the intervention sites and 80 at the comparison sites), we would have 80% power to detect a 15% difference in binomial variables (e.g., if test was done or not). For continuous variables, we estimated that we would have 80% power to detect a difference of 0.314 SD. This sample size also provided 80% power to detect a difference of 0.5 of a test in a simple composite of six tests (i.e., eye examinations, urine microalbumin measurement, foot examinations, and measurement of HbA_{1c}, blood pressure, and cholesterol). The power calculation did not take into account within-site correlation. We believed it was necessary to randomize by site to avoid within-site contamination. We randomized all nine of the available sites.

To control for random subject effects and random practice-site effects, we used hierarchical linear mixed models for continuous variables and hierarchical logistic mixed models for categorical variables (28). Statistical significance was determined by testing coefficients of the hierarchical models. $P < 0.05$ was defined as the limit of statistical significance. All statistical analyses were performed using SAS software version 8.12 (SAS Institute, Cary, NC) (29,30).

RESULTS — The progress of the study is shown in Fig. 1. At the nine IM sites, the MCO Diabetes Registry identified 503 subjects who were ≥18 years of age and enrolled in the MCO for at least 1 year. Of

Table 1—*Characteristics of subjects*

	Intervention site	Comparison site	*P*
n	83	71	
Mean age	59 ± 14	59 ± 12	NS*
Men	36 (43)	36 (51)	NS
Race/ethnicity			
Caucasian	69 (83)	56 (79)	NS
African American	6 (7)	10 (14)	NS
Other	8 (10)	5 (7)	NS
Type 2 diabetes	71 (86)	60 (85)	NS
Mean number of health care visits in prior year	6 ± 4	5 ± 2	NS

Data are *n* (%) or means ± SD. *NS, $P > 0.05$.

these, 219 were ineligible (no longer receiving care at the primary care site = 67, unable to contact = 42, provider discretion = 39, no diabetes = 29, deceased = 16, not MCO member = 14, no visit record for >2 years = 6, and enrolled in another study = 6). The 284 eligible members were contacted by mail with telephone follow-up. Of 173 eligible members at the intervention sites, 103 (60%) had a year 1 ADAP visit. Reasons for nonparticipation included no interest ($n = 39$), transportation difficulties ($n = 16$), poor health ($n = 9$), and failure to attend ($n = 6$). Of those who participated in the first ADAP, 83 (81%) returned for a year 2 visit, 18 (18%) could not be contacted by mail or phone and 2 (1%) refused follow-up. Among the 111 eligible members at the comparison sites, 71 (64%) participated in the ADAP visit and are included in the final analysis. Reasons for nonparticipation were no interest ($n = 23$), poor health ($n = 6$), transportation difficulties ($n = 6$), and failure to attend ($n = 5$).

The study population was middle-aged, and most subjects were white and had type 2 diabetes. PCPs had between 1 and 17 patients participating in the study, with a mean of four patients per physician at both the intervention and comparison sites. There were no significant demographic differences between the intervention-site and comparison-site subjects (Table 1).

Between years 1 and 2, there was an increase in the frequency of urine microalbumin tests, foot examinations, and LDL cholesterol measurements in subjects at the intervention sites (Table 2). There was no change in any of these process measures at the comparison sites, and the sum of measures was unchanged. At year 2, intervention-site subjects had 1.5 more of the process measures performed. Compared with comparison-site subjects at year 2, more intervention-site subjects underwent urine microalbumin tests, foot examinations, HbA_{1c} measurements, and LDL cholesterol measurements. More intervention-site subjects reported having received diabetes education at year 2 compared with baseline (27 vs. 12%, $P = 0.02$) and compared with comparison-site subjects at year 2 (13%, $P = 0.03$). Tobacco cessation was as likely to be addressed at year 1 and year 2 in intervention-site subjects (90 vs. 88%, $P = 0.87$) as in comparison-site subjects (70 vs. 100%, $P = 0.09$).

Table 3 shows subjects at the intervention and comparison sites by levels of HbA_{1c}, blood pressure, LDL cholesterol, tobacco use, and aspirin use as assessed during the ADAP exams. No significant differences were noted in HbA_{1c} levels, blood pressure levels, LDL cholesterol levels, tobacco use, or aspirin use.

We determined what had happened to intervention-site subjects for whom treatment with ACE inhibitors or ARBs, statins, and aspirin were recommended at the year 1 ADAP visit. At year 1, 11 of 25 subjects (44%) with microalbuminuria or proteinuria were not receiving ACE inhibitors or ARBs. The ADAP recommendation was to confirm the diagnosis and consider ACE inhibitor or ARB therapy. At year 2, four subjects (36%) had been placed on ACE inhibitor/ARB treatment, three subjects (27%) had reverted to normal without treatment, and four subjects (36%) had persistent untreated microalbuminuria or proteinuria. During the first ADAP visit, 23 of 30 individuals (77%) with LDL >100 mg/dl were not receiving statin therapy. The ADAP recommendation was dietary intervention followed by use of HMG-CoA reductase inhibitors to achieve target LDL levels (<100 mg/dl). At follow-up, 1 of the 23 individuals (4%) was receiving statin therapy, 5 subjects (22%) had reverted to normal without pharmacologic treatment, and 17 subjects (74%) had LDL levels >100 mg/dl and were not receiving statin therapy. At visit 1, 26 of 62 participants (42%) ≥50 years of age were not receiving aspirin therapy. At visit 2, 8 (31%) of them were receiving aspirin therapy.

All patients completing visit 2 and 53% (23 of 43) of their physicians completed satisfaction surveys. There was fairly good acceptance of the ADAP: 99% of patients and 78% of providers found it "desirable to have all the tests done at one time;" and 94% of patients and 67% of providers believed the program would assist doctors in treating patients with diabetes. However, whereas 99% of patients found it "beneficial to have the results of

Table 2—*Diabetes process of care measures*

	Intervention ($n = 83$)			Comparison ($n = 71$)			
Measure	Year 1	Year 2	*P**	Year 1	Year 2	*P**	*P*†
Eye examination	58 (70)	70 (84)	NS‡	43 (61)	47 (67)	NS	NS
Urine microalbumin test	36 (43)	83 (100)	<0.001	26 (37)	32 (45)	NS	<0.001
Foot examination	52 (63)	83 (100)	<0.001	43 (61)	34 (48)	NS	<0.001
HbA_{1c}	81 (98)	83 (100)	NS	67 (94)	64 (90)	NS	0.004
Blood pressure	83 (100)	83 (100)	NS	71 (100)	71 (100)	NS	NS
LDL cholesterol	51 (61)	81 (98)	<0.001	44 (62)	50 (70)	NS	0.027
Mean sum of measures	4.3 ± 1.2	5.8 ± 0.4	<0.001	4.2 ± 1.2	4.2 ± 1.4	NS	0.014

Data are *n* (%) and means ± SD. *Within-group comparisons (intervention and comparison) from year 1 to year 2; †between-group comparison (intervention versus comparison) at year 2; ‡NS = *P* value >0.05.

Table 3—*Diabetes intermediate outcome measures*

Measure	ICC	intervention Year 1	intervention Year 2	P*	comparison Year 2	P
n		83	83		71	
HbA_{1c} (%)	0.46			NS‡		NS
<7.0		28 (34)	23 (28)		21 (30)	
7.1–8.0		18 (22)	27 (32)		23 (32)	
8.1–10.0		27 (32)	23 (28)		21 (30)	
>10.0		10 (12)	10 (12)		6 (8)	
Systolic blood pressure (mmHg)	−0.72			NS		NS
SBP <135		55 (66)	50 (60)		41 (58)	
SBP ≥135		28 (34)	33 (40)		30 (42)	
Diastolic blood pressure (mmHg)	0.01			NS		NS
DBP <80		63 (76)	64 (77)		53 (75)	
DBP ≥80		20 (24)	19 (23)		18 (25)	
SBP ≥135 and/or DBP ≥80		37 (45)	35 (42)		34 (48)	
LDL cholesterol (mg/dl)	0.25			NS		NS
<100		43 (52)	40 (48)		25 (35)	
100–130		15 (18)	19 (23)		24 (34)	
>130 and/or triglycerides >400		25 (31)	24 (29)		22 (31)	
Current tobacco use	—	8 (10)	10 (12)	NS	9 (13)	NS
Current aspirin use	—	46 (55)	49 (59)	NS	37 (52)	NS

Data are *n* (%). *Within intervention group comparison at year 1 and year 2; †between-group (intervention versus comparison) comparison at year 2; ‡NS = *P* value >0.05. DBP, diastolic blood pressure; ICC, interclass correlation coefficient; SBP, systolic blood pressure.

tests reviewed with the CDE at the end of the session" and 97% of patients believed that the program "will help patients maintain or improve their health," only 52 and 48% of physicians, respectively, shared these opinions. Overall, 97% of patients and 58% of physicians agreed that the program should be continued. Because only 53% of physicians completed the survey, the latter number may be an overestimate of physician support for the program.

CONCLUSIONS — ADAP participation resulted in improvements in some measures of diabetes care in IM practices affiliated with an Independent Practice Association model MCO. At the intervention sites, a 6-point composite score of recommended assessments improved from 4.3 at year 1 to 5.8 at year 2 and was significantly better than the composite score at comparison sites at year 2 (4.2). To the extent that a greater proportion of intervention-site subjects underwent foot examinations, urine microalbumin tests, LDL cholesterol measurements, and HbA_{1c} measurements documented in their medical records, ADAP participation improved compliance with the Health Plan Employer Data and Information Set and Diabetes Quality Improvement measures (31). These findings are consistent with other studies that have shown improvement in processes of care with the implementation of systematic interventions (32–36).

We observed no significant differences in intermediate outcomes (e.g., HbA_{1c}, blood pressure, and LDL levels) at intervention sites between years 1 and 2 and when compared with comparison-site subjects at year 2. Montori et al. (35) reported that after implementing the Mayo Health Diabetes Translation Project, planned care resulted in more frequent testing and improvements in HbA_{1c} levels, cholesterol levels, and calculated 10-year coronary disease risk. Unfortunately, with their before/after study design, there was no comparison group to confirm that improvement in outcomes was due to the intervention and not due to secular trend. Clark et al. (32) showed that a comprehensive diabetes management program that included risk stratification and social marketing improved clinical outcomes. They reported an increase in the proportion of patients having low-risk HbA_{1c} (<7%) and blood pressure (<130/85 mmHg) and a decrease in the proportion of patients with LDL cholesterol >130 mg/dl after 12 months. More recently, Meigs et al. (37) demonstrated that use of a web-based decision support tool among providers in a mixed-payor group practice was associated with improvement in processes of care but no improvement in outcomes compared with a control group.

Our failure to see an improvement in intermediate outcomes may be because our study involved university-affiliated IM practices that demonstrated good compliance with clinical practice guidelines at baseline. A recent audit of independently practicing PCPs showed that foot examinations were performed in 15% of patients, HbA_{1c} measurements in 20%, eye referrals in 23%, urine protein screening in 33%, and lipid profile measurements in 44% of patients (33). In contrast, recommended measurements were performed in 43–98% of our study population at baseline (Table 2). Thus, a greater sample size may have been needed to detect significant differences in intermediate outcomes between the intervention- and comparison-site subjects at year 2.

It is also likely that additional interventions are needed to improve outcomes in an Independent Practice Association model MCO. Both of the studies that demonstrated an improvement in outcomes (32,35) involved staff-model MCOs in which shared infrastructure might have facilitated the adoption of guidelines and implementation of multifaceted interventions. Interventions that provide more detailed advice about changes in medication, provide more refined decision-support systems, and facilitate generalist-specialist communication may also be needed to improve outcomes (35,37,38).

The fact that providers were less enthusiastic about the ADAP than their patients may also explain why intermediate outcomes were unchanged despite improved processes of care. Improvements in HbA_{1c}, blood pressure profiles, and LDL cholesterol have been reported with a comprehensive approach using clinic-based personnel to influence physician behaviors in a staff-model health mainte-

nance organization (29). Although we conducted ADAP visits at individual practice sites, we did not directly involve practice personnel or provide active care management. The clinical nurse coordinator and nonphysician providers traveled to the practice sites only for ADAP visits. Their lack of integration into the practice may have contributed to lower enthusiasm in the providers compared with patients and to the lack of impact on intermediate outcomes.

Despite our inability to convincingly demonstrate improvements in intermediate outcomes, there were improvements in care. For example, 7 of 11 individuals (64%) at the intervention sites with untreated microalbuminuria or proteinuria at baseline were receiving ACE inhibitor/ARB therapy or had reverted to normal at follow-up; 6 of 23 individuals (26%) with untreated LDL ≥100 mg/dl at baseline were on statin therapy or had LDL cholesterol levels <100 mg/dl at follow-up; among individuals who were ≥50 years of age and not receiving aspirin at baseline, 8 of 26 (31%) were receiving aspirin at follow-up. Aspirin use among adults with diabetes during 1988–1994 was estimated to be only 20% (95% CI 16–23) (39).

In summary, systematic patient education and patient and provider feedback improved processes of diabetes care in the primary care setting. Additional interventions are needed to improve intermediate outcomes (e.g., HbA_{1c}, blood pressure, and LDL cholesterol levels). In evaluating interventions, it is important to include comparison groups to adjust for secular trend and not to limit evaluation to processes of care because these may not be associated with improvements in actual biochemical and physical measures that may be more closely related to clinical outcomes.

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