

Clinical outcomes in patients with type 2 diabetes managed by a diabetes resource nurse in a primary care practice

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Objectives: The purpose of this observational cohort study was to observe outcomes in geriatric (aged ≥ 65 years) and nongeriatric (< 65 years) patients after employing a diabetes resource nurse (DRN) case manager in a suburban 12-physician family practice.

Study design: Data were collected by retrospective chart review of 106 patients enrolled in the diabetes care project who completed at least 6 months of the project between March 1999 and January 2001.

Population: Patients were recruited by either referral from their primary physician or invitation from the DRN.

Outcomes measured: Utilizing measures from the American Diabetes Association and the Diabetes Quality Improvement Project, comprehensive protocols were developed for implementation of process measures and management of glucose by the DRN. Active management protocols were not put in place for hypertension, lipids, or depression, but appropriate clinical measures were taken during patient visits. Data were collected at baseline, 6 months, and 12 months.

Results: Improvements in process measures were seen for geriatric and nongeriatric patients: 77% of patients had foot exams, 100% had ≥ 2 blood pressure measurements, 92% had eye exams, and 99% had lipid profiles. Both groups had improvement in hemoglobin A_{1c} levels (means 7.2% to 6.6% for geriatric patients and 8.9% to 6.8% for nongeriatric patients). The number of hypoglycemia incidents decreased in both groups. Depression scores improved in the nongeriatric group.

Conclusions: Results appear to corroborate a growing body of evidence supporting nurse intervention protocols as a way to improve diabetes care. A randomized controlled trial is planned to examine the effectiveness of the DRN.

Diabetes is estimated to affect over 16 million people in the USA (1) and accounts for over \$44 billion annually in direct medical expenditures (2). Most medical care for diabetes is delivered by general internists and family practitioners. Despite the evidence that appropriate diabetes management improves outcomes (3, 4), recent studies indicate that primary care providers are not meeting published standards of care recommended by the American Diabetes Association (ADA) (5–7). Interdisciplinary programs that target diabetes management have been shown to improve clinical outcomes (8–10).

The Diabetes Quality Improvement Project (DQIP) was created by organizations involved in diabetes to increase the quality of care provided to patients aged ≥ 65 years with diabetes and to improve health system accountability (11, 12). This project encourages health care organizations and physicians to routinely perform and improve the performance of preventive diabetes services. A summary of DQIP measures and ADA guidelines is found in Table 1.

Promulgation of both the DQIP measures and the ADA guidelines has been helpful in providing standards for improving the treatment of diabetes. In addition, the ADA has set up a provider recognition program to acknowledge physician practices that demonstrate they are following ADA guidelines. As shown in Table 1, outcome measures of the 2 programs differ. The most distinctive difference lies in the goals for hemoglobin A_{1c} levels. The DQIP set the hemoglobin A_{1c} goal at $< 9.5\%$ for individuals aged ≥ 65 years (11, 13, 14) since 9.5% signified truly poor glucose control, a level at which most patients with diabetes

Table 1. Measures from the Diabetes Quality Improvement Project (DQIP) measures and guidelines from the American Diabetes Association (ADA)

Category	DQIP measures	ADA guidelines
Process measures		
Measure hemoglobin A _{1c}	Once a year	Twice a year
Measure blood pressure	Once a year	Routine visits
Measure lipid panel	Twice a year	Once a year
Measure microalbumin	Once a year	Once a year
Perform dilated retinal exam	Once a year	Once a year
Perform foot exam	Once a year	Once a year
Outcome measures		
Hemoglobin A _{1c} level	$< 9.5\%$	$< 7.0\%$
LDL level	< 130 mg/dL	< 100 mg/dL
Blood pressure	$< 140/90$ mm Hg	$< 130/80$ mm Hg

LDL indicates low-density lipoprotein.

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would exhibit clinical symptoms of hyperglycemia. The ADA goal of <7.0% was set at a level known to minimize the development of microvascular complications.

Baylor Health Care System and HealthTexas Provider Network, a large physician organization, developed a comprehensive diabetes care management program to assist primary care physicians in implementing DQIP measures and ADA guidelines.

The objectives of this pilot study were 1) to observe clinical outcomes in patients with type 2 diabetes after employing a diabetes resource nurse case manager (DRN) in a suburban 12-physician family practice setting; and 2) to characterize baseline and outcome differences in geriatric (aged ≥ 65 years) and nongeriatric (aged <65 years) patients in a typical primary care group practice.

METHODS

Comprehensive protocols for the DRN were developed for patient assessment, chronic diabetes care, patient education, and medication management by a team of physicians and certified diabetes educators. Additional assessment tools were used to facilitate identification of comorbid diagnoses of dementia, incontinence, and depressive disorders.

The DRN for the project was an experienced registered nurse and certified diabetes educator who was employed full-time for this study by the 12-physician family practice group. Patients enrolled in the project were to be seen by the DRN a minimum of 4 times, including a comprehensive initial visit and visits 3 months, 6 months, and 12 months later. Additional DRN patient visits, in the office or by telephone consultation, occurred as necessary for patient care. Patient appointments were made directly with the DRN. All DRN visit information was recorded by the DRN on forms developed for diabetes management and was included in the patient medical record. The DRN periodically reviewed each case with the patient's primary physician.

The initial goal of this pilot study was to recruit 150 geriatric patients. The DRN received a list of all of the practice's patients who were aged ≥ 65 years and had type 2 diabetes. She contacted all those for whom she had current contact information. When it became evident that the number of eligible geriatric patients was insufficient to fulfill study requirements, the DRN worked with the physicians to recruit younger patients with diabetes, and the 2 age groups were examined separately. A total of 137 patients enrolled in the study. Of those, 106 completed at least 6 months of follow-up, including 84 patients who completed the 12-month visit. Of these 106 patients, 62 (58%) were aged ≥ 65 years, and 44 (42%) were aged <65 years; 48 (45%) were men and 58 (55%) were women.

Data collected from the charts of the 106 patients included demographic information, hemoglobin A_{1c} levels, lipid profiles, comorbid conditions, blood pressure measurements, weights, dates of eye exams, dates of dental exams, foot exam information, microalbumin laboratory values, vaccination history, depression screening scores, hospital admission data, diabetes management plan information, and medication information.

Table 2. Clinical process measures

Measure	Geriatric (n = 62)	Nongeriatric (n = 44)	Total (n = 106)
Patient examined feet daily: baseline	14/62 (23%)	9/44 (20%)	23/106 (22%)
Patient examined feet daily: ending	36/59 (61%)*	22/42 (52%)*	58/101 (57%)*
Nurse performed foot exam	48 (77%)	34 (77%)	82 (77%)
Eye exam performed during study	57 (92%)	41 (93%)	98 (92%)
Microalbumin measured during study	51 (82%)	39 (89%)	90 (85%)
Lipid panel drawn	62 (100%)	43 (98%)	105 (99%)
Blood pressure measured during study	62 (100%)	44 (100%)	106 (100%)

* $P < 0.05$ from baseline to ending value within geriatric, nongeriatric, or total group.

Data were analyzed by using Microsoft Access, Minitab, and SAS statistics software. The significance level for all statistical tests was set a priori at $P < 0.05$. Paired t tests were used to compare baseline with ending data for continuous variables. McNemar's test or Fisher's exact test (for incomplete ending low-density lipoprotein [LDL] data) was used for proportions. When comparing interval data from geriatric and nongeriatric groups, an independent t test was used for continuous variables; Fisher's exact test was used for proportions.

Patient and physician surveys were conducted to determine satisfaction with the DRN model. The patient survey questions were derived from the Baylor Health Care System outpatient satisfaction survey. Staff attempted to contact every patient by telephone during the first 2 weeks of March 2001; 62 patients (45%) completed the survey. The physician questionnaire was written for this study and administered to 12 physicians, including all physicians in the Baylor Family Medical Center at Garland. The questionnaires were distributed in February 2001 and returned in March 2001.

RESULTS

At the time of the initial visit with the DRN, 75% of patients were using oral medications and 20% were using insulin to control blood glucose. Patients were stratified by duration of diabetes before enrollment into the diabetes management program: 36% of patients had had diabetes for ≥ 10 years; 28% had had diabetes for 4 to 9 years; 16% had had diabetes for 1 to 3 years; and 20% had had diabetes for <1 year.

The mean number of comorbid conditions was 3.1 per patient (range 0 to 7) based on chart review and patient reports at the time of the initial assessment. The most common comorbid conditions included hypertension (22% of patients); depression and anxiety (10% of patients); gastrointestinal disorders (7% of patients); and heart disease, such as a history of myocardial infarction, coronary artery bypass grafting, coronary atherosclerosis, or angina (6% of patients). Thyroid disorders, pulmonary disorders such as asthma or emphysema, allergies, arthritis, and congestive heart failure each affected 4% to 5% of patients. Only 12 patients (11%) reported that they used tobacco.

All patients showed improvements on the measures recommended by ADA and DQIP. Comparison data for geriatric and nongeriatric patients are shown for clinical process measurements (Table 2) and clinical outcome measurements (Table 3).

Table 3. Clinical outcome measures

Measure	Geriatric (n = 62)			Nongeriatric (n = 44)			Total (n = 106)		
	Baseline	Ending	Change	Baseline	Ending	Change	Baseline	Ending	Change
Hemoglobin A _{1c} *†	7.2% ± 1.3% (62)	6.6% ± 0.8% (59)	−0.7% ± 1.4% (59)‡	8.9% ± 2.5% (44)	6.8% ± 1.3% (41)	−2.0% ± 2.7% (41)‡	7.9% ± 2.0% (106)	6.7% ± 1.0% (100)	−1.2% ± 2.1% (100)‡
Body mass index*	32.8 ± 7.8 (61)	32.1 ± 7.3 (62)	−0.8 ± 1.9 (61)‡	34.6 ± 6.0 (41)	34.7 ± 6.7 (42)	0.2 ± 2.7 (40)	33.5 ± 7.1 (102)	33.2 ± 7.1 (104)	−0.4 ± 2.3 (101)
LDL <130 mg/dL (%)	41/55 (75%)	22/26 (85%)		20/34 (59%)	18/21 (86%)‡		61/89 (69%)	40/47 (85%)‡	
LDL <100 mg/dL (%)	20/55 (36%)	12/26 (46%)		9/34 (26%)	9/21 (43%)		29/89 (33%)	21/47 (45%)	
BP <130/80 mm Hg (%)	14/61 (23%)	21/62 (34%)		10/41 (24%)	10/43 (23%)		24/102 (24%)	31/105 (30%)	

*Values represent mean ± standard deviation (n).

†P < 0.05 for comparison of change between geriatric and nongeriatric groups.

‡P < 0.05 from baseline to ending value within geriatric, nongeriatric, or total group.

LDL indicates low-density lipoprotein; BP, blood pressure.

Hemoglobin A_{1c} measures significantly improved overall, from a mean of 7.9% (range 5.4%–15.2%) to a mean of 6.7% (range 4.6%–11.1%) during the study period ($P < 0.05$). Comparisons of baseline and ending hemoglobin A_{1c} levels for nongeriatric and geriatric patients are shown in the Figure. The geriatric group mean improved from 7.2% to 6.6% ($P < 0.05$), whereas the nongeriatric group mean improved from 8.9% to 6.8% ($P < 0.05$). Baseline data showed that the geriatric group had a lower mean hemoglobin A_{1c}, 7.2%, than the nongeriatric group, 8.9% ($P < 0.05$). This lower mean baseline included 20 patients (33%) who were experiencing episodes of hypoglycemia, as reported on their initial visit.

Lipid management was not included in the DRN protocol. All but 1 patient had a lipid panel drawn during the 1 year of evaluation. Only 89 patients (55 geriatric and 34 nongeriatric), however, had LDL cholesterol values recorded at the baseline visit. Of these patients, 12 geriatric patients had an LDL of <100 mg/dL and 9 nongeriatric patients had an LDL of <100 mg/dL at their last test recorded by the DRN.

Similarly, blood pressure management was not included in the DRN protocols. Using the ADA blood pressure treatment goal of <130/80 mm Hg, only 24 patients (24%, n = 102) had blood pressure at this goal at the initial visit. For those not at goal (n = 78), blood pressures ranged from 136/76 to 212/60 mm Hg. At the last visit, 31 patients (30%, n = 105) had a blood pressure <130/80 mm Hg. These changes were not significant and were similar for both geriatric and nongeriatric groups.

Over three fourths of the patients (77%) had foot exams performed and documented by the DRN at each of the initial, 3-, 6-, and 12-month visits. Additionally, patients were asked at each visit if they were examining their own feet. According to patient self-reports upon the initial visit with the DRN, only 23% (n = 14) of geriatric patients were examining their feet daily at baseline. This improved to 61% (n = 36) at the last visit. Simi-

larly, only 20% (n = 9) of nongeriatric patients were examining their feet daily at baseline. This also improved to 52% (n = 22) at the last visit.

No significant changes in the mean body mass index occurred overall. However, within the geriatric group, body mass index decreased from 32.8 at baseline to 32.1 at the endpoint ($P < 0.05$). A total of 68 patients overall maintained or lost weight during the study. Among those patients, the mean weight loss was 10.5 lb (range 0–67 lb).

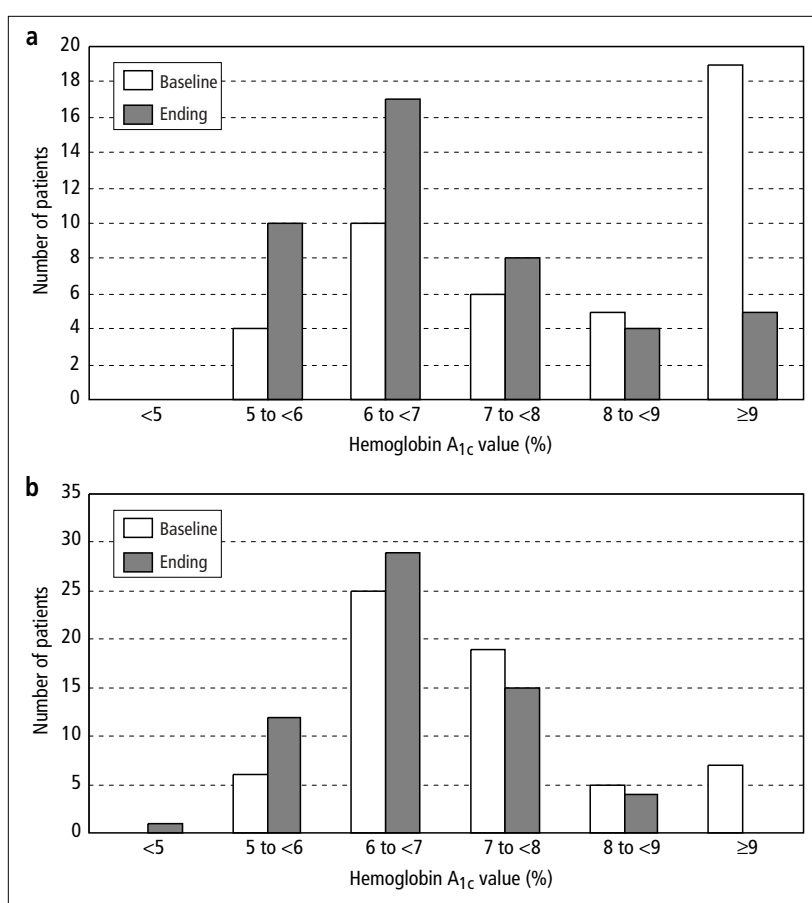


Figure. Change in hemoglobin A_{1c} levels for (a) nongeriatric patients (n = 44) and (b) geriatric patients.

As part of the DRN protocol, the Geriatric Depression Scale was administered to all patients at the initial, 6-month, and 12-month visits. Table 4 shows that patient depression scores improved. The nongeriatric patients showed more improvement from baseline to ending scores than the geriatric patients ($P < 0.05$). At the initial visit, 21 patients (20.0%) were depressed. Of these, 8 patients scored ≥ 23 (very depressed). By the 12-month visit, the mean depression score for the depressed patients was 6.38; only 9 patients had a score of ≥ 15 (mildly depressed), and none had a score indicating very depressed.

In the patient satisfaction survey, all 62 respondents agreed that appointment times and wait times to see the DRN were acceptable. All respondents either agreed or strongly agreed that the DRN was respectful and answered questions in an understandable fashion, and all were satisfied with the quality of care they received from the DRN. Ninety-five percent felt that the DRN responded quickly enough to their requests. When asked about the educational value and overall benefits of the program, 95% knew warning signs and symptoms to watch for when at home, better understood their medical condition, felt that they benefited from the program, and believed that the DRN and their physician were working together to provide better service. Nearly all (97%) would recommend the DRN to a friend, and 98% were satisfied overall with the DRN.

All 15 physicians who completed the physician satisfaction questionnaire felt that patients were seen in a timely manner, with 93% agreeing that the referral process was timely and patient charting was accurate, complete, and finished in an acceptable time. In assessing patient understanding of the program, 87% of the physicians felt that their patients gained an increased awareness of diabetes or demonstrated an improvement in their diabetes self-management skills. Only 53% of the physicians felt that they were kept informed of their patient's progress. Overall, 93% were satisfied with the DRN's services and would recommend the program to a colleague.

DISCUSSION

While no control group was employed that could allow analysis of the effectiveness of the DRN compared with other diabetes quality of care interventions, results of this pilot study suggest that the DRN strategy is promising. Both geriatric and nongeriatric patients whose care was managed by the DRN in the setting of a small primary care clinic had favorable process measures and outcomes measures.

In terms of the major outcome measure of hemoglobin A_{1c} levels, values in both the nongeriatric and geriatric populations surpassed the ADA goal of 7.0%. Interestingly, the geriatric group mean baseline hemoglobin A_{1c} level of 7.2% was already close to the ADA goal, but it was characterized by a high incidence of hypoglycemia. With appropriate management changes, the incidence of hypoglycemia was significantly reduced while hemoglobin A_{1c} levels were significantly improved at the same time.

The difference in the mean baseline hemoglobin A_{1c} levels of the geriatric group and the nongeriatric group is of interest. It is difficult to assess the current average hemoglobin A_{1c} level in the USA. Data published from the Third National Health and Nutrition Examination Survey for the period of 1988 to 1994

Table 4. Depression score measures*

	Depression score: mean \pm standard deviation (n)		
	Baseline	Ending	Change
Geriatric (n = 62)	8.8 \pm 6.7 (62)	7.7 \pm 7.0 (58)	-1.0 \pm 4.7 (58)
Nongeriatric (n = 44)	9.3 \pm 7.6 (44) [†]	5.7 \pm 5.9 (42) [†]	-3.3 \pm 5.4 (42) ^{†‡}
Total (n = 106)	9.0 \pm 7.1 (106)	6.9 \pm 6.6 (100)	-2.0 \pm 5.1 (100) [‡]

*Geriatric Depression Scale was administered at initial, 6-month, and 12-month visits. A score of 5 = normal; 15 = mildly depressed; 23 = very depressed. The maximum score is 30 points.

[†] $P < 0.05$ for comparison of change between geriatric and nongeriatric groups.

[‡] $P < 0.05$ from baseline to ending value within geriatric, nongeriatric, or total group.

indicate that roughly 38% of the population had a hemoglobin A_{1c} level $>8\%$ (15). However, a more recent study that evaluated the percentage of patients with a hemoglobin A_{1c} level $>9.5\%$ showed that improvements came with age: 23.5% of adults aged 18 to 44 years had a high level, whereas 19.1% of those aged 45 to 64 years and 14.5% of those aged 65 to 75 years had high levels, differences that were statistically significant (16). Perhaps the DQIP program should lower its hemoglobin A_{1c} outcome goal and make it equivalent to the ADA goal of 7%.

A recent review of interventions to improve the management of diabetes in primary care, outpatient, and community settings indicated that professional interventions and organizational changes that facilitated structured and regular review of patients were effective in changing process measures but not in affecting outcomes. However, interventions that included patient education and enhancement of nurse roles were effective in changing outcomes (17). Our study supports the importance of the role of a nurse manager in changing both process of care and outcomes. It gives credence to the employment of such a person in a practice that includes care of patients with diabetes. To reduce costs, a DRN could be shared among a number of smaller primary care practices.

Part of this study addressed the prevalence of depression in patients with type 2 diabetes. The incidence of depression is known to be higher in this population than in the general population (18). Certainly depression can interfere with a patient's ability to carry out the behaviors necessary for an optimal diabetes regimen. After entering the program, both groups of patients showed a reduction in depression, but the reduction was significant only in the nongeriatric group. This group showed the most improvement in their diabetes, which could lead to improvement in both physical and mental well-being.

It is important to note that the DRN did not have lipid or blood pressure management included in the diabetes protocols under which she practiced. Since patients with type 2 diabetes have a high prevalence of both hypertension and hyperlipidemia, there is a need to improve blood pressure and lipid control in these patients. Protocols for such management should be included in any future intervention process.

In conclusion, this study appears to corroborate a growing body of evidence supporting nurse intervention protocols as key components in the improvement of diabetes treatment in primary care settings. The importance of such an approach is em-

phasized by the fact the 85% of all patients with diabetes receive their care in such settings. The authors have followed up on this pilot study by initiating an institutional review board–approved, randomized, controlled trial of strategies to improve diabetes care across 22 HealthTexas Provider Network primary care centers. These strategies include physician profiling as well as care coordination by a DRN, and the trial is examining costs as well as outcomes (19). If outcomes of the follow-up study are positive, the DRN model may be extended to other practice sites in the HealthTexas Provider Network.

1. Harris MI, Flegal KM, Cowie CC, Eberhardt MS, Goldstein DE, Little RR, Wiedmeyer HM, Byrd-Holt DD. Prevalence of diabetes, impaired fasting glucose, and impaired glucose tolerance in U.S. adults. The Third National Health and Nutrition Examination Survey, 1988–1994. *Diabetes Care* 1998;21:518–524.
2. American Diabetes Association. Economic consequences of diabetes mellitus in the U.S. in 1997. *Diabetes Care* 1998;21:296–309.
3. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med* 1993;329:977–986.
4. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 1998;352:837–853.
5. American Diabetes Association. Clinical practice recommendations 2001. *Diabetes Care* 2001;24(Suppl 1):532–542.
6. Peters AL, Legorreta AP, Ossorio RC, Davidson MB. Quality of outpatient care provided to diabetic patients. A health maintenance organization experience. *Diabetes Care* 1996;19:601–606.
7. Ho M, Marger M, Beart J, Yip I, Shekelle P. Is the quality of diabetes care better in a diabetes clinic or in a general medicine clinic? *Diabetes Care* 1997;20:472–475.
8. Streja DA, Rabkin SW. Factors associated with implementation of preventive care measures in patients with diabetes mellitus. *Arch Intern Med* 1999;159:294–302.
9. Peters AL, Davidson MB. Application of a diabetes managed care program. The feasibility of using nurses and a computer system to provide effective care. *Diabetes Care* 1998;21:1037–1043.
10. Aubert RE, Herman WH, Waters J, Moore W, Sutton D, Peterson BL, Bailey CM, Koplan JP. Nurse case management to improve glycemic control in diabetic patients in a health maintenance organization. A randomized, controlled trial. *Ann Intern Med* 1998;129:605–612.
11. Harris MI. Health care and health status and outcomes for patients with type 2 diabetes. *Diabetes Care* 2000;23:754–758.
12. Fleming BB, Greenfield S, Engelgau MM, Pogach LM, Clauser SB, Parrott MA. The Diabetes Quality Improvement Project: moving science into health policy to gain an edge on the diabetes epidemic. *Diabetes Care* 2001;24:1815–1820.
13. Eastman RC, Javitt JC, Herman WH, Dasbach EJ, Copley-Merriman C, Maier W, Dong F, Manninen D, Zbrozek AS, Kotsanos J, Garfield SA, Harris M. Model of complications of NIDDM. II. Analysis of the health benefits and cost-effectiveness of treating NIDDM with the goal of normoglycemia. *Diabetes Care* 1997;20:735–744.
14. Vijan S, Hofer TP, Hayward RA. Estimated benefits of glycemic control in microvascular complications in type 2 diabetes. *Ann Intern Med* 1997;127:788–795.
15. Harris MI. Racial and ethnic differences in health care access and health outcomes for adults with type 2 diabetes. *Diabetes Care* 2001;24:454–459.
16. Saaddine JB, Engelgau MM, Beckles GL, Gregg EW, Thompson TJ, Narayan KM. A diabetes report card for the United States: quality of care in the 1990s. *Ann Intern Med* 2002;136:565–574.
17. Renders CM, Valk GD, Griffin SJ, Wagner EH, Eijk Van JT, Assendelft WJ. Interventions to improve the management of diabetes in primary care, outpatient, and community settings: a systematic review. *Diabetes Care* 2001;24:1821–1833.
18. Anderson RJ, Freedland KE, Clouse RE, Lustman PJ. The prevalence of comorbid depression in adults with diabetes: a meta-analysis. *Diabetes Care* 2001;24:1069–1078.
19. Ballard DJ, Nicewander D, Skinner C. Health care provider quality improvement organization Medicare data-sharing: a diabetes quality improvement initiative. *Proc AMIA Symp* 2002;22–25.