Quality of Diabetes Care in U.S. Academic Medical Centers

Low rates of medical regimen change

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OBJECTIVE — To assess both standard and novel diabetes quality measures in a national sample of U.S. academic medical centers.

RESEARCH DESIGN AND METHODS — This retrospective cohort study was conducted from 10 January 2000 to 10 January 2002. It involved 30 U.S. academic medical centers, which contributed data from 44 clinics (27 primary care clinics and 17 diabetes/endocrinology clinics). For 1,765 eligible adult patients with type 1 or type 2 diabetes with at least two clinic visits in the 24 months before 10 January 2002, including one visit in the 6 months before 10 January 2002, we assessed measurement and control of HbA_{1c}, blood pressure, and cholesterol and corresponding medical regimen changes at the most recent clinic visit.

RESULTS — In this ethnically and economically diverse cohort, annual testing rates were very high (97.4% for HbA_{1c}, 96.6% for blood pressure, and 87.6% for total cholesterol). Fewer patients were at HbA_{1c} goal (34.0% <7.0%) or blood pressure goal (33.0% <130/80 mmHg) than lipid goals (65.1% total cholesterol <200 mg/dl, 46.1% with LDL cholesterol <100 mg/dl). Only 10.0% of the cohort met recommended goals for all three risk factors. At the most recent clinic visit, 40.4% of patients with HbA_{1c} concentrations above goal underwent adjustment of their corresponding regimens. Among untreated patients, few with elevated blood pressure (10.1% with blood pressure >130/80 mmHg) or elevated LDL cholesterol (5.6% with LDL >100 mg/dl) were started on corresponding therapy. Patients with type 2 diabetes were no less likely to be intensified than patients with type 1 diabetes.

CONCLUSIONS — High rates of risk factor testing do not necessarily translate to effective metabolic control. Low rates of medication adjustment among patients with levels above goal suggest a specific and novel target for quality improvement measurement.

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R esults from clinical trials over the past decade have led to national guidelines that advocate aggressive management of hyperglycemia, hyperten-

sion, and hyperlipidemia for patients with diabetes (1–7). Other research has established the evidence base for specific screening and prophylactic recommenda-

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*A list of UHC Diabetes Benchmarking Project Team members can be found in the APPENDIX. **Abbreviations:** CAD, coronary artery disease; DQIP, Diabetes Quality Improvement Project; NHANES, National Health and Nutrition Examination Survey.

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

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tions, including retinal and foot examinations and daily aspirin (8–10). Despite this scientific progress, patients with diabetes continue to suffer from high rates of cardiovascular and microvascular complications and can expect a lifespan reduction of 10–15 years (11,12). This inability to effectively and widely translate clinical evidence into usual practice represents a major barrier to reducing the burden of diabetes and its complications.

With the continued increase in the worldwide epidemic of diabetes (13), the quality of care for patients with diabetes has come under increasing scrutiny. In 2001, the Diabetes Quality Improvement Project (DQIP) was initiated to define a comprehensive set of national measures for population-level evaluation of the quality of diabetes care (14). DQIP measures included rates of annual testing (e.g., for HbA_{1c}), screening (e.g., for foot problems and retinal disease), and levels of diabetes-related risk factor control (such as HbA_{1c} and cholesterol). Subsequent studies using both national and local data have found significant shortcomings in most DQIP quality measures (15-17). Indeed, recently published data from the National Health and Nutrition Examination Survey (NHANES) have demonstrated little improvement in risk factor control from the 1988-1994 to 1999-2000 surveys, particularly with regard to HbA_{1c} and blood pressure (18).

Academic medical centers represent a key health delivery system in the U.S. whose mission includes training new health professionals and advancing clinical research while caring for a diverse population of patients. We report here the results of a clinical benchmarking project to assess both established and novel quality measures of ambulatory diabetes care among 30 U.S. academic medical centers. The goals of this analysis are to describe the current state of care provided by our nation's academic health centers and to assess medication changes in this setting among the subset of patients not meeting evidence-based goals of care.

RESEARCH DESIGN AND

METHODS — A total of 30 U.S. academic medical centers located in 20 different states from every region of the county contributed patients to this study. Within each participating institution, individual clinics with a minimum of 500 annual diabetes patient visits were eligible for inclusion. Clinics included both primary care practices (family practice, internal medicine, and general medicine) and specialty practices (diabetes/ endocrinology). Overall, 44 separate clinical practices were selected for further data collection and analysis.

Patients were eligible for inclusion if they were aged ≥ 18 years, had type 1 or type 2 diabetes according to their medical records, and had at least two visits to the study clinic in the 24 months before 10 January 2002, with the most recent visit occurring in the 6 months before 10 January 2002. For each clinic, patients were systematically identified in reverse chronologic order from the most recent visit date, and the first 40 patients with an even medical record number were selected for analysis. Each practice contributed unique patients with no overlap between practices within a single academic medical center.

For each patient, data for the prior year and for the most recent clinic visit were collected using standardized chart review forms. Data abstraction personnel each received 1 h of individual training in use of the form. A clinic visit was defined as a visit with a physical assessment by either a physician or nurse practitioner. The following variables were assessed: testing in the prior year and the last measured value for HbA1c and cholesterol before the most recent clinic visit (or during the visit for point-of-care testing); recorded blood pressure measurement during the most recent visit; documentation of foot examination, retinal examination, smoking cessation counseling, urine microalbumin screening, self-glucose monitoring, and antiplatelet therapy; and medical regimen changes during the most recent visit.

Medication changes at the most recent visit

We recorded medical regimens for patients at the time of the most recent clinic visit and assessed whether changes in therapy were made during this visit among the subset of patients with corresponding risk factor elevation. We used the most recent HbA_{1c} and cholesterol results available to the attending physician at the time of the visit and the blood pressure values obtained during the visit.

Detailed dose information and dose adjustments were collected for all glycemia-related medicines (sulfonylureas, metformin hydrochloride, thiazolidinediones, α -glucoside inhibitors, and insulin). However, because of the large number of possible antihypertensive and lipid-lowering agents, we did not collect detailed dose data for these medicines. Therefore, for hypertension and hyperlipidemia, we report the proportion of currently untreated patients above various risk factor thresholds who were initiated on corresponding therapy during the target clinical visit.

Statistical methods

Continuous variables were compared by Student's t tests if normally distributed or Wilcoxon's rank-sum test if nonnormal, and proportions were compared using χ^2 tests. In an exploratory analysis, we identified univariate predictors of change in therapy (for $HbA_{1c} > 7.0\%$) or initiation of therapy if untreated (for systolic blood pressure >130/80 mmHg or LDL cholesterol >100 mg/dl) using patient demographics (age, sex, insurance status, race, and English language skills), specialty versus general medicine practices, and clinical factors (type 1 versus type 2 diabetes, treatment modalities, comorbid diagnoses, and risk factor levels). Variables that were significantly associated with change or initiation in therapy in univariate analysis (P < 0.05) were then entered into logistic models to determine adjusted odds ratios for independent predictors of medication change (SAS statistical software, version 9.0; SAS Institute, Cary, NC). Separate models were constructed for each risk factor (HbA1c, blood pressure, and LDL cholesterol).

RESULTS — A total of 30 academic medical centers contributed 44 clinics and 1,765 patients to this analysis. Patients received care from diabetes/ endocrinology (33.6% of patient cohort), internal medicine (30.9%), and family practice (19.8%) clinics (Table 1). The remaining 15.7% of patients were cared for in other primary care or indigent care clinics. Overall, patients were middle aged and racially/ethnically diverse, and a

little more than half were women. Most patients had type 2 diabetes, and both coronary artery disease (CAD) and obesity were highly prevalent. Patients attending diabetes/endocrinology clinics were significantly younger, more often white, better insured, and less obese. Prevalence of type 1 diabetes and use of insulin was also greater in the diabetes/ endocrinology practices.

Measurement and control of diabetes-related risk factors

Diabetes risk factor management was of high quality in terms of risk factor testing rates, but quality was lower in terms of proportions of patients meeting goals for risk factor levels (Table 2). Overall, only 11.8% of patients were simultaneously below goal for HbA_{1c}, blood pressure, and total cholesterol. This proportion was 10.0% when the LDL cholesterol goal was used instead of the total cholesterol goal.

Table 2 also shows rates of other recommended screening and care practices. Approximately two-thirds of patients were self-monitoring glucose or had undergone urine albumin screening, but fewer than half had a documented retinal or foot examination in the prior year. Less than half of patients with diagnosed CAD had prescription of prophylactic aspirin or other antiplatelet agents documented in the medical record (477 of 1,430 patients, 33.4%).

Medical regimen changes among patients with risk factors above goal

At the time of the target clinical visit, 92.6% of patients were taking medication for hyperglycemia, 73.4% were taking medication for hypertension, and 42.4% were taking medication for hyperlipidemia.

Fewer than half of patients with elevated HbA1c levels had changes in hypoglycemic therapy during their clinic visit (Table 3). The farther the patient was from goal, the more likely that therapy was adjusted: The proportion of patients with glycemic regimen adjustment increased from 40.4% (HbA_{1c} >7%) to 45.6% (HbA $_{\rm lc}$ >8%) to 48.5% (HbA $_{\rm lc}$ >9.0%, *P* for trend = 0.002). Overall, the mean HbA_{1c} for above-goal patients whose regimens were adjusted was 9.4 \pm 1.9 vs. $8.6 \pm 1.7\%$ for patients without medication changes (P < 0.001). Of 47 patients above HbA_{1c} goal and not on therapy at the time of the target visit

n	27 clinics/1,175 patients	17 clinics/590 patients	
Age (years)	57.9 ± 12.7	54.0 ± 15.9	< 0.001
Women	719 (61.2)	322 (54.6)	0.008
Race			
Caucasian/white	350 (29.8)	302 (51.2)	< 0.001
African American	457 (38.9)	157 (26.6)	
Hispanic	236 (20.1)	40 (6.8)	
Other	132 (11.2)	91 (15.4)	
English fluency	875 (74.5)	433 (73.4)	0.6
Primary insurer			
Medicare	369 (31.4)	195 (33.1)	< 0.001
Managed care	258 (22.0)	114 (19.3)	
Private	106 (9.0)	140 (23.7)	
Self-pay	179 (15.2)	51 (8.6)	
Medicaid	126 (10.7)	61 (10.3)	
Other	137 (11.7)	24 (4.9)	
Type 2 diabetes	1,072 (91.5)	436 (73.9)	< 0.001
Glycemic therapy			
Diet/exercise only	114 (9.7)	16 (2.7)	< 0.001
Oral medications only	683 (56.1)	178 (30.2)	
Any insulin use	378 (32.2)	396 (67.1)	
CAD	967 (82.3)	463 (78.5)	0.06
Obesity	492 (41.9)	184 (31.2)	< 0.001
Data are means \pm SD or <i>n</i> (%). practices; specialty clinics inclu	General clinics include internal ide diabetes and endocrinology p	medicine, family practice, and p practices.	orimary care

Table 1—Characteristics of 1,765 patients cared for in 44 clinics from 30 U.S. academic medical centers

General medicine

(2.7% of cohort), therapy was initiated in 11 (23.4%) patients during the visit.

A total of 449 patients were not on antihypertensive therapy at the time of the most recent clinic visit. Of the 208 patients (46.3% of 449) with blood pressures >130/80 mmHg, only 21 patients (10.1%) were started on antihypertensive therapy (Table 3). Patients started on therapy had higher systolic (147.4 ± 14.8 vs. 140.0 ± 15.4 mmHg, P = 0.04) but similar diastolic (82.0 ± 10.3 vs. 79.0 ± 10.8 mmHg, P = 0.2) blood pressure levels compared with patients in whom treatment was not initiated.

Most patients with LDL >100 mg/dl were untreated (55.9%, 427 of 763 patients) and of these patients, only 24 (5.6%) were initiated on therapy during the clinic visit (Table 3). As with hyper-glycemia and hypertension, the likelihood that a patient was initiated on lipid-lowering therapy increased with increasing LDL level (*P* for trend = 0.005) but remained low in absolute terms. Above-goal patients who were started on therapy had a mean LDL level of 152.7 \pm 34.7 mg/dl, compared with 132.0 \pm 29.6

mg/dl for patients in whom therapy was not initiated (P = 0.001).

Diabetes/endocrinology

P value

We also analyzed therapy intensification according to type of diabetes. A total of 216 patients (12.2% of cohort) had type 1 diabetes. These patients were younger (42.8 vs. 58.5 years, *P* < 0.001), more likely to be white (63 vs. 33%, P <0.001), and less likely to be diagnosed with hypertension (35 vs. 73%, P <0.001). Overall levels of risk factor control were similar for type 1 versus type 2 diabetes (HbA $_{1c}$ 8.2 \pm 1.9 vs. 8.0 \pm 2.1%, respectively, P = 0.3; LDL 103.1 ± $38.4 \text{ vs. } 107.1 \pm 38.8 \text{ mg/dl}, P = 0.2)$ and among patients with hypertension (blood pressure $134.4/71.7 \pm 20.1/11.7$ vs. 138.4/76.1 ± 19.9/12.1 mmHg, P = 0.07/0.004). For the primary outcome of medication change among patients above goal, we found that patients with type 1 diabetes were somewhat more likely to have a regimen change if $HbA_{1c} > 7.0\%$ (51.1 vs. 38.9% among patients with type 2 diabetes, P = 0.01) but not for HbA_{1c} >8.0 or >9.0%. There were no statistically significant differences in medication

initiation at any level of elevated blood pressure or LDL (data not shown).

We constructed multivariate logistic regression models to identify independent predictors of change in therapy among patients above goal at the target visit. Factors associated with glycemic therapy intensification included attendance at a diabetes/endocrinology clinic (adjusted odds ratio [aOR] 2.5, 95% CI 2.0-3.2), current use of insulin (1.3, 1.01–1.7), decreasing age (1.09/decade, 1.01–1.2), and increasing HbA_{1c} level (1.3/unit, 1.2–1.3). For control of blood pressure and cholesterol, only higher risk factor levels at baseline significantly predicted initiation of corresponding therapy at the target visit: the aOR for antihypertensive medication initiation was 4.3 (95% CI 3.0-8.1) for every 10-mmHg increase in systolic and 2.9 (1.8-6.5) for every 10-mmHg increase in diastolic blood pressure, whereas the aOR for initiating lipid-lowering agents was 10.2 (6.1-30.5) for every 10-mg/l increase in LDL cholesterol. In this exploratory multivariate analysis, demographic factors such as age, race/ethnicity, type of diabetes, and overall cardiovascular risk (as represented by diagnosed CAD and by concurrent elevations of other risk factors such as blood pressure in the analysis of lipid therapy change and vice versa) were not significantly associated with corresponding changes in therapy at the target visit

CONCLUSIONS — A very high proportion of patients cared for in this sample of academic medical center ambulatory clinics received annual HbA_{1c}, blood pressure, and cholesterol measurement. However, the proportion of patients meeting corresponding goals of risk factor control was considerably lower. Moreover, rates of medication initiation and dose adjustment for patients with elevated risk factor levels seemed to be low. Because appropriate medication adjustment is a critical intermediate step between measurement and effective control, our findings suggest that future efforts to improve the quality of diabetes care should focus on rates of, and barriers to, medical regimen changes.

The proportion of academic medical center patients reaching recommended goals for all three diabetes-related risk factors, although low in absolute terms, was higher than the national average (11.8 vs.

Table 2—Diabetes-related risk	factor control and ot	per auality_of_care measures
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	General medicine	Diabetes/ endocrinology	P value
Risk factor control*			
HbA _{1c}			
Measured in prior year	1,136 (96.7)	583 (98.8)	0.01
Patients at goal	34.0%	34.0%	0.7
Mean value (%)	8.1 ± 2.1	7.9 ± 1.8	0.01
Blood pressure			
Measured in prior year	1,142 (97.2)	563 (95.4)	0.08
Patients at goal	30.4%	38.2%	0.01
Mean value (mmHg)			
Systolic	136.0 ± 19.9	132.1 ± 20.5	0.01
Diastolic	75.7 ± 11.7	73.3 ± 11.1	< 0.01
Total cholesterol			
Measured in prior year	1,029 (87.6)	513 (86.9)	0.9
Patients at goal	64.2%	66.9%	0.2
Mean value (mg/dl)	189.7 ± 47.5	187.1 ± 62.4	0.2
LDL cholesterol			
Measured in prior year	963 (82.0)	490 (83.0)	0.4
Patients at goal	45.8%	52.9%	< 0.01
Mean value (mg/dl)	108.9 ± 38.8	102.1 ± 38.0	< 0.01
Other quality measures			
Documented foot examination, prior year	415 (35.2)	375 (63.6)	< 0.01
Documented retinal examination, prior year	489 (41.6)	327 (55.4)	< 0.01
Urine albumin screening, prior year	464 (39.5)	384 (65.1)	< 0.01
Self-glucose monitoring	641 (54.6)	520 (88.1)	< 0.01
Smoking assessment, prior year	464 (39.5)	246 (41.7)	0.4
Antiplatelet therapy/patients with coronary artery disease	311/967 (32.1)	166/463 (35.9)	0.2

style counseling are fundamental to effective diabetes management, titration of medical therapy represents the major strategy by which levels of glucose, blood pressure, and lipids are lowered to improve patient outcomes. Lack of medication adjustment in patients not meeting therapeutic goals of therapy has been termed "clinical inertia" and has been associated with poor risk factor control (20-22).

The decision to initiate or increase medical therapy can be complex, is poorly understood, and requires collaboration between physicians and patients. Patients with complex chronic diseases such as diabetes can expect to see a physician for perhaps 20 min approximately every 3 months (23). Prior research has implicated time limitations and competing demands (24,25), medication costs and burden of comorbid illness (26,27), and clinic organization as potential barriers to evidence-based care (28,29). Current efforts to overcome barriers to therapy intensification have included "academic detailing" of physicians and use of treatment protocols by midlevel providers (30) and informatics-based decision support (31). In one innovative study, physicians received content-rich E-mail messages linked to the electronic medical record that allowed them to view timely

Data are means \pm SD, *n* (%), or percentages. *All risk factor control *P* values adjusted for age. Goals are as follows: HbA_{1c} <7.0%, blood pressure <130/80 mmHg, total cholesterol <200 mg/dl, and LDL cholesterol <100 mg/dl. Patients at goal = among patients with measured risk factors.

7.3%) estimated by the NHANES 1999–2000 (n = 441) (18). In addition, there was a high prevalence of diabetes education and other recommended practices, particularly in diabetes/endocrinology practices.

Despite these generally favorable levels of commonly applied quality measures, significant proportions of patients above their risk factor goal remained untreated, and there were low rates of medication initiation and dose adjustment during the target clinic visit in these above-goal patients. Our finding of infrequent hypertensive therapy adjustment is consistent with results from prior studies of patients with diabetes cared for in Veterans Association hospitals (19). These data add to the literature demonstrating that excellent performance on diabetes care process measures does not necessarily translate into adequate metabolic control (15,18), the key mechanism leading to reduced risk of diabetes complications.

Although patient education and life-

Table 3—Medical man	agement changes at	most recent visit
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	Patients with medication changes	Patients with medication initiation	P value
Changes in therapy among patients			
with elevated HbA _{1c}			
HbA _{1c} threshold			0.002
>7.0%	40.4% (440/1,088)		
>8.0%	45.6% (317/695)		
>9.0%	48.5% (199/410)		
Medication initiation among untreated			
patients with elevated blood pressure			
Blood pressure threshold			0.3
>130/80 mmHg		10.1% (21/208)	
>140/90 mmHg		15.1% (14/93)	
>150/100 mmHg		13.9% (5/36)	
Medication initiation among untreated			
patients with elevated LDL cholesterol			
LDL cholesterol threshold			0.005
>100 mg/dl		5.6% (24/427)	
>130 mg/dl		8.7% (16/185)	
>160 mg/dl		15.4% (10/65)	

Percentages of patients at each risk factor threshold are not mutually exclusive. *P* values are derived from the Mantel-Haenszel test for trend.

test result information and make corresponding prescription changes with "oneclick" order writing (32). More research is needed to better understand the clinical process of medication initiation and adjustment for diabetes control and to identify effective strategies for overcoming barriers to making these changes.

Several limitations of our study must be considered. Our analysis of the actions at a single visit does not account for the series of changes that may occur over consecutive visits or for the acute problems that can dominate a single visit to the exclusion of other problems. However, other studies suggest that inaction at one visit is likely to reflect inaction over a series of visits, at least for hypertension management (33). In addition, although we did identify low rates of initiation among untreated patients with elevated blood pressure and cholesterol levels, we did not collect sufficiently detailed medication adjustment data for the subset of patients already on therapy. Further research is needed to confirm the reasonable assumption that rates of medication change are also low in this patient subset. Finally, our patient sampling method may have preferentially selected patients more engaged in regular care. To the extent that this is true, our finding of low rates of medication initiation and adjustment in our study cohort is even more striking. Although more clinical detail is required to fully understand the management decision for an individual patient at a single clinic visit, our population-based assessment of medication change patterns per clinic visit represents an important and innovative approach to measuring quality of diabetes care.

Initial efforts to standardize and improve the quality of diabetes care focused on easily assessed parameters such as screening rates and measured risk factor levels (23). Despite high risk factor testing rates, a minority of visits in our analyses resulted in medication adjustment. This marked discrepancy between very high levels of risk factor testing and relatively low levels of actual risk factor control points to the need for novel measures of clinical quality in diabetes and other chronic disease care. A new paradigm for quality measurement focused on facilitating the process of initiating and advancing effective medical therapies in chronic, medication-intensive diseases like type 2 diabetes may be needed. Our findings

suggest that attention must now be turned to the next critical step in the management pathway leading to reduced risk factor levels: overcoming barriers to effective medical regimen changes.

APPENDIX — UHC Diabetes Benchmarking Project Team (Oak Brook, IL): Brenda Karas, RN, MS, MBA; Steve Wonder, MS; and Joanne Cuny, RN, BSN.

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