An Instrumental Variable Analysis of the Impact of Practice Guidelines on Improving Quality of Care and Diabetes-Related Outcomes in the Elderly Medicare Population

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American Journal of Medical Quality 2008 23: 222
DOI: 10.1177/1062860608314940

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The effect of the diabetes practice guideline recommending ≥2 HbA1c tests annually on diabetes-related outcomes was evaluated using Medicare claims data. The study population included 1998 and 1999 incident diabetes patients aged ≥ 67 years, who were Medicare eligible and without known diabetes-related complications at baseline. Number of HbA1c tests was measured 1 year after diabetes incidence. All-cause death and diabetes complications were identified during follow-up, through December 2003. The analysis was conducted with an instrumental variable method and a bivariate probit model, controlling for individual, social, and health care system characteristics. Among 13 033 patients, 27.1% followed the practice guideline. Receiving ≥2 HbA1c tests annually was significantly associated with a decrease in probability of 28.8 percentage points for macrovascular complications, 28.7 for atherosclerotic heart disease, and 23.1 for chronic kidney disease or end-stage renal disease in the 4-year follow-up period. (Am J Med Qual 2008;23: 222-230)

Keywords: diabetes; diabetes education program; HbA1c testing; instrumental variable; Medicare

Care and management of patients with diabetes is important; diabetes prevalence in 2005 in the United States was 7.0% of the population (20.8 million people) and 20.9% of the population aged 60 years or older (10.3 million people).[1] People with diabetes have 2 to 4 times the risk of developing heart disease or stroke compared with people without diabetes.[2] Diabetes is the leading cause of complications such as blindness and kidney disease.[1] Effective diabetes treatment requires glycemic control, a fundamental aspect of patient management.[3] Two clinical trials—the Diabetes Control and Complications Trial (DCCT)[4] for type-1-diabetes patients aged 13 to 39 years and the United Kingdom Prospective Diabetes Study (UKPDS)[5] for type-2-diabetes patients aged 25 to 65 years—showed that glycemic control was effective in reducing risks of microvascular and macrovascular complications.

Based on these and other clinical trials, and on epidemiological studies, the American Diabetes Association (ADA) established guidelines aimed at improving quality of care for people with diabetes,[3] emphasizing assessment of glycemic control through

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American Journal of Medical Quality, Vol. 23, No. 3, May/June 2008
DOI: 10.1177/1062860608314940

HbA1c testing. The ADA recommends that HbA1c testing should be performed at least twice a year for persons with stable glycemic control and quarterly for persons not meeting their glycemic goals. In Healthy People 2010, the diabetes-related objectives include improving diabetes education, increasing glycemic control monitoring through laboratory services such as HbA1c testing, and decreasing the risk of diabetes complications. These objectives address both the diabetes care process and care outcomes. But although clinical trials have shown the effect of intensive glycemic control on diabetes outcomes, evidence is lacking regarding the relationship between practice guidelines such as monitoring glucose and diabetes-related outcomes.

Our objective was to evaluate the impact of practice guidelines on improving quality of diabetes care through examining the effect of HbA1c testing on the risks of diabetes-related outcomes in elderly Medicare patients with diabetes. A randomized clinical trial may be the best method for designing such a study; however, in practice, patients cannot be randomly assigned to receive or not receive HbA1c testing. Therefore, we performed this study using Medicare claims data. One potential problem in using Medicare claims data is selection bias. Healthier patients or patients with diabetes-related conditions, such as hypertension, might be more likely to receive HbA1c testing. To address this potential selection issue, we applied instrumental variable (IV) methodology using a joint model with diabetes-related outcomes in a follow-up period and receiving HbA1c testing in a prior period. Through modeling diabetes-related outcomes and receiving HbA1c testing jointly, we estimated the effect of the practice guideline (ie, at least 2 HbA1c tests in a year) on diabetes-related outcomes (ie, all-cause death and diabetes complications).

METHODS

Data, Population, and Study Design

Data sources were the denominator and claims files in the Medicare 5% random sample database, the Small Area Income Dataset from the US Census Bureau,[6] and ADA Diabetes Education Program (DEP) data, available at the ADA Web site.[7]

The study population included 1998 and 1999 incident diabetes patients who were Medicare Part A and Part B eligible, aged 67 years or older, and without known retinopathy, neuropathy, renal disease, or cardiovascular disease at baseline. The 1998 diabetes incidence was defined if the appropriate International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes appeared at least once in Part A inpatient or at least twice in outpatient or Part B 1998 Medicare claims for persons with no diabetes-related claims during 1996 to 1997.[8,9] The 1999 incidence of diabetes was defined similarly. The ICD-9-CM diagnosis codes for diabetes are listed in the appendix.

The entry periods were 1998 to 1999 for the 1998 cohort or 1999 to 2000 for the 1999 cohort. In the entry period, we measured receipt of HbA1c testing (Physicians' Current Procedural Terminology [CPT] code 83036), diabetic education (Healthcare Common Procedure Coding System [HCPCS] codes G0108 and G0109), lipid testing (CPT codes 80061, 82465, 83715-83721, and 84478), or flu vaccination (CPT codes 90724, 90657, 90658, 90659, and 90660; HCPCS code G0008). The incident cohorts were alive, not enrolled in a health maintenance organization, continuously enrolled in Medicare, and without known end-stage renal disease (ESRD), chronic kidney disease (CKD), retinopathy, neuropathy, or cardiovascular disease during the entry period. Patient comorbid conditions, such as hypertension and anemia, were identified in the entry period. The follow-up periods were 2000 to 2003 for the 1998 cohort and 2001 to 2003 for the 1999 cohort. Diabetes-related complications were measured in the follow-up period; relevant ICD-9-CM codes appear in the appendix.

Measurements of Practice Guideline for Assessing Glycemic Control

According to the ADA guidelines, glycemic control is the fundamental requirement for the management of diabetes. Glycemic control is assessed through HbA1c testing. HbA1c testing is considered a quality indicator by agencies such as the Centers for Medicare & Medicaid Services[10] and the National Committee for Quality Assurance.[11] The ADA recommends that HbA1c testing should be performed at least twice a year. We created 2 indicators for measuring the practice guideline for assessing glycemic control. For example, for the 1998 incident cohort, we calculated the number of HbA1c tests received in 1999. The first indicator was whether a patient received at least 1 HbA1c test in 1999, and the second indicator was whether a patient received at least 2 HbA1c tests in 1999. We created the same indicators for the 1999 incident cohort.

Measurements of Outcomes

Diabetes-related outcomes included all-cause death and diabetic complications measured in the follow-up period. We defined 2 aggregated complications: macrovascular and microvascular. Macrovascular complications included atherosclerotic heart disease (ASHD), congestive heart failure, peripheral vascular disease, cerebrovascular accident/transient ischemic attack, and other cardiovascular disease. Microvascular complications included diabetic retinopathy, neuropathy, and CKD/ESRD. Complications were measured from Part A and Part B claims by a set of binary variables: yes/no with the corresponding values 1/0. Follow-up time was calculated from the beginning of follow-up until December 31, 2003, or the appearance of an outcome, date of death, or end of Medicare entitlement. In addition to all-cause death, macrovascular complications, and microvascular complications, we also defined 2 single complications as study outcomes, ASHD and CKD/ESRD, because they were the most frequently observed macrovascular and microvascular complications, respectively.

Measurements of Covariates

The covariates included individual characteristics, social factors affecting diabetes care, and factors related to the health care system. Individual characteristics were measured by age; gender; preexisting health conditions including hypertension, anemia, and chronic obstructive pulmonary disease (COPD); and length of hospital stay in the entry period. Social factors were measured by race (ie, white, black, other), Medicaid eligibility, and zip-code-level median family income grouped based on its distribution by quartile. Health care system characteristics were measured as follows: (1) access to a physician and number of diabetes visits identified by provider specialty codes from Medicare Part B files and (2) volume of care based on number of providers ever visited by a patient and number of Medicare patients cared for by those providers in the entry period. Other health care system measures used were patient residence (rural vs urban), region (Midwest/West vs Northeast/South), year diabetes was diagnosed (1998 vs 1999), and whether patients received lipid testing or flu vaccinations in the entry period.

Analysis With Instrumental Variable

We used the IV method to correct for the potential selection bias in receiving HbA1c testing. Recipients of HbA1c testing might be healthier or have better access to health services. Nonrecipients might be more likely to develop diabetes-related diseases. Patient characteristics also might differ between the 2 groups. Effects of HbA1c testing reported in this observational study might be biased unless selection bias is controlled.

An IV method can be used to address selection bias when comparing 2 or more treatments or prevention strategies. IV use relies on 2 assumptions[12]: IV affects treatment or prevention choices; IV does not directly affect outcomes, but affects them indirectly through its effect on treatments or prevention strategies. Therefore, the IV estimate describes the effect in the marginal population whose treatment or prevention effects are because of variation in the IV.[13,14]

Under the Balanced Budget Act of 1997, Medicare began covering physician-prescribed diabetes outpatient education furnished by providers who meet the ADA-endorsed National Standards for DEP.[7] According to Medicare coverage policy, beneficiaries are eligible for coverage for diabetes education if they are newly diagnosed with diabetes, at an inadequate glycemic control as indicated by an HbA1c level of 8.5 or higher, changing to oral diabetes medication from diet control or to insulin from oral diabetes medication, or at high risk for diabetic complications. Each eligible Medicare patient with diabetes has a onetime benefit of initial diabetes education training and 2 hours of follow-up training each year after the initial training. However, DEPs are not available in all areas because not every provider can meet the national standards. In most cases, patients receive education from a DEP near their homes, if one is available. Diabetes education includes general information on diabetes, information on risks and the benefits of blood sugar control, information on blood sugar testing, and instructions for using the information to improve diabetes control.

We considered an IV related to the distance between a patient and a DEP, calculated by 2 zip codes. If a patient and a DEP have the same zip code, the distance is 0 (IV value = 1); if not, the distance is greater than 0 (IV value = 0).

Model Specification

We used the bivariate probit model to jointly model diabetes-related outcomes and receiving or not receiving HbA1c testing. The model takes into account the correlation between unobserved factors both in outcomes and in receiving or not

receiving HbA1c testing. The specifications for the bivariate probit model are

$$Y_1^* = \alpha_0 + \alpha_1 X_1 + \alpha_2 X_2 + \alpha_3 X_3 + \alpha_4 Z + v_{1i}, \quad Y_1 = 1 \text{ if } Y_1^* > 0, 0 \text{ otherwise} \tag{1}$$

$$Y_2^* = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 Z_1 + v_{2i}, \quad Y_2 = 1 \text{ if } Y_2^* > 0, 0 \text{ otherwise} \tag{2}$$

and $E[v_{1i}] = E[v_{2i}] = 0$, and $\text{Var}[v_{1i}] = \text{Var}[v_{2i}] = 1$.

In Equations 1 and 2, X_1, X_2, and X_3 are a set of exogenous variables, including sociodemographic variables, patient health status variables, and health care system variables. Z in Equation 1 is the IV. We defined $Y_1 = 1$ if a person received at least 2 HbA1c tests in 1 year and $Y_1 = 0$ otherwise. Similarly, we defined $Y_2 = 1$ if a person developed any macrovascular complication in the follow-up period and $Y_2 = 0$ otherwise.

The maximum likelihood estimation was performed using LIMDEP software (Econometric Software, Inc, Plainview, NY). Details of the maximum likelihood estimation and marginal effects have been discussed by Greene.[15,16] The effect of receiving at least 2 HbA1c tests on the probability of an outcome event in the follow-up period would be computed as

$$\text{Prob}[Y_2 = 1 \mid Y_1 = 1, X_1, X_2, X_3] - \text{Prob}[Y_2 = 1 \mid Y_1 = 0, X_1, X_2, X_3]$$

For the discrete variable of receiving at least 2 HbA1c tests, we obtained the difference in probability of an outcome event with all other covariates being evaluated at mean values.

RESULTS

The final sample size was 13 033 patients. Table 1 presents summary statistics for patient characteristics at baseline and diabetes care practice guideline adherence for the entire sample. Within the maximum 4-year follow-up, the mean time was 3.23 years (standard deviation [SD] = 0.87). The mean duration of diabetes (censoring at death, end of Medicare entitlement, or December 31, 2003) was 5.23 years (SD = 0.87). In a 1-year period after incident diabetes, only about half of patients received at least 1 HbA1c test and only 27% received at least 2.

Table 1

Patient Baseline Characteristics, Analysis Sample

Characteristic	Mean ± SD, Number (%), or %
Sociodemographic characteristics	
Mean age ± SD (years)	72.6 ± 5.6
Female gender (n, %)	7914 (60.7)
Race (n, %)	
White	11 274 (86.5)
Black	1110 (8.5)
Other	649 (5.0)
Dually eligible, Medicare and Medicaid (n, %)	1959 (15.0)
Median family income (n, %)	
Less than $32 885	1303 (10.0)
$32 885 to less than $46 307	5212 (40.0)
$46 307 to less than $58 542	3258 (25.0)
$58 542 and higher	3260 (25.0)
Health conditions	
Hypertension (n, %)	8663 (66.5)
Anemia (n, %)	1937 (14.9)
Chronic obstructive pulmonary disease (n, %)	1558 (12.0)
Mean hospital days in entry period ± SD	2.1 ± 10.8
Mean hospital days in entry period, hospitalized persons only, ± SD	9.4 ± 21.4
Practice guideline adherence	
At least 2 HbA1c tests in 1 year (%)	27.1
At least 1 HbA1c test in 1 year (%)	49.8
At least 1 lipid test in 1-2 years (%)	71.9
Flu vaccination in 1-2 years (%)	62.2

Abbreviation: SD, standard deviation.

Main Results: Effect of At Least 2 HbA1c Tests

In each of the 5 bivariate probit models with different diabetes-related outcomes, the IV was a significant predictor for receiving at least 2 HbA1c tests (Table 2). The coefficients for covariates in Equation 1 are not reported in Table 2. Patients of white race; those with hypertension, more frequent diabetes visits, and more recently diagnosed diabetes; and those who received lipid tests or influenza vaccinations were more likely to receive at least 2 HbA1c tests.

Receiving at least 2 HbA1c tests was significantly associated with reduction in the probability of development of macrovascular complications, ASHD, and CKD/ESRD in the follow-up period (Table 2). Compared with receiving 1 or no HbA1c tests, receiving at least 2 HbA1c tests was associated with decreases in probability of 28.8 percentage points for macrovascular complications ($P = .0001$),

Table 2

Estimated Effect of At Least 2 HbA1c Tests on Diabetes-Related Outcomes: Results From 5 Bivariate Probit Models[a]

	Equations for ≥ 2 HbA1c Tests		Equations for Outcomes			Disturbance Correlation	
Outcomes	β for IV	*P*	β for ≥ 2 HbA1c Tests	Marginal Effect[b]	*P*	ρ	*P*
Death	.0747	.0231	−.0903	−.0183	.7433	−.0155	.9229
Macrovascular complication	.0746	.02	−.7248	−.2878	.0001	.3832	.0005
ASHD	.0944	.0034	−.7543	−.2873	.0064	.4052	.0178
Microvascular complication	.0845	.0092	−.4996	−.1756	.1218	.3618	.0624
CKD/ESRD	.0917	.0043	−.7936	−.2314	.022	.4908	.0195

Abbreviations: ASHD, atherosclerotic heart disease; CKD, chronic kidney disease; ESRD, end-stage renal disease; IV, instrumental variable.
[a]Each outcome corresponds to a bivariate probit model; coefficients for covariates are not reported here.
[b]Incremental probability when receiving at least 2 HbA1c tests given other covariates evaluated at the mean values.

28.7 percentage points for ASHD ($P = .0064$), and 23.1 percentage points for CKD/ESRD ($P = .022$). However, receiving at least 2 HbA1c tests had no significant effect on all-cause death or microvascular complications. The coefficients for covariates in Equation 2 are not reported in Table 2. Main factors significantly related to diabetes-related outcomes included age, gender, race, COPD, hypertension, diabetes incident year, and preventive care. For example, older patients, men, or patients with hypertension were more likely to develop diabetes-related complications. African Americans were less likely to develop macrovascular complications but more likely to develop microvascular complications such as CKD/ESRD.

We performed similar analyses to compare receiving at least 1 HbA1c test with receiving no tests, for the same outcomes using the same models. We found no significant difference between receiving at least 1 HbA1c test and receiving no HbA1c tests (results are not reported here).

Analyses on Selection Bias and IV Validation

The disturbance correlations of the 2 equations were positive and significant for models with outcomes of macrovascular complications, ASHD, and CKD/ESRD (Table 2). These significant disturbance correlations suggest selection bias, and results would be biased if we did not correct for it. Table 3 shows evidence of selection bias in the entire sample. Recipients of at least 2 HbA1c tests differed from nonrecipients by age, gender, race, and comorbid conditions. Recipients were more likely to be younger and of white race, to have hypertension, and to have fewer hospitalization days at baseline; they were less likely to have anemia or COPD. In terms of unadjusted outcomes, recipients were less likely to die or develop macrovascular complications and more likely to develop microvascular complications.

Our analysis suggests that the IV significantly affected whether a patient received at least 2 HbA1c tests. Based on the IV values, patients were divided into 2 groups: DEP available (IV value = 1) and DEP not available (IV value = 0). In the DEP-not-available group, 26.6% of patients received at least 2 HbA1c tests, compared with 29.1% in the DEP-available group ($P = .0114$). In a logistic regression analysis, the odds ratio of receiving at least 2 HbA1c tests for patients in the DEP-available group was 1.13 (95% confidence interval 1.03-1.24). The χ^2 value from a likelihood ratio test was 6.3 with 1 degree of freedom. In the DEP-not-available group, 0.8% received diabetes education in 1998, 3.5% in 1999, and 7.3% in 2000; in contrast, in the DEP-available group, 0.9% received diabetes education in 1998, 4.3% in 1999, and 11.8% in 2000. Patients who received diabetes education were more likely to receive diabetes care. Among patients who did not receive diabetes education, 68.6% received HbA1c testing, 71.3% lipid testing, 66.1% kidney screening, 54.3% eye exams, and 20.1% self-monitoring glucose in the entry period. Among patients who received diabetes education, 95.3% received HbA1c testing, 81.8% lipid testing, 79.1% kidney screening, 66.7% eye exams, and 64.0% self-monitoring glucose.

To check whether the IV is uncorrelated with patient health status and outcomes, we used the

Table 3

Patient Characteristics at Baseline and Outcomes in the Follow-up Period, by Receiving HbA1c Testing and Distance to a Diabetes Education Program (DEP)

	Receiving ≥ 2 HbA1c Tests			Distance to DEP		
Characteristics	No	Yes	*P*[a]	>0	0	*P*[a]
Total n	9499	3534		10 348	2685	
Demographics						
Mean age (years)	72.9	71.9	<.0001	72.6	72.9	.0114
Male (%)	39.0	40.2	.2119	39.2	39.5	.8105
White (%)	85.5	89.3	<.0001	86.4	87.0	.3620
Black (%)	9.0	7.2	<.0001	8.3	9.3	.1148
Comorbidity						
Anemia (%)	16.4	10.7	<.0001	15.0	14.5	.5405
COPD (%)	12.7	9.9	<.0001	12.0	11.6	.5492
Hypertension (%)	64.4	72.1	<.0001	66.6	65.9	.4710
Mean hospital stay in 2-year entry period (days)	2.3	1.4	<.0001	2.0	2.3	.2253
Outcomes						
Death (%)	17.0	11.6	<.0001	15.6	15.3	.7849
Macrovascular complication (%)	48.0	45.3	.0047	47.4	47.0	.7201
Microvascular complication (%)	16.1	22.4	<.0001	18.1	16.9	.1478
Receiving ≥2 HbA1c tests (%)				26.6	29.1	.0114

Abbreviation: COPD, chronic obstructive pulmonary disease.
[a] χ^2 test for category variables and Wilcoxon rank sum test for age and hospital days.

approach developed by McClellan et al,[17] which is based on the idea that if the distributions of patient characteristics and observed health status were independent of the IV, the unobserved risk factors should also be independent of the IV. The hypothesis is that those potential omitted variables could affect both treatment and outcomes. We assumed in our study that the potential omitted variables included omitted health status variables and omitted income variables. These omitted variables affect both glycemic control monitoring and outcomes. Table 3 shows that distributions of age, gender, race, and observed health status measured by preexisting comorbidity and hospitalization days were independent of the IV. As shown, there are no significant differences in baseline patient characteristics by distance to DEP except for age. The significant difference in age may be because of the large sample size; the actual difference in age is quite small (mean difference 0.3 year).

Correlation of HbA1c Testing With Other Diabetes Care

Table 4 presents the correlations of receiving HbA1c testing and other diabetes care. More frequent HbA1c testing was significantly associated with higher likelihood of receiving lipid testing, flu vaccinations, eye exams, self-monitoring glucose, and kidney screening. If one guideline is followed, other guidelines are more likely to be followed. Therefore, adherence to the practice guideline regarding HbA1c testing can be an indicator of comprehensive diabetes management.

Table 4

Correlations of HbA1c Testing and Other Diabetes Care

Percentage of Patients Receiving Other Diabetes Care	Number of HbA1c Tests				
	0	1	2	≥ 3	*P*
Lipid testing	63.5	77.5	82.1	84.0	<.0001
Flu shot	57.6	64.2	67.4	71.4	<.0001
Eye exam	51.6	56.0	59.1	62.0	<.0001
Self-monitoring blood sugar	11.7	25.6	33.5	37.7	<.0001
Kidney screening	61.7	69.8	71.9	74.5	<.0001

DISCUSSION

Among 13 033 incident diabetes patients reported in 1998 and 1999 Medicare data, only about a quarter (27.1%) followed the ADA practice guideline by monitoring their glycemic control. In this Medicare sample, the guideline of at least 2 HbA1c tests in 1

year was more likely to be followed by younger or white patients, patients less likely to have anemia or COPD, patients less likely to be hospitalized at baseline, and patients with hypertension. Using IV analysis, we found that at least 2 HbA1c tests in 1 year was associated with a decrease in probability of 28.8 percentage points for macrovascular complications, 28.7 percentage points for ASHD, and 23.1 percentage points CKD/ESRD in the 4-year follow-up period.

Given the assumption that HbA1c testing is a surrogate for glycemic control, these results are generally consistent with clinical trials. The DCCT showed that intensive glycemic control significantly reduced the risk of microalbuminuria by 39%, albuminuria by 54%, and retinopathy by 63%.[4] The UKPDS showed intensive glycemic control, with significant relative risks of 0.75 for microvascular complications and 0.71 for retinal photocoagulation.[5] A recent clinical trial conducted in Denmark (the Steno-2 study) showed that intensive treatment for patients with diabetes significantly reduced the risks of cardiovascular disease, nephropathy, retinopathy, and autonomic neuropathy.[18]

The effect of glycemic control on renal disease in the UKPDS[5] was not significant. In the UKPDS, renal failure was defined as dialysis or plasma creatinine greater than 250 μmol/L, not related to any acute intercurrent illness. The event rate was low: 0.6% in the intensive-treatment group and 0.8% in the conventional-treatment group developed renal failure in 10 years.[5] Our study included CKD/ESRD as outcomes in kidney disease, giving us a much higher event rate. The 4-year incidence rate of CKD/ESRD was 9.3%. Our study's higher incidence of CKD/ESRD may be because of our subjects' older age and higher prevalence of hypertension (66.4%) at baseline; UKPDS patients with malignant hypertension were excluded. Elevated blood pressure is an early accompaniment of incipient diabetic nephropathy and is associated with the progression of microalbuminuria; therefore, hypertension could accelerate deterioration of renal function. In our study, the incidence of CKD/ESRD was 7.3% for patients without hypertension at baseline and 10.3% for patients with it. We controlled for hypertension but did not observe its severity. Hence, the significant effect of HbA1c testing on kidney disease might be because of a larger sample size and higher event rate due to older age and higher prevalence of hypertension. A recent population-based ecologic study also provided evidence of the association between adequate diabetes care and lower incidence of diabetic ESRD in 159 Georgia counties.[19]

Rationale for HbA1c Testing as a Surrogate for Glycemic Control

Epidemiological analysis of the association of glycemia and diabetes complications from UKPDS data showed that every 1% reduction of mean HbA1c led to risk reductions of 21% for any diabetes-related end point, 21% for diabetes-related death, 14% for myocardial infarction, and 37% for microvascular complications.[20] Results from both DCCT and UKPDS suggest that any improvement in HbA1c can potentially reduce the risk of diabetes-related complications.[19,21]

HbA1c testing is recommended by the ADA,[3] the Canadian Diabetes Association,[22] and the American College of Endocrinology[21] for diabetes management; it is used as a major diabetes quality of care measurement by the Centers for Medicare & Medicaid Services[10] and the National Committee for Quality Assurance Health Plan Employer Data and Information Set (HEDIS).[11] Testing HbA1c is necessary to accurately assess treatment efficacy and sufficient to assess glycemic control. The test is central to intensive glucose control; failure to perform it indicates poor glycemic control monitoring. HEDIS 2002 considers lack of HbA1c testing to indicate poor HbA1c control, defined as a HbA1c value >9.5%.[11] Therefore, HbA1c testing can be a marker or surrogate for glycemic control and comprehensive diabetes management. Our study also shows that increasing the number of HbA1c tests positively correlates with the likelihood of receiving other diabetes care.

Policy Implications

Our study has limitations. Results were limited to 1998 and 1999 incident diabetes patients reported in the Medicare claims data. Results were also limited by the IV analysis itself; IV results are restricted to only "marginal patients."[12] In our study, the "marginal patients" were those who resided in the same zip code as a DEP, followed the practice guideline by monitoring glucose due to diabetes education obtained from a DEP, and carried the effect to fewer diabetes-related complications. Despite these limitations, policy implications can be drawn. We show that receiving at least 2 HbA1c tests due to DEP accessibility was associated with decreases in the probability of developing macrovascular

complications, ASHD, and CKD/ESRD. However, most patients in our study had not received the best standard of diabetes care early in the course of the disease. The assurance of timely, consistent diabetes care according to established guidelines is worth seeking. Public policies aimed at establishing well-organized delivery systems should be strengthened.

This study demonstrates the role of ADA DEPs in delivering better quality of care for diabetes patients. Currently, DEPs are not available in all areas of the United States, especially in rural areas. Distribution of DEPs in terms of patient numbers is not balanced across the states; they are less likely to be distributed in the South and East. Studies should be initiated to explain the lower availability of DEPs in rural and in populous areas and to explore ways to extend programs nationally. In addition, the rate of patients receiving diabetes education was very low in the study period; policy should encourage health providers to prescribe this training.

Quality of care assessment should include disease-related outcomes and care processes such as HbA1c testing. The results of this study have an additional implication: the assessment of quality of care should evaluate not only the care process (which includes elements such as HbA1c testing) but also disease-related outcomes, better controlling for individual characteristics. To improve the quality of care for Medicare beneficiaries, Medicare has tried several initiatives to encourage improved quality of care in all health care settings; these include the case-mix adjustment payment, disease management, and pay for performance, among others. The current study linked quality of care measure processes and outcomes. The study results and study methods may be of use to Medicare in assessing the quality of care for Medicare beneficiaries.

ACKNOWLEDGMENTS

This project was supported with federal funds from the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Contract No N01-DK-9-2343. The authors thank Drs. Donna McAlpine and Paul Eggers for valuable comments and suggestions for this study, and Nan Booth, MSW, MPH, and Beth Forrest for help in manuscript editing and preparation and regulatory assistance.

APPENDIX
International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and Current Procedure Terminology (CPT) Codes for Diabetes, Diabetes-Related Complications, and Other Comorbidities

Diseases	Categories	ICD-9-CM and CPT codes
Diabetes		250.xx (exclude 250.x1 and 250.x3), 357.2, 362.01, 362.02, 366.41
Diabetic retinopathy	Background, nonproliferative	250.5, 362.01, 362.10
	Proliferative	362.02, 379.23
	Macular edema	362.83
Kidney disease	Chronic kidney disease	016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.4, 271.4, 274.1, 283.11, 403.x1, 404.x2, 404.x3, 440.1, 442.1, 447.3, 572.4, 580-588, 591, 642.1, 646.2, 753.12-753.17, 753.19, 753.2, 794.4
	End-stage renal disease	V45.1, V56, 996.56, 996.68, 996.73
Diabetic neuropathy	Polyneuropathy	357.2
	Diabetes, neurologic manifestation	250.6, 250.60, 250.61, 250.62, 250.63
Amputation	Peripheral vascular disease amputation, CPT codes	23900, 23920, 24900, 24920, 25900, 25905, 25920, 25927, 27295, 27590-27592, 27598, 27880-27882, 27888, 27889, 28800, 28805
Cardiovascular disease	Atherosclerotic heart disease	410-414, V45.81, V45.82
	Congestive heart failure	398.91, 402.x1, 404.x1, 404.x3, 425, 428
	Cerebrovascular accident/ transient ischemic attack	430-438
	Peripheral vascular disease	440-444, 447, 451-453, 557
	Cardiac, other	420-424.9, 426, 427, 429, 785.0-785.3, V42.1, V42.2, V43.3, V45.0, V53.3
Hypertension		362.11, 401.x-405.x, 437.2
Chronic obstructive pulmonary disease		491-494, 496, 510
Anemia		280-285

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