The burden of comorbid medical conditions and quality of diabetes care

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Abstract

Objective: With performance-based reimbursement pressures, it is concerning that most performance measurements treat each condition in isolation, ignoring the complexities of patients with multiple comorbidities. We examined the relationship between comorbidity and commonly assessed services for diabetic patients in a managed care organization.

Research Design and Methods: In 6,032 diabetic patients, we determined the association between the independent variable medical comorbidity, measured by the Charlson Comorbidity Index (CCI), and the dependent variables hemoglobin A1c (A1c) testing, lipid testing, dilated eye exam, and urinary microalbumin testing. We calculated predicted probabilities (PP) of receiving tests for patients with increasing comorbid illnesses, adjusting for patient demographics.

Results: A1c and lipid testing decreased slightly at higher CCI: PP (95% CI) for CCI quartiles 1, 2, 3, and 4 were 0.83 (0.70, 0.91), 0.83 (0.69, 0.92), 0.82 (0.68, 0.91), 0.78 (0.61, 0.88) for A1c and 0.82 (0.69, 0.91), 0.81(0.67, 0.90), 0.79 (0.64, 0.89), 0.77 (0.61, 0.88) for lipids. Dilated eye exam and urinary microalbumin testing did not differ across CCI quartiles: PP (95% CI) were 0.48 (0.33, 0.63), 0.54 (0.38, 0.69), 0.50 (0.34, 0.65), 0.50 (0.34, 0.65) for eye exam and 0.23 (0.12, 0.40), 0.24 (0.12, 0.42), 0.24 (0.12, 0.41), 23 (0.11, 0.40) for urinary microalbumin.

Conclusions: Services received did not differ based on comorbid illness burden. Because it is not clear whether equally aggressive care confers equal benefits to patients with varying comorbid illness burden, more evidence confirming such benefits may be warranted prior to wide spread implementation of Pay for Performance programs using currently available “one size fits all” performance measures.
Delivering high-quality medical care is a major focus in today’s healthcare market. To achieve the desired gains in quality, performance measures rooted in guideline-recommended care have been widely implemented and are being publicly reported (1). Accumulating reports suggest that these practices are having measurable effects, but progress may not be sufficiently rapid (2). This commitment to quality has spawned a new direction in accountability, with clear movement toward tightening the link between reimbursements and “high-quality” care (3).

The growing enthusiasm for “pay for performance” (P4P) may also usher in a new set of problems. Most performance measures focus on the quality of care provided for a single disease (4). Yet, as the U.S. population ages, the number of patients with a high burden of chronic medical conditions is increasing. In 1999, 48% of Medicare enrollees 65 years or older had at least three chronic medical conditions, and 21% had five or more (5). Patients having multiple conditions create considerable management complexity, forcing the clinician to consider and prioritize a large array of recommended interventions and preventive services. Market forces may encourage physicians to “play to the test,” (6) possibly replacing valuable time in the office visit that could be spent addressing issues which have a greater impact on quality of life. Ultimately, how we should adjust performance measurement to reflect this complexity presents a major challenge.

The forces of quality measurement, performance-based reimbursement, and multiple comorbidities dramatically converge for patients who have diabetes mellitus, which affects 20.8 million Americans (7). Many patients with diabetes are older and have several other medical problems, forcing the busy clinician to balance the relative benefits of multiple competing recommendations (7,8). Some of these recommendations, such as closely monitoring and controlling blood glucose or blood lipids, take years to deliver benefits in terms of risk reduction (9-11). For many older patients with multiple comorbid illnesses and limited life expectancy, the benefits of routinely recommended disease monitoring may not be as great as those for younger patients. The extent to which clinicians forego routinely recommended screening practices because of illness burden and life expectancy is not known.

We examined the relationship between illness burden and receipt of diabetes services in a population of older patients with diabetes enrolled in a Medicare managed care health plan, which spans three Southern states. We assessed illness burden with a commonly used index of comorbid illness burden that predicts mortality, the Charlson Comorbidity Index (CCI). We studied four commonly assessed services for diabetic patients: hemoglobin A1c (A1c) testing, lipid testing, dilated eye exam, and urinary microalbumin testing. We hypothesized that testing frequency would diminish as comorbid illness burden rose.

Methods
Study participants were enrolled in a Medicare managed care health insurance plan providing coverage in Alabama, Florida, and North Carolina. We included patients who were at least 65 years old, enrolled with the health plan continuously from January 1, 2003 through December 31, 2003, and alive on December 31,
2003. Eligible patients had: 1) at least one pharmacy claim for diabetes medication or 2) an International Classification of Diseases Coding Manual, 9th edition (ICD-9) code for diabetes from an in-person visit with a clinician in the outpatient or inpatient setting. We also merged data from the Center for Medicare and Medicaid Services (CMS) with the health plan’s claims and pharmacy data, allowing us to ascertain race/ethnicity. Only patients identified as African American or European American were included in our analysis. The Western Institutional Review Board approved this study. All analyses were conducted using SAS version 9.1 (SAS Institute Inc., Cary, NC)

Comorbid conditions were identified using ICD-9 codes from encounters in the health insurance claims data. We used Romano’s modification of the Charlson Comorbidity Index (CCI) (12). The CCI includes 17 specific illnesses and weights them according to severity (1, 2, 3, or 6). The CCI score for each patient is calculated by summing the weighted number of points for each diagnosis carried by the patient. The CCI (range 0-15) reflects mortality risk at 1 and 10 years, with low scores representing lowest risk (13).

For our main analyses, we used four separate commonly recommended performance measures for diabetes (14). We used data collected as part of the managed care organization’s reporting activities to the National Committee on Quality Assurance (NCQA) Health Plan Employer Data and Information Set (HEDIS). Based on claims data, we determined for the calendar year 2003 if patients had A1c testing in the past year, lipid testing in the past two years, dilated eye exam in the past year, and urinary microalbumin screening in the past year. Because screening for microalbumin is not clinically indicated once a patient has renal disease, we excluded the 780 participants with known renal disease from the urinary microalbumin analyses.

Initially, we examined performance for each of these measures at every level of the CCI: 0-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, and 11+. Because only eight patients had a CCI of 0, we constructed a single category for patients with 0 and 1 comorbidity. Likewise, because of small numbers, we combined all patients with comorbidity indices > = 11 into a single category. Because the data were not normally distributed, we also classified CCI by quartile, which represented a clinically reasonable approach. For multivariable modeling, the main independent variable was quartile of CCI.

Using the proc logistic command in SAS, we developed separate multivariable logistic regression models for each of the four dependent variables adjusting for age, sex, race/ethnicity, and diabetes medications. Diabetes medications were defined by presence or absence of pharmacy claims for either oral hypoglycemic medications or insulin. These covariates represented important confounders of the relationship between CCI and the outcomes. All patients were included in the models testing the association between CCI and A1c testing and lipid testing. As in the unadjusted analyses, for the microalbumin screening model we excluded the 780 individuals with known renal disease, for whom microalbuminuria screening is no longer indicated. All patients were included in the dilated eye exam model, because the presence or absence of diabetic
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Retinopathy does not change the recommendation for at least annual dilated eye exam. However, to account for differential treatment in patients with recognized diabetic retinopathy, we included a variable that reflected presence or absence of diabetic retinopathy in the dilated eye exam model.

Next, we calculated unadjusted and adjusted predicted probabilities for each model. More specifically, for each of the four models, we calculated the average probability of the outcome having a positive response within each comorbidity quartile (15). For the adjusted predicted probabilities, we entered the mean values of all remaining covariates from each comorbidity quartile. Based upon the individual variance estimates for each model parameter, we calculated an overall standard deviation for the predicted logit of the outcome. Finally, we transformed each predicted logit along with the upper and lower bounds for the 95% confidence intervals into probabilities.

To test for bias from the possible misidentification of patients with diabetes based on ICD-9 codes, we repeated all analyses on the subset of patients taking hypoglycemic medications (n = 2,472) (16).

Results

For the 6,032 patients included in the study, the average age was 74.5 years, 56.8% were female, and 39.8% were African American (Table 1). The subset of patients without renal failure, which made up the study population for the urinary microalbumin analyses (n=5,252), was similar demographically to the overall cohort (data not shown). The CCI ranged from 0-15 with a mean (standard deviation) of 3.2 (2.2). The mean age and the proportion of patients with diabetic complications increased as CCI increased. The figure shows the unadjusted percentage of patients who received each diabetes service by category of CCI. A1c and lipid testing were somewhat lower in patients with higher CCI. Rates of dilated eye exam and urinary microalbumin were similar across CCI.

In the multivariable analysis, results were similar after adjustment for age, sex, race/ethnicity, and receipt of diabetes medications. The models showed little difference in predicted probability of testing as comorbid disease burden increased (Table 2). Repeating all analyses for the 2,472 patients with pharmacy claims for oral diabetes medications or insulin provided results of similar direction and magnitude (data not shown).

Discussion

Contrary to our expectations, we found few differences in routine testing by comorbidity burden for this elderly population with diabetes enrolled in a Medicare managed care health plan. While rates of A1c and lipid testing were slightly lower in patients with higher comorbidity than those with the least comorbidity, rates of dilated eye exam and urinary microalbumin testing did not differ by comorbid burden. These results suggest that physicians are not adjusting the provision of routine diabetes services for patients with varying levels of comorbidity, although our study does not inform the appropriateness of this observation.
In acute settings, tight glycemic control has been shown to improve outcomes (17,18). But in chronic care management, tight glycemic or lipid control yield clinically meaningful benefits only after several years of intervention (9-11). Distinct from lipid and glucose control, detection of proliferative diabetic retinopathy and treatment with laser photocoagulation has been shown to significantly reduce severe visual loss over as short a time period as two years (19). Therefore, dilated eye exams should be performed in all patients with diabetes, yet only half of patients in this managed care organization, regardless of comorbid burden, received dilated eye exams.

Patients with multiple comorbid conditions have often been excluded from the evidence-generating randomized controlled trials that form the basis for performance measures (4,20-23). Randomized clinical trials, evidence-based guidelines, and quality measures are remarkably silent on the inevitable trade-off decisions that must be made during the routine clinical care of medically complex, older patients. In the absence of evidence regarding the benefit or harm of applying these guidelines to patients with multiple comorbid conditions, we are unable to definitively determine whether our finding of almost constant testing across comorbidity quartile represents appropriate or inappropriate care.

In the P4P era, physicians may feel pressure to adopt a "one size fits all" approach and order tests to improve their performance on quality indicators developed from trials that excluded patients with multiple comorbid conditions (24). In patients with limited life expectancy, the appropriate clinical course may be to decrease testing associated with delayed benefit and focus on interventions with high short-term potential for improving quality of life. Until evidence is available that confirms current performance measures are appropriate in patients with multiple comorbidities or advanced age, P4P programs and Managed Care Organizations may wish to limit accountability to only those populations for which strong evidence of benefit exists.

Currently, there is only limited evidence that the healthcare quality industry acknowledges life expectancy. For example, the Veterans Health Administration (VHA)/Department of Defense Clinical Practice Guideline for the Management of Diabetes include the recommendation to consider life expectancy in setting treatment targets. Similarly, the American Geriatric Society and the California Healthcare Foundation have endorsed guidelines that recognize the complexity of managing older patients with diabetes and multiple comorbid conditions (8). However, these acknowledgements have not been translated into measures designed to assess quality of care in these individuals. Indeed, the National Committee for Quality Assurance (NCQA) applies an upper age limit (75 years) for its HEDIS measures, effectively excluding older individuals from quality assessments (14). Rather than exclude such patients, validated measures that assess their quality of care and that incorporate life expectancy directly are needed.

With increasing implementation of performance-based reimbursement, the intersection of multiple comorbidity and
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quality measurement has become a high-profile topic. Two recent articles, one by Boyd and colleagues and the other by Tinetti and colleagues, used hypothetical patients to consider possible concerns with applying current guidelines to patients with multiple comorbid conditions. Both manuscripts concluded that guideline concordant care may result in great expense and marginal benefits, and the authors cautioned that enforcing quality measurement for older complex patients may result in unintended harm unless future quality measures consider chronic conditions, life-expectancy, and patient preferences (4,24).

Higashi, Min, and colleagues examined the association of comorbidity with quality of care in two papers based on three adult cohorts, the Community Quality Index study, the Assessing Care of Vulnerable Elders (ACOVE) study, and the Veterans Health Administration quality of care project. They examined from 236-439 quality indicators covering 22-30 clinical areas and found, “contrary to [their] expectations,” that as the number of comorbid conditions increased, adherence to quality measures increased (25,26). Both papers concluded that multiple comorbid conditions result in better quality of care.

In an editorial accompanying the Min et al paper, Ritchie argues that the study raises as many questions as it answers (27). Although the ACOVE study attempted to account for patient preferences by including desire for hospitalization or surgery, the study did not balance the added patient burden of guideline adherence with goals of reduced patient/caregiver burden and symptom control. In fact, current quality measures focus on reducing mortality and mainly ignore functional status and quality of life, which may be more important in older populations. Ritchie also notes that the patient and provider may place different values on symptom relief versus control of asymptomatic risk factors for disease progression. Consistent with our main thesis, Ritchie, and others, conclude that more research must be done to assist providers in making evidence-based decisions that reflect multiple competing clinical factors for patients with high co-morbidity (27-29).

This study has important limitations. First, it is well documented that ICD-9 codes in claims data have variable sensitivity and specificity for the actual presence of disease (16,30). To increase the sensitivity of our algorithm for identifying patients with diabetes, we required only one ICD-9 code from a face-to-face physician encounter. Hebert, et al, found that a single diagnosis of diabetes in Medicare claims data from a face-to-face physician encounter had a sensitivity of 57.9% and a specificity of 96.9% (30). The ICD-9 code used to determine testing for urine protein is specific to urinary microalbumin, thus we did not capture other methods of proteinuria screening such as 24-hour urine collection, which may have contributed to the low observed testing rate. Using this ICD-9 code allowed us to be specific for microalbumin and to not over estimate testing by including routine urinalysis. The analysis of patients only on diabetes medications confirmed our findings in the larger group. Likewise, claims data may not adequately document patient comorbidity. However, in an analysis of older men with diabetes, there was a 38% increase in 1-year mortality for each point increase in the CCI, suggesting that the CCI could serve as an important factor for tempering
guideline adherence (31). We note that many patients did not participate in this health plan’s pharmacy benefit; thus, we lacked complete medication data. Our study population included patients of a Medicare Managed Health Organization, so we lacked data on other elderly populations. We were unable to examine treatment rates or patient preferences. Finally, unlike recent studies on the topic of the association between multiple comorbid conditions and quality measurement, we focused on quality measures associated with only one disease, diabetes, rather than multiple disease-associated quality measures (4,24-26).

Conclusion
Providers in this Medicare managed care health plan had similar rates of adherence to diabetes performance measures across all quartiles of comorbid illness burden. It is not clear whether equally aggressive care confers equal benefits to patients with varying comorbid illness burden. Empiric research should evaluate the optimal screening intervals for A1c, lipid, and urinary microalbumin testing in patients with high comorbid illness burden and decreased life expectancy, as well as possible unintended consequences of such testing. Finally, patient outcomes in the P4P era should be carefully monitored to assure that health outcomes and quality of life in complex patients are not compromised by pressures to perform well on “required” tests.

Acknowledgments
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REFERENCES


31. Kahler K: Mortality and hypoglycemic drug use among patients with diabetes in the VA. New Brunswick, NJ, Rutgers
Table 1. Characteristics of Patients with Diabetes from a Managed Care Organization by Charlson Comorbidity Index (CCI)* Quartile, 2003.

<table>
<thead>
<tr>
<th></th>
<th>Less Comorbidity---------------------</th>
<th>More Comorbidity</th>
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<tbody>
<tr>
<td></td>
<td>Total 1st Quartile (CCI=0-1)</td>
<td>2nd Quartile (CCI=2)</td>
</tr>
<tr>
<td>N (%)</td>
<td>6032</td>
<td>1514 (25.1)</td>
</tr>
<tr>
<td>Mean age, years (sd)</td>
<td>74.5 (6.2)</td>
<td>73.3 (5.6)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>3428 (56.8)</td>
<td>912 (60.2)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American, n (%)</td>
<td>2403 (39.8)</td>
<td>584 (38.6)</td>
</tr>
<tr>
<td>European American, n (%)</td>
<td>3629 (60.1)</td>
<td>930 (61.4)</td>
</tr>
<tr>
<td>Diabetic complications†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retinopathy, n (%)</td>
<td>863 (14.3)</td>
<td>99 (6.5)</td>
</tr>
<tr>
<td>Neuropathy, n (%)</td>
<td>785 (13.0)</td>
<td>0</td>
</tr>
<tr>
<td>Nephropathy, n (%)</td>
<td>264 (4.4)</td>
<td>0</td>
</tr>
</tbody>
</table>

*Charlson Comorbidity Index (CCI) includes 17 specific illnesses, weights them according to severity (1, 2, 3, or 6), and sums the weighted conditions into a index that reflects risk for 1-year and 10-year mortality.

†Based on International Classification of Diseases, 9th Edition (ICD-9) physician claims.
Table 2. Adjusted predicted probabilities* with 95% Confidence Intervals for Diabetes Performance Measures by Charlson Comorbidity Index (CCI) Quartile for Patients in a Medicare Managed Care Plan, 2003†

<table>
<thead>
<tr>
<th>Less Comorbidity</th>
<th>1st Quartile (CCI=0-1)</th>
<th>2nd Quartile (CCI=2)</th>
<th>3rd Quartile (CCI=3-4)</th>
<th>4th Quartile (CCI&gt;=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>95% CI</td>
<td>95% CI</td>
<td>95% CI</td>
<td>95% CI</td>
</tr>
<tr>
<td>A1c Testing‡</td>
<td>0.83 (0.81, 0.85)</td>
<td>0.83 (0.81, 0.85)</td>
<td>0.82 (0.80, 0.84)</td>
<td>0.78 (0.75, 0.80)</td>
</tr>
<tr>
<td>Lipid Testing</td>
<td>0.82 (0.80, 0.84)</td>
<td>0.81 (0.79, 0.83)</td>
<td>0.79 (0.77, 0.82)</td>
<td>0.77 (0.74, 0.79)</td>
</tr>
<tr>
<td>Dilated Eye Exam§</td>
<td>0.48 (0.44, 0.51)</td>
<td>0.54 (0.50, 0.58)</td>
<td>0.50 (0.47, 0.54)</td>
<td>0.50 (0.46, 0.54)</td>
</tr>
<tr>
<td>Urinary Microalbumin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.23 (0.21, 0.26)</td>
<td>0.24 (0.22, 0.27)</td>
<td>0.24 (0.22, 0.27)</td>
<td>0.23 (0.20, 0.26)</td>
</tr>
</tbody>
</table>

* Models adjusted for age, sex, race/ethnicity, and receipt of diabetes medication (oral hypoglycemic medications or insulin)
† Separate logistic regression models were constructed for each test. For all models the main independent variable was CCI quartile, with quartile 1 as the reference. Predicted probabilities were calculated from the logistic regression parameter estimates.
‡ p<.05 for overall association of Charlson Comorbidity Index across all quartiles.
§ Model adjusted for above variables and the presence of diabetic retinopathy
|| Model excludes patients with renal disease (n=780).
Figure. Unadjusted percentage of Patients with Diabetes Receiving Testing by Charlson Comorbidity Index (CCI) Quartile, 2003

Q1-Q4: first quartile, lowest comorbidity, through fourth quartile, highest comorbidity, of Charlson Comorbidity Index
Urinary Microalbumin excludes patients with renal disease (n=780).