Diabetes Quality Improvement in Department of Veterans Affairs Ambulatory Care Clinics

A group-randomized clinical trial

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OBJECTIVE — To conduct a group-randomized clinical trial to determine whether regular feedback to primary care providers of synthesized information on patients' health, function, and satisfaction would demonstrate improved outcomes for their patients with diabetes.

RESEARCH DESIGN AND METHODS — Patients in General Internal Medicine Clinics Department of Veterans Affairs (VA) Medical Centers were randomized into seven intervention or control firms. Patient self-reported information was collected by mail on general health, diabetes, and up to five other chronic conditions. Patients with diabetes received the Seattle Diabetes Questionnaire, the 36-item Medical Outcomes Study short form (SF-36), and a validated patient satisfaction questionnaire at regular intervals. Data from self-report, clinical, pharmacy, and laboratory sources were synthesized into patient-specific feedback reports that intervention providers received before patients' visits.

RESULTS — The timely delivery to primary care providers of state-of-the-art patient-feedback reports that identified patient issues and areas for improvement did not result in significant improvements in patient outcomes between the intervention and control firms.

CONCLUSIONS — Outcomes in diabetic patients whose providers received synthesized patient data before visits were no better than in those receiving care from control firms. Future studies may benefit from substantial involvement in patients discussing, problem solving, and goal setting in addition to use of timely synthesized patient data.

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The Department of Veterans Affairs (VA) is committed to providing quality health care to the 3.5 million veterans served by the VA. These veterans are reported to have greater comorbidity and greater activity limitation than age- and sex-comparable counterparts in the general population (1). Diabetes is a common chronic condition among veterans, with an estimated prevalence of 16% in veterans using VA services compared with 10% in veterans not receiving VA care.

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Abbreviations: ACQUIP, Ambulatory Care Quality Improvement Project; VA, Department of Veterans Affairs.

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

There is an evidence gap between the quality of diabetes care, as published in the literature, and clinician practice. Most systems of diabetes care make outstanding patient management difficult or impossible for providers (2). Closing this gap includes developing and implementing a wide array of strategies to integrate medical evidence into clinical practice (3). Randomized clinical trials have identified strategies targeted to health care providers. The Cochrane Effective Practice and Organization of Care Review Group identified priority areas for providers that included point-of-care decision support, audit and feedback reports comparing performance of clinicians and practice groups, and evidence-based patient management recommendations (4).

Several randomized clinical trials evaluated the effectiveness of professional interventions focusing on providers in intervention practices compared with usual care (5–10). These trials identified improvements in diabetes process measures but did not directly assess outcomes. There is a need to determine whether state-of-the-art synthesized patient data provided at the point of care can improve patient outcomes.

In 1996 the VA funded a randomized clinical trial, the Ambulatory Care Quality Improvement Project (ACQUIP), to enhance quality of outpatient care, functional status, and satisfaction with care. Six common chronic conditions were targeted: diabetes, hypertension, chronic obstructive pulmonary disease, symptomatic coronary disease, depression, and problem drinking. The study hypothesized that if primary care providers regularly received timely information on patients' health, function, and satisfaction, patient care quality, satisfaction, and outcomes would be improved. This article describes the results of this randomized trial in veterans with diabetes.

RESEARCH DESIGN AND METHODS

— The ACQUIP trial was a group-randomized trial in General Internal Medicine (primary care) clinics at seven VA facilities: Birmingham, Alabama; Little Rock, Arkansas; Richmond, Virginia; San Francisco, California; Seattle, Washington; West Los Angeles, California; and White River Junction, Vermont. Firms at each site (established teams staffed by a group of physicians caring for a panel of patients) were randomized by the study statistician to intervention or control status. Patients were identified through the Veterans Health Information Systems and Technology Architecture (**V***ist***A**), a comprehensive patient and system database that included automated information on inpatient stays, outpatient visits, medications, laboratory and radiology findings, pharmaceuticals, and mortality. Eligibility was restricted to veterans who were assigned to a primary care provider and who had at least one visit in the prior year. Human subjects approval was obtained at each of the seven sites.

Included in the study were all patients from intervention firms and a random sample of patients in control firms to ensure at least 1,500 completed disease-specific questionnaires for each target condition. Potential participants were mailed a self-administered health screening questionnaire and requested to identify their major chronic medical conditions, including diabetes. Those identifying a history of diabetes received the Seattle Diabetes Questionnaire, a 29-item instrument with the following seven domains: symptoms, complications, education, diabetes self-care, emotional function, control, and satisfaction (11). A number of clinical diabetes experts participated in the design and testing of the diabetes intervention.

Participants were also requested to complete the 36-item Medical Outcomes Study short form (SF-36) to map eight domains for the impact of disease on health status. The SF-36 physical component scale and the mental component scale were also used to summarize overall physical and mental function (12). Participants also completed the 21-item Seattle Outpatient Satisfaction Questionnaire, which includes 12 items from the American Board of Internal Medicine Humanistic Scale to measure providers' interpersonal skills and additional questions, as adapted from the RAND questionnaire to measure organizational aspects of care, including waiting time and ease of getting appointments (13).

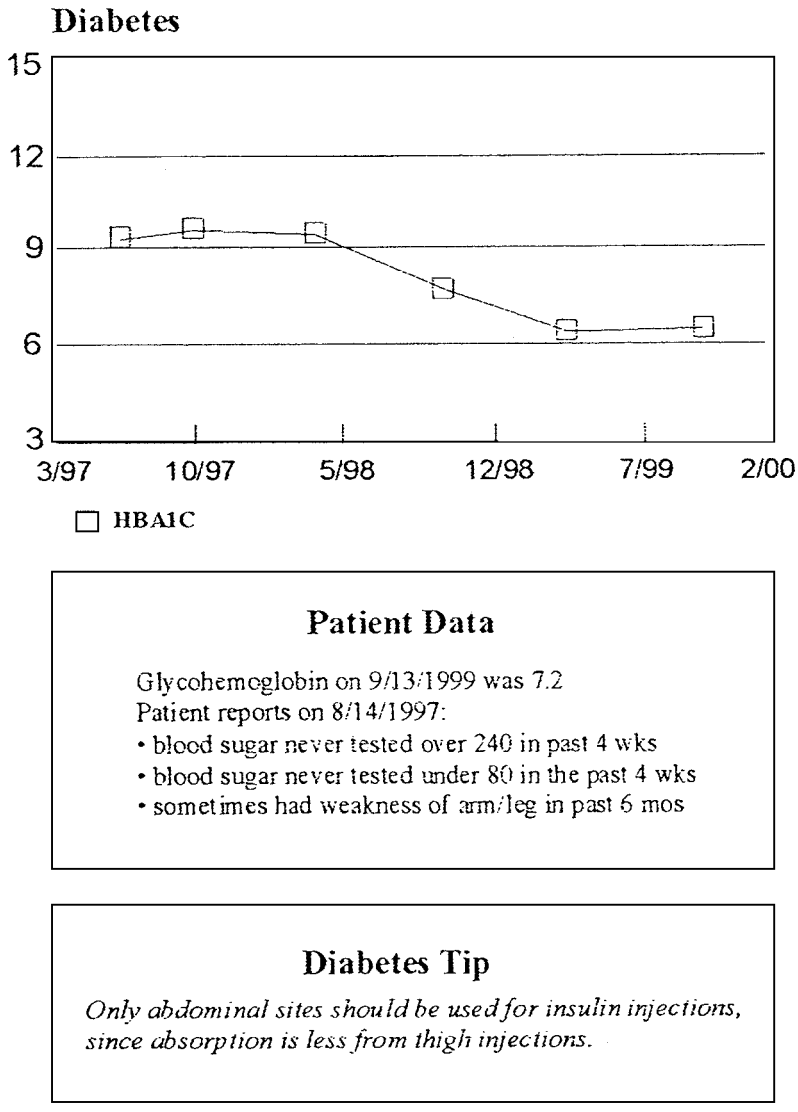

Figure 1—*Example of one-page patient-feedback report.*

Patient self-reported data were collected every 4 months for intervention patients and annually for control patients. Before primary care visits, intervention firm health care providers received a one-page, graphical, user-friendly, patient-feedback report (Fig. 1). Included were pertinent patient self-reported data and clinical, pharmacy, laboratory, and radiology findings. The report also included rotating practice tips derived from state-of-the-art clinical studies. Control firm providers did not receive patient summaries or practice tips.

The diabetes entry cohort represented patients returning the first health screen, indicating that they had been told by a health provider that they had diabetes. Included in this analysis are only those who completed baseline and 2-year diabetes questionnaires. Participant enrollment was from 1 February 1997 to 30 December 1999, and participants were followed for 2 years.

Analysis

The firm was the unit of randomization and analysis (n = 14 firms, 7 pairs). The analysis compared demographic findings at baseline between the intervention and control firms. The primary analysis examined the change between 2-year and baseline scores (T2 − T0) by firm. We tested whether the change in intervention firms

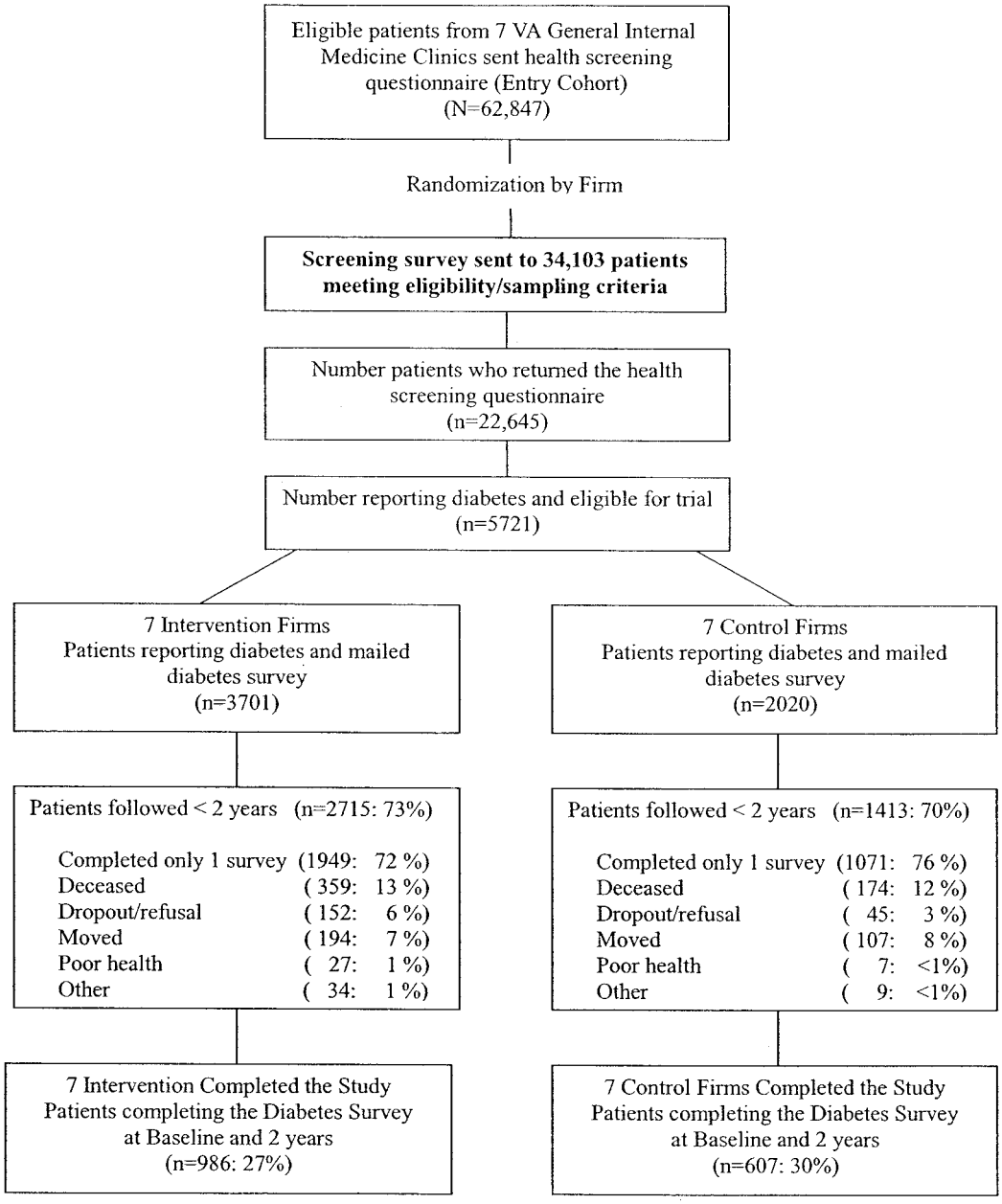

Figure 2— *ACQUIP diabetes participant recruitment flowchart.*

was significantly different from the change in control firms, using both paired and unpaired *t* tests, with the two firms within a clinic as a pair. Two-year comparisons were adjusted for age, sex, race, site, income, education, marital status, employment status, years of VA care, and baseline chronic conditions.

RESULTS — A total of 62,847 eligible subjects from seven VA General Internal Medicine Clinics were enrolled between 1 February 1997 and 30 December 1999 and were mailed a health screening questionnaire. Of this group, 34,103 were enrolled before 1 July 1997 and comprised the entry cohort. Of these subjects, 22,645 returned the health screening questionnaire. Diabetes was reported by 5,721 of the 22,645 patients (25.2%). Randomization by firm at seven sites resulted in 3,701 patients in the seven intervention firms and 2,020 patients in the control firms. Figure 2 shows the proportion of patients who responded to the diabetes survey at baseline and at 2 years for the intervention and control firms, together with reasons for patient loss to follow-up. Patient response was sufficient for analysis by firm; however, a majority of patients in both groups completed only one survey and were therefore not eligible for the final analysis. Loss to follow-up included patient withdrawal, moving, and unable to complete the study due to poor health or other reasons. The 2-year mortality in both groups was ~12%.

At baseline, demographic and health history characteristics were similarly dis-

Table 1—*Baseline demographic and health history findings for participants with diabetes returning the baseline and year 2 questionnaires* (n = 1,593)

Variable	Intervention (n = 7 firms; n = 986 patients)	Control (n = 7 firms; n = 607 patients)	Total	P
Average age (years)	65.7	65.8	65.7	0.84
Type 1 diabetes (%)	4.3	4.9	4.5	0.61
Years diagnosed diabetes (%)				0.84
≤5	37.0	35.9	36.6	
6–15	37.0	38.5	37.6	
≥16	26.0	25.6	25.8	
Received VA care <5 years (%)	33.1	33.8	33.4	0.78
Receiving care outside VA (%)	33.0	35.7	34.0	0.29
Education <12 years (%)	16.8	15.7	16.4	0.62
Married (%)	68.0	65.4	67.0	0.30
Retired (%)	59.9	61.6	60.6	0.53
Disabled (%)	39.4	42.9	40.8	0.19
Ethnic background (%)				0.001
White	79.2	70.1	75.7	
African American	16.0	21.6	18.2	
Hispanic	1.6	3.4	2.3	
Asian	1.4	1.5	1.4	
Other	1.9	3.4	2.5	
Annual income (%)				0.40
<$10,000	25.5	22.7	24.5	
$10,000–19,999	41.3	42.0	41.6	
$20,000–39,000	27.3	27.7	27.4	
$40,000+	5.8	7.6	6.5	
Health history (%)				
Hypertension	66.1	68.9	67.2	0.27
Prior myocardial infarction or coronary artery bypass graft	24.3	23.1	23.8	0.62
Stroke	13.5	16.5	14.6	0.11
Congestive heart failure	12.6	8.7	11.1	0.02
Prior ulcer/foot sore	13.1	13.4	13.2	0.88
Peripheral vascular surgery	5.6	7.3	6.2	0.20
Prior amputation	5.1	5.1	5.1	1.00
Laser treatment	15.9	22.1	18.3	0.003
Legal blindness	2.9	3.6	3.2	0.47
Kidney dialysis or transplant	1.7	1.8	1.8	1.00
Any prior diabetic comas	7.2	4.8	6.3	0.06
Cancer	10.0	10.4	10.2	0.87
Depression	22.3	21.3	21.9	0.66
Prior smoker	63.0	61.8	62.5	0.89
Current smoker	15.8	16.1	15.9	0.86

tributed between patients in the intervention and the control firms, as shown in Table 1. The average veteran's age was 65.7 years. Approximately one-third of these veterans had received VA care for <5 years. One-third of participants received both VA and private health care. Only 16% of participants in these firms had <12 years of education. The majority of participants were married and retired. Approximately 41% reported that they were also disabled. The control firms had a significantly higher proportion of African Americans, Hispanics, and patients of other ethnic origins than did the intervention firm, and ~25% of these veterans reported an annual income of <$10,000.

Health history findings identified that 67% of these participants had hypertension, 24% had a prior myocardial infarctions or coronary artery bypass surgery, and ~15% had a history of stroke. The two health conditions with significant baseline differences between groups were a higher percentage of patients with a history of laser therapy in the control firm (22.1 vs. 15.9%, $P < 0.003$) and a higher percentage of intervention firm patients with congestive heart failure (12.6 vs. 8.7%, $P = 0.02$). Lower-extremity findings were similar and indicated prior foot sores in 13%, peripheral vascular surgery in 6%, and lower-limb amputations in 5%. A diagnosis of cancer was reported by 10% of participants, and 22% reported a history of depression. Smoking history was reported by 63%, although only 16% were current smokers.

Changes in physical and self-care findings are presented in Table 2. In terms of clinical improvement, the proportion of patients with an average HbA_{1c} ≤8% declined by 10% in both groups. The frequency of patients with a diastolic blood pressure <90 mmHg decreased in intervention firms but not in the control firms. Systolic blood pressure <140 mmHg and LDL >130 mg/dl actually increased in both groups. Approximately 8% of intervention firm patients improved their HDL levels over 2 years compared with baseline findings, while control firm patients stayed the same. Small improvements in patients checking feet and following meal plans were noted comparing patients in intervention and control firms, but they did not reach statistical significance.

Self-management awareness improved to a greater extent in intervention than in control firm patients, but only to a statistically significant extent on awareness for selecting shoes (Table 3). More intervention firm patients than control firm patients gained confidence that they knew which clinician to call (change = 0.08 vs. 0.01) and when to call with health care issues (change = 0.10 vs. 0.05). A majority of patients felt comfortable with their knowledge and awareness at baseline in terms of taking medications, meal planning, controlling blood glucose, and weight control.

Participants in the intervention firm and control firm were similarly satisfied with their provider's explanations and diabetes management (Table 4). The score indicating satisfaction with providers' interpersonal skills and organization score remained relatively constant in both firms.

Analysis of the SF-36 findings identified that the intervention firm scores

Table 2—*Changes in physical and self-care findings in patients with diabetes by firm

Variable	Intervention (n = 7 firms; n = 986 patients)	Control (n = 7 firms; n = 607 patients)	Intervention minus control		
	Mean	Mean	Mean	SD	*P*
Mean HbA_{1c} ≤8%					
Baseline	0.59	0.58	0.01	0.25	0.97
Two years	0.49	0.48	0.01	0.10	0.69
T2 − T0	−0.10	−0.10	0.00	0.09	0.98
Mean diastolic blood pressure <90 mmHg					
Baseline	0.52	0.41	0.11	0.10	0.03
Two years	0.48	0.44	0.04	0.07	0.25
T2 − T0	−0.04	0.03	−0.07	0.08	0.23
Mean systolic blood pressure <140 mmHg					
Baseline	0.87	0.91	−0.04	0.04	0.07
Two years	0.94	0.97	−0.03	0.05	0.62
T2 − T0	0.07	0.06	0.01	0.05	0.20
Mean LDL <130 mg/dl					
Baseline	0.56	0.59	−0.03	0.15	0.55
Two years	0.68	0.68	0.00	0.11	0.92
T2 − T0	0.12	0.09	0.03	0.09	0.07
Mean HDL >35 ng/dl					
Baseline	0.60	0.67	−0.07	0.09	0.09
Two years	0.68	0.67	0.01	0.07	0.94
T2 − T0	0.08	0.00	0.08	0.08	0.47
Check blood sugar ≥4 times/week					
Baseline	0.49	0.49	0.00	0.08	0.96
Two years	0.54	0.55	−0.01	0.05	0.69
T2 − T0	0.05	0.06	−0.01	0.08	0.89
Check feet ≥4 times/week					
Baseline	0.58	0.60	−0.02	0.05	0.20
Two years	0.69	0.66	0.03	0.07	0.35
T2 − T0	0.11	0.06	0.05	0.11	0.22
Follow meal plan					
Baseline	0.54	0.57	−0.03	0.07	0.30
Two years	0.60	0.59	0.01	0.08	0.69
T2 − T0	0.06	0.02	0.04	0.08	0.15
QOL - not concerned					
Baseline	0.68	0.66	0.02	0.05	0.36
Two years	0.68	0.68	0.00	0.05	0.93
T2 − T0	0.00	0.02	−0.02	0.08	0.39

*Means at baseline (T0), 2 years (T2), and 2-year change (T2 − T0); firm-based analysis (n = 7 pairs); adjusted for age, sex, race, site, income, education, marital status, employment status, VA years of care, and baseline chronic condition. QOL, quality of life.

showed minor improvement on six of the eight subscales and on the physical summary composite score. However, comparing intervention and control firms over 2 years showed no overall statistically or clinically significant differences (data not shown).

CONCLUSIONS — This study was designed to test whether providing primary care providers in intervention firms with timely patient information before visits would significantly improve outcomes, as compared between intervention firms and control firms. Despite the minimal clinician burden accompanying this 2-year intervention, patients in intervention firms fared no better with their diabetes outcomes than did those in control firms.

Several studies have addressed the likelihood of physicians' implementing guidelines or recommendations. Streja and Rabkin (14) examined physician characteristics associated with implementation of preventive care measures in patients with diabetes. They found that the most important predictor for implementation of recommendations was a practice style reflecting lower numbers of patients seen per unit time. The study reported that most physicians believed they implemented preventive care measures at a >90% level, which in reality happened infrequently. These authors recommended computer reminders as a solution.

Findings from the Cochrane Effective Practice and Organization of Care Review

Table 3—*Change in diabetes awareness: percent who specify that they "know enough"**

Has knowledge about:	Intervention (n = 7 firms; n = 986 patients) Mean	Control (n = 7 firms; n = 607 patients) Mean	Intervention minus control Mean	SD	P
Who to call					
Baseline	0.54	0.55	−0.01	0.13	0.92
Two years	0.62	0.56	0.06	0.06	0.21
T2 − T0	0.08	0.01	0.07	0.08	0.10
When to call					
Baseline	0.55	0.55	0.00	0.11	0.89
Two years	0.65	0.60	0.05	0.08	0.15
T2 − T0	0.10	0.05	0.05	0.08	0.14
Medications					
Baseline	0.77	0.77	0.00	0.07	0.54
Two years	0.81	0.80	0.01	0.08	0.37
T2 − T0	0.04	0.03	0.01	0.06	0.10
Meal plan					
Baseline	0.66	0.64	0.02	0.05	0.44
Two years	0.73	0.71	0.02	0.05	0.17
T2 − T0	0.07	0.07	0.00	0.04	0.69
Controlling blood sugar					
Baseline	0.76	0.79	−0.03	0.05	0.23
Two years	0.82	0.81	0.01	0.09	0.82
T2 − T0	0.06	0.02	0.04	0.08	0.37
Weight control					
Baseline	0.62	0.58	0.04	0.07	0.23
Two years	0.70	0.64	0.06	0.13	0.26
T2 − T0	0.08	0.06	0.02	0.10	0.35
Checking feet					
Baseline	0.60	0.62	−0.02	0.07	0.50
Two years	0.73	0.71	0.02	0.10	0.57
T2 − T0	0.13	0.09	0.04	0.07	0.13
Choosing shoes					
Baseline	0.50	0.54	−0.04	0.07	0.15
Two years	0.66	0.61	0.05	0.09	0.23
T2 − T0	0.16	0.07	0.09	0.08	0.03†
Complications					
Baseline	0.62	0.59	0.03	0.08	0.42
Two years	0.75	0.68	0.07	0.08	0.07
T2 − T0	0.13	0.09	0.04	0.06	0.18

*Means at baseline (T0), 2 years (T2), and 2-year change (T2 − T0); firm-based analysis (n = 7 pairs); adjusted for age, sex, race, site, income, education, marital status, employment status, VA years of care, and baseline chronic condition.†$P \leq 0.05$.

Group (5) indicated that in studies of providers and organizations that also facilitated patient education and an expanded nursing role, there were improvements in patient care processes and outcomes. O'Connor et al. (15) also identified patient involvement as an important factor and further targeted those indicating a readiness to change in an intervention designed to improve diabetes processes and outcomes.

There were multiple steps needed to effect a change in patients' diabetes outcomes. However, this intervention focused on provider, not patient actions. Diabetes control is strongly influenced by the quality of the partnership between the clinician and patient; thus, the lack of direct patient involvement in goal setting and developing strategies for goal achievement may have been a limitation in this study. Successful models for diabetes care usually include strategies that promote and maintain improved self-care behaviors. Had the same serial information been provided to patients, their awareness and involvement in the process of changing outcomes may have been more substantial.

Wagner (16) addressed the role of patient-care teams in chronic disease management and identified that interventions generally work better when delivered by a multidisciplinary team. Often nurses and pharmacists with clinical and behavioral skills can ensure delivery of critical ele-

Table 4—*Diabetes satisfaction: percent rating satisfaction with diabetes care provider as good to excellent and Seattle Outpatient Satisfaction Questionnaire Scores

Variable	Intervention (n = 7 firms; n = 986 patients)	Control (n = 7 firms; n = 607 patients)	Intervention minus control		
	Mean	Mean	Mean	SD	P
% Satisfied with doctor's explanations					
Baseline	0.87	0.86	0.01	0.02	0.10
Two years	0.87	0.89	−0.02	0.05	0.45
T2 − T0	0.00	0.03	−0.03	0.04	0.47
% Satisfied with current treatment for diabetes					
Baseline	0.89	0.89	0.00	0.03	0.73
Two years	0.90	0.90	0.00	0.03	0.59
T2 − T0	0.01	0.01	0.00	0.03	0.74
Humanistic score (ABIM)					
Baseline	74.51	74.55	−0.04	4.28	0.98
Two years	74.45	73.61	0.84	3.74	0.58
T2 − T0	−0.06	−0.94	0.88	3.55	0.61
Organization score					
Baseline	65.89	64.41	1.48	4.11	0.38
Two years	64.38	62.04	2.34	2.58	0.05†
T2 − T0	−1.51	−2.37	0.86	3.16	0.51

*Means at baseline (T0), 2 years (T2), and 2-year change (T2 − T0); firm-based analysis (n = 7 pairs); adjusted for age, sex, race, site, income, education, marital status, employment status, VA years of care, and baseline chronic condition. †$P \leq 0.05$

ments of care that physicians may not have the training or time to do, including medication regulation, self-management support, and intensive follow-up.

Although we were not able to demonstrate it in our trial, quality of care in the VA has improved since 1995, but there is still room for further improvement. A recent article described the proportion of VA patients with diabetes who received quality of care as defined by three indicators: measuring HbA_{1c}, annual eye exams, and semiannual lipid screening (17). From FY1995 to FY2000, performance on these indicators improved significantly comparing VA patients with Medicare patients ($P < 0.001$).

A review by Balas (18) of 98 randomized clinical trials addressed clinical information systems largely in outpatient care. Provider prompts and reminders were related to a significant increase in process measures. However, when outcome measures were assessed, statistically significant findings were reported only for patient knowledge and attitude and limited physiologic and psychological measures.

There are several explanations for negative findings. The involved clinicians may have been unable to interpret the data and/or simply ignored it. This is possible given the many quality-improvement initiatives concurrently conducted in the VA during the study period. Providers may have been overwhelmed. It is also possible that more initial provider education and ongoing problem solving by firms delivering the intervention could have had a beneficial effect on patient outcome.

It is also possible that, while the provider acted on recommendations and feedback provided, patient nonadherence to provided recommendations influenced the outcome. Adherence was indirectly measured on the self-reported questionnaires. Many of the participating providers were residents and fellows rotating through the VA with small patient panels. Thus, their exposure to the intervention may have been too limited.

Another potential limitation is that this trial had inadequate statistical power to detect a true difference. We think that this is unlikely, even though by employing the clinic firm as the unit of analysis we had only 13° of freedom (6° for paired analyses). Despite the large number of comparisons made, they were largely negative, and chance alone could account for the few findings with $P < 0.05$.

In summary, this group-randomized trial providing intervention firms with a comprehensive and sustained program of collecting and reporting patient data did not improve outcomes in patients with diabetes. Effective multicomponent (combined goal setting, provider prompts, and feedback) interventions with more patient involvement in goal setting and feedback may be indicated. Providing patient feedback reports to both patients and providers could foster beneficial joint problem solving.

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