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Measurement of glycemic control in diabetic patients—an evaluation of risk adjustment using a primary care registry

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BACKGROUND: The ability to measure hemoglobin A1c in populations under the care of physicians or physician groups has become increasingly important with the advance of system-based interventions that can affect this outcome and with payment linked to levels of diabetes control.

OBJECTIVE: To evaluate the effect of patient and system factors on the rate of glycemic control as measured by a hemoglobin A1c of <7% using a diabetes mellitus registry from osteopathic training programs in internal medicine and family medicine.

DESIGN: Observational study.

PARTICIPANTS: A cohort of 4715 diabetes cases abstracted from the medical records of 127 residency programs nationally between 2003 and 2008. Measurements and main results**:** Associations between glycemic control and age, gender, medications used, insurance type, race/ethnicity, levels of appointment adherence, hypertension, and presence of evidence of nephropathy were evaluated. In bivariate and multivariate analysis, age, medication type, insurance type, level of appointment adherence, and presence of evidence of nephropathy had a statistically significant association with hemoglobin A1c control. Age was associated with increased levels of control, whereas use of insulin, insurance other than Medicare, non-Caucasian race, missing more than 20% of office visits, and the presence of microalbuminuria or nephropathy were associated with decreased glycemic control.

CONCLUSIONS: System and patient factors not under the control of the physician have a significant effect on levels of glycemic control. To evaluate physician or practice performance, methods of controlling for these factors need to be developed and implemented.

The role that glycemic control plays in the reduction of complications from diabetes mellitus alone, or in combination with lipid and blood pressure control, has been well established in type 2 diabetes over the past decade.[1,2] Studies show a 1% reduction in hemoglobin A1c has been associated with a 30% reduction in the rate of microvascular complications.[1,3] Despite having the knowledge of these benefits, the rate of glycemic control nationally has re-

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mained unchanged from 1988 to 2002. However, the proportion of diabetics with a hemoglobin A1c between 6% and 8% increased from 34.2% to 47.0% during this time frame.[4] Because of the disparity between current treatment recommendations and actual glycemic control of diabetes mellitus, payers in the United States have developed programs linking payment to specific levels of glycemic control. Programs such as the National Committee for Quality Assurance, Bridges to Excellence Program, and the Center for Medicaid and Medicare Services Physician Quality Reporting Initiative are linking payment to reporting levels of glycemic control.[5,6] Because these payment programs use unadjusted rates of control, they implicitly infer that control of hemoglobin A1c is fully attributable to the physician or practice. In clinical practice, however, physicians acknowledge that many factors contribute to glycemic goal achievement including patient and system factors. The same issues have been raised for hospital performance measures over the past two decades. Research has resulted in a consensus that outcome performance measures—that quantify the result of the interaction between health care and patients—need to be risk-adjusted for factors the patient brings to the interaction.[7] As a result, most hospital performance reports or internal hospital outcomes measures are currently risk adjusted.[8-10] As ambulatory measurements of diabetes management increase, specifically those that focus on intermediate outcomes such as glycemic, blood pressure, or lipemic control, it becomes more important to evaluate methods of isolating the portion of performance attributable to the provider and practice. This becomes even more critical because these outcomes are increasingly tied to provider ranking and reimbursement. Recent studies have begun to investigate which factors affect intermediate outcomes in diabetes mellitus. Evaluation of the association between glycemic controls and chronic illness with complexity (CIC) demonstrated varying associations between glycemic control and CIC in diabetic patients depending on the domain of complexity, including nondiabetes physical illness, diabetes-related complications, and mental illness/substance abuse conditions.[11] A study investigating the association between patient appointment adherence and glycemic control demonstrated that adherence was a strong predictor of diabetes metabolic control, independent of the number of visits.[12] Although there have been studies associating chronic disease with glycemic control and patient adherence to glycemic control, there have been few that have looked at combining patient factors and system factors to determine the effect of nonphysician glycemic management. It is important to control for patient and system factors that also affect the outcome. In this study, we used a diabetes mellitus registry sponsored by the American Osteopathic Association (AOA) to evaluate the use of patient factors (as represented by comorbid and severity of disease) and systematic factors (as represented by insurance and missed visits) on glycemic control across a national sample of internal medicine and family medicine residency programs.

Methods

The study used data from the AOA Clinical Assessment Program (AOA-CAP), a web-based registry developed to provide osteopathic internal medicine and family medicine residency programs with measures to improve the quality of patient care and a training tool to enhance the core competencies of practice-based learning and systems-based practice.[13] Standardized data and case definitions are used to ensure that residencies collect information in a consistent manner. The registry collects patient-level data that are then analyzed using measures recommended by the National Quality Forum and Physicians Consortium for Performance Improvement.[14,15] As part of the residency accreditation requirements, programs contribute data to the diabetes mellitus measure set on a random sample of type 1 or type 2 diabetic patients who had at least 2 visits for diabetes within the previous 12 months. The accreditation requirement is based on reporting, not performance. Patients with diet-controlled diabetes, or those lacking information on independent variables including race, haemoglobin A1c level, albuminuria screen, missed visits, hypertension, or insurance type were excluded from analysis. Data outcome of interest in this analysis was glucose control as measured by hemoglobin A1c of $<7\%$ on the most recent patient visit with laboratory information. The variables tested for association with the outcome of interest are listed in Table 1.

Information regarding the number of missed appointments during the study period was collected and patients were dichotomized by the percentage of missed visits (no show), with those missing $>20\%$ of scheduled visits classified as nonadherent by the investigators. χ^2 tests were used to evaluate bivariate associations for dichotomous variables and t-tests were used for continuous variables. We used

Table 1 Attributes included in analysis of glycemic control

Age category	Patient age at the time of the abstracted visit
Gender	Patient gender
Diabetes mellitus medications	Medications used to control diabetes at the most recent visit stratified by oral, insulin, or both
Insurance type	Insurance as of the most recent visit including Medicare, Medicaid, commercial, self-pay, and other
Race/ethnicity	Race/ethnicity stratified by Caucasian, African American, Latino, and other
Category of missed visits	Number of scheduled visits the patient missed expressed as a percentage of the total visits over the study year, with patients missing $>20\%$ of visits classified as missing visits.
Hypertension	Presence of diagnosed hypertension treated with medication
Albuminuria or nephropathy	Presence of albuminuria or previously diagnosed nephropathy

logistic regression to evaluate the association between glucose control and independent variables and report adjusted odds ratios and 95% confidence intervals using Wald statistics. All analysis was completed using SAS version 9.1 (SAS Institute, Cary, NC).

Results

A total of 4751 diabetes cases were available for analysis. The population was predominantly female (55%) with a mean age of 56.9 years (Table 1). The majority of patients (86.2%) were receiving oral medications or a combination of oral and insulin, with only 13.6% receiving insulin alone (Table 2). Government insurance programs accounted for >53% of the payment source for these patients. Distribution of race showed that 54% of the population was Caucasian, 23% were African American, and the remaining patients were either Latino or other nonspecified ethnicities. The patients missed >20% of the scheduled visits. The mean haemoglobin A1c in the study group was 7.6%, with 44.8% of patients having their most recent reading as <7%. Table 3 shows the associations between risk factors and glycemic control. We found that age, medication types, insurance type other than commercial, race with the exception of "other," increased frequency of missed visits, and albuminuria/nephropathy all had statistically significant associations with glucose control when evaluated on a bivariate basis. Using a multivariable model, only age ≥60 years, oral medications without insulin, missing <20% of visits, lack of albuminuria or nephropathy, and Caucasian race were associated with a statistically significant increased likelihood of glycemic control. The discrimination of the model, with inclusion of all variables, was moderate, with a C-statistic of 0.663. A mixed effects model was used to evaluate the effect of individual programs on the outcome of interest. Associations between the covariates did not change, whereas the variables listed in the multivariable model remained statistically significant.

Table 2 Characteristics of study population

Characteristics of cohort (n = 4715)	
Age category (y)	**% (n)**
<40	10.8 (510)
40-49	19 (897)
50-59	27.6 (1301)
60-69	24.2 (1140)
>69	18.4 (867)
Gender	
Males	42.3 (1996)
Females	57.7 (2719)
Diabetes mellitus medications	
Oral	66.4 (3130)
Insulin and oral	19.8 (935)
Insulin	13.8 (650)
Insurance type	
Medicare	13.4 (1481)
Medicaid	22.4 (1054)
Commercial	29.2 (1377)
Self-pay	7.8 (368)
Other	9.3 (435)
Race/ethnicity	
Caucasian	54.1 (2549)
African American	23 (1085)
Latino	13.7 (648)
Other	9.2 (433)
Number of visits (annual)	
Mean	7.9
Median	6
Category of missed visits	
≤20% of total visits	79.9 (3766)
>20% of total visits	20.1 (949)
Mean HbA1c %	
Glucose control	
<7%	44.8 (2113)
7 to <8%	23.7 (1115)
>8%	31.5 (1487)
Hypertension	79.8 (3760)
Albuminuria or nephropathy	47.2 (2227)

Discussion

This evaluation furthers research into determinants of glycemic control of diabetic patients in the community setting by including measures of patient demographics, comorbid disease, and system factors such as insurance type and patient adherence. We were able to evaluate the independent effect of (1) comorbid illness and (2) severity of illness as intermediate outcome of glycemic control in type 1 and type 2 diabetics. In our analysis use of insulin, younger age, self-pay or other insurance type, non-Caucasian race, missing >20% of visits, and presence of albuminuria were all associated with significantly higher risk of poor glycemic control. Although the clinical significance of these findings is intriguing, they have significant implications on how physician performance is judged. These risk factors serve as a starting point for discussions regarding which factors may be appropriate for inclusion in risk adjustment models to determine physician attribution to the control of diabetics within their practice. Performance assessment using outcomes measures is rapidly expanding in health care both in quality improvement and pay for performance models.

Since the early 1900s, when Ernest Codman first suggested that outcomes should be measured in hospitalized patients, there have been discussions and research directed at the development of methods of removing the risk of the outcome the patient brings to the interaction.[16] These efforts have led to the development of risk adjustment systems that take into account patient factors such as demographics, the severity of underlying disease, and the presence of comorbid illness that may influence the ultimate outcome of pa-

Table 3 Bivariate and multivariate associations between hemoglobin A1c <7% and risk factors

Associations between glycemic control and risk factors (n = 4715)	Glycemic control in cohort with attribute (% <7%)	Bivariate comparison to patients without attribute: *p*-value for bivariate comparison	Multivariable comparison: Adjusted odds ratio
Age category, y (%)			
<40	38.6	0.008	
40-49	39.5	<0.001	0.979 (0.776,1.237)
50-59	39.9	<0.001	0.945 (0.755,1.182)
60-69	50.4	<0.001	1.414 (1.119,1.786)
>69	54.1	<0.001	1.564 (1.207,2.027)
Gender (%)			
Males	44.9	0.929	1.045 (0.925,1.181)
Diabetes mellitus medications (%)			
Oral	52.7	<0.001	
Insulin and oral	26.7	<0.001	0.343 (0.291,0.404)
Insulin	32.9	<0.001	0.464 (0.386,0.557)
Insurance type (%)			
Medicare	50.9	<0.001	
Medicaid	42.0	0.039	0.9 (0.750,1.081)
Commercial	45.0	0.852	0.892 (0.754,1.056)
Self-pay	37.0	0.002	0.653 (0.506,0.844)
Other	37.0	<0.001	0.689 (0.541,0.878)
Race/ethnicity (%)			
White	47.8	<0.001	
African American	41.0	0.004	0.812 (0.699,0.945)
Latino	39.5	0.003	0.718 (0.597,0.863)
Other	44.7	0.916	0.861 (0.695,1.067)
Category of missed visits (%)			
≤20% of total visits	46.2		
>20% of total visits	38.8	<0.001	0.829 (0.712,0.966)
Hypertension (%)	45.4	0.094	1.056 (0.903,1.235)
Albuminuria or nephropathy (%)	39.6	<0.001	0.695 (0.614,0.786)

tients presenting to the hospital. Although there may be arguments regarding the precision of these models, the fact that they are necessary to evaluate a hospital performance is unquestioned. The impact that risk adjustment can have on hospital rank, used as measures of improvement for absolute performance, was demonstrated in a study of hospital ranking in primary cesarean section rates in the Cleveland area.[17] The findings of this study demonstrated a dramatic change in ranking, with one hospital moving from an outlier status having a risk adjustment.

The science of risk adjustment of hospital care has advanced dramatically over the past several decades to the point where the federal government and others are publicly distributing risk-adjusted reports.[10] However, it is imperative to keep performance measurement in the context of improving care and not forcing physicians to "cherry pick" their patients to improve performance measurement. The development of risk adjustment of ambulatory measures has just begun. These measures should include standard methods of defining of risk adjustment systems including identification of dimensions of risk for the outcome, testing associations between dimensions of risk and the outcome of interest, development of multivariable predictive models using these dimensions, and then clinical and statistical validation of these models.

Several articles have demonstrated association among comorbid disease, patient compliance with visits, and ethnicity as determinants of glycemic control in diabetic patients.[11,12] Our findings replicate the effect these variables have had on glycemic control and allow evaluation of the effect they have independently on control. By evaluating both comorbid illness and patient factors, we demonstrate that after multivariable adjustment, both factors can remain predictive of glycemic control. When evaluating hospital outcomes risk adjustment models, it is important to select risk factors that make statistical and clinical sense.

The measurement of outcomes in the ambulatory environment requires a reassessment of what is considered a dimension of risk compared with what has traditionally been used in the inpatient environment. The exposure of a patient to a hospital within a clinical entity, such as in the case of myocardial infarction, is finite in time and usually unaffected by factors other than the patient's age, severity of illness, and burden of comorbid disease. Although not considered in inpatient risk adjustment methods, factors such as insurance status and patient motivation are important if we are using the physician as the unit of analysis and thus implying the physician's control of the outcome. The locus of control for some of these risk factors can be attributed to the patient, the physician, or the system. For example, the association between insulin use and poor glycemic control may be the result of prescription inadequacy by the physician, poor acceptance and adherence by the patient, or the inability to acquire the necessary instruments and medication because of a lack of monetary resources as a system issue.

Several previous studies have raised issues regarding methods of measuring physician contribution to glycemic control even after case-mix adjustment.[18,19] None of these studies used measures of patient adherence, although one suggested that only 4% of the variance found in profile measures after case-mix adjustment was attributable to the physician.[18] On the other hand, there is evidence that a well-designed systematic intervention to improve the care of diabetic patients does have an effect on glycemic control. A recent meta-regression analysis demonstrated the effect a variety of systematic changes in delivering care to people with diabetes has on their hemoglobin A1c, thus implying that there are opportunities to improve the care and outcomes of these patients.[20]

The need for risk adjustment when evaluating glycemic control in diabetics and attributing the level of control to a physician practice is apparent. The dialogue in terms of selection of dimensions of risk has yet to begin. As organizations measuring quality, along with payers, move forward with measure development, some checks and balances need to be put in place so that the art of measurement does not move ahead of science. The impact of poorly designed measures implemented in a pay-for-performance setting may not be under control of the physician. These practices are more likely those that provide care for underserved populations. In this study we demonstrate that: (1) Patient factors associated with financial issues have a significant impact on glycemic control, (2) having self-pay as an insurance status reduces the likelihood of maintaining glycemic control by 35%, and (3) missing >20% of visits reduced the same likelihood by 17% independent of all other risk factors within the model.

Strengths of this study include the voluntary nature of data entry. Residency requirements are for contribution of data only. They are not based on levels of performance. This lack of consequences should offer a safer environment for ascertaining true practice patterns. Weaknesses of this study include generalizability because the populations represented here are generally underserved and under the care of physicians in training. We chose a hemoglobin A1c of <7% as a marker of control; there has been recent evidence that intensive therapy with a goal of 6% was associated with increased mortality.[21] The target in this study is less important than the associations. Analysis of the associations when using 7.5% as a goal revealed identical findings as when using 7.0% as the outcome of interest in the current study. The intermediate outcome of glucose control in diabetes is affected by patient factors, such as adherence, and system factors, such as insurance and physician factors. It is important to adjust for these factors to determine physician attribution and to identify which factors present the largest opportunity gap to improve care.

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