

## Use of a Disease Severity Index for Evaluation of Healthcare Costs and Management of Comorbidities of Patients With Diabetes Mellitus

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**Objectives:** To evaluate a stratification system for patients with diabetes mellitus according to severity of illness and care requirements and to correlate severity of illness with total medical and pharmaceutical costs of care.

**Study Design, Patients, and Methods:** A cohort of 697 patients with diabetes mellitus was followed in a diabetes clinic under a managed care plan. Patients were stratified according to severity of illness in 6 clinical areas: glycemic control, cardiovascular disease, peripheral vascular disease/peripheral neuropathy, eye disease, renal disease, and autonomic neuropathy. Stratification was based on clinical elements in patients' medical records related to diabetes mellitus care and its comorbidities. Total medical and pharmaceutical costs were identified for 508 patients who participated in the managed care program for at least 8 months.

**Results:** Patients in high- and very high-risk categories for cardiovascular disease, peripheral vascular disease/peripheral neuropathy, eye disease, and renal disease had markedly increased medical and pharmaceutical costs compared with those in low-risk categories. Pharmaceutical costs for patients in the glycemic control clinical area show a trend toward lower costs at higher risk. Pregnancy and depression were also associated with markedly increased healthcare costs. Patients who were in multiple high- and very high-risk categories had dramatically increased medical costs, as much as 10-fold those of patients who were in none of these categories.

**Conclusions:** A diabetes mellitus-specific risk stratification system related to required care intensity can be used to identify patients with high medical costs and can enable care providers to select patients for case management and triage into specific care programs

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reducing morbidity requires targeting appropriate services and training to "at-risk" patients to maximize use of limited resources. Participation of patients in their own diabetes mellitus management care plan is an essential contributing factor to the success of medical treatment, including decreased development and slowed progression of complications. Therefore, patient education in self-care, including efforts to ensure patient adherence to the medical regimen, is an important component of the medical care plan. Systematic identification of patients allows placement in appropriate medical and educational intervention pathways. Because of its complexity, diabetes mellitus has become an important target of efforts at disease management—systematic preventive interventions designed to reduce the risk of complications and to ameliorate the comorbidities of the disease.<sup>2</sup>

Objective evaluation of illness severity in patients with diabetes mellitus is used to assess health costs and treatment outcomes. Identifying the severity of illness of patients in different populations and practices is necessary to target treatment interventions, assess their effectiveness, and compare medical costs and hospital utilization.<sup>3</sup> Disease management efforts directed at the entire diabetes mellitus population become inefficient when they are attempted without the ability to provide educational programs and medical interventions to the high-risk patients who need them. We developed an index for stratify-

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Diabetes mellitus is a complex chronic illness that is associated with multiple complications involving diverse organ systems. Treatment of complications is a major part of the medical care of patients with diabetes mellitus, accounting for a large proportion of care costs.<sup>1</sup> Managing costs and

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ing patients with diabetes mellitus according to severity of illness and intensity of care required, and we tested it in a population of patients treated at the Joslin Diabetes Center, Boston, Mass, under a capitated contract in which endocrinologists served as both primary care providers and specialists for the care of diabetes mellitus. The stratification index assessed medical risk associated with a variety of organ systems related to diabetes mellitus or its comorbidities. This approach allows for triage of patients to specific clinical pathways and assessment of the effects that each comorbid condition has on the overall treatment plan and on medical care costs.

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METHODS

**Sample**

Of 820 patients followed under a capitated managed care program at the Joslin Diabetes Center, 754 (92%) had diabetes mellitus. Chart abstractions were performed for 697 of these patients. The 508 patients with diabetes mellitus who had been cared for under the plan for at least 8 months of the study and for whom data on total medical and pharmaceutical expenses were available formed the study population.

**Clinical Setting**

The primary care physicians caring for these patients were also endocrinologists or specialists in the care of diabetes mellitus. Patient care was overseen by a disease management team consisting of a medical director who was an endocrinologist, a nurse case manager who also was a certified diabetes educator, a nurse disease management program manager, and a research psychologist who was also a nurse. The disease management team reviewed the disease management and case management requirements of this specific patient population. The case manager followed the more severely ill patients and facilitated specific quality improvement programs to address the care needs of the patient population. The team developed a medical record abstraction tool that included the following key data elements: patient history, physical examination, and laboratory tests. Abstractors used this tool to review the medical charts of all patients with diabetes mellitus in the study.

**Disease Severity Index**

The severity of illness stratification system was developed a priori based on the consensus of a panel

of experts that included endocrinologists, nephrologists, a cardiologist, a podiatrist, a vascular surgeon, mental health providers, nurse educators, and nutritionists. Severity of illness was divided into 4 levels based on the intensity of care required: low, moderate, high, and very high. The individual levels were related to the intensity of medical care required for management of these problems rather than to estimates of future risk or absolute severity of illness. The principal categories evaluated using the stratification index included glycemic control, cardiovascular disease, eye disease, renal disease, peripheral vascular disease and foot-related problems, and autonomic neuropathy. The matrix for classification of patients into specific disease severity categories is given in **Table 1**. The stratification system also included risk categories not directly related to diabetes mellitus; health behaviors, mental health, health education, women's and men's health, osteoporosis, metastatic disease, and respiratory tract illness. Only data from diabetes mellitus-related categories are presented in this article. To evaluate the usefulness of the diabetes mellitus-related categories within the risk stratification system, we applied the system to data abstracted from patient medical charts.

**Costs**

Physicians were globally capitated for the medical care of patients, ie, the clinic was paid a fixed amount per patient per month. From this was deducted all inpatient and outpatient medical care expenses under the health plan, as well as the costs of all prescription medications and durable medical goods.

Total medical and pharmacy costs for these patients were obtained from administrative data from the insurer. The medical costs included inpatient and outpatient charges against the capitated pool, as well as patient expenses for copayments. The categories of inpatient costs included medical/surgical facility, obstetric facility, nonacute facility (including psychiatric, substance abuse, skilled nursing home, rehabilitation, and any other unclassified admission), and inpatient professional costs. The outpatient cost categories were primary care visits; subspecialist visits; laboratory; radiology; ambulatory surgery; diagnostics (eg, echocardiograms, cardiac stress tests, and pulmonary function tests); durable medical equipment; physical, occupational, and speech therapy; and all other outpatient expenses (including ambulance and transportation). Pharmaceutical costs were for all

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**Table 1.** Diabetes Mellitus Disease Severity Index

	Very High Risk	High Risk	Moderate Risk	Low Risk
Glycemic control	HbA <sub>1c</sub> ≥10% Hypoglycemia: severe/unconscious Frequent DKA (≥2/y)	HbA <sub>1c</sub> ≥9% Hypoglycemic >3 times per week DKA <2/y	HbA <sub>1c</sub> <9% and >7%	HbA <sub>1c</sub> ≤7%
Cardiovascular disease	CHF: new or a change in treatment CABG or PTCA: recent/≤6 mo New MI/other CVD event: recent/≤6 mo Angina: unstable	CHF: stable, no change in treatment >6 mo CABG: History of (>6 mo) MI: History of (>6 mo) Angina: stable CAD CVA	Use of HTN, lipid medications Any 1 of the following risk factors (current/Hx): current smoker; BMI >27/obesity; triglycerides >400 mg/dL; LDL >130 mg/dL; HTN/BP >130/85 mm Hg; microalbuminuria/pro- teinuria; PVD (levels 2, 3, and 4); LVH; autonomic neuropathy	No risk factors, signs and symptoms, or evidence of cardiac disease
PVD/peripheral neuropathy	Amputation: <1 y ago Ulcer/infection: recent/current Bypass: recent, <1 y Gangrene: current Charcot foot: active Acute ischemic foot	Amputation: >1 y ago Ulceration/infection: History of >1 y ago Bypass for PVD >1 y Gangrene: History of >1 y ago Charcot: chronic	Peripheral neuropathy PVD Sensation: diminished or absent Ischemic changes Intermittent claudication Abnormal NIVS	Intact sensation (pinprick ≥2) and pulses or vibratory sense
Eye disease	PDR: high risk Retinal detachment Vitreous hemorrhage CSME Glaucoma: neovascular Postoperative care New blindness/vision loss	PDR: early NPDR: severe/very severe Early macular edema Pregnancy Mononeuropathy	PDR: quiescent NPDR: moderate Cataract: visually significant Glaucoma: chronic	No retinopathy NPDR: mild Cataract: not visually significant
Renal disease	Dialysis Transplant (recent) Chronic renal failure	Transplant >1 y Nephrotic syndrome Overt nephropathy Proteinuria: A/C ratio >300 µg/mg Serum creatinine >2.0 mg/dL	Microalbuminuria A/C ratio 20-300 µg/mg	A/C ratio <20 µg/mg Protein = negative
Autonomic neuropathy	(category not used)	Gastroparesis Hypoglycemia unawareness Neurogenic bladder Autonomic neuropathy Orthostatic hypotension Sexual dysfunction	(category not used)	No autonomic neuropathy

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A/C ratio indicates ratio of albumin to creatinine concentration in the urine; BMI, body mass index; BP, blood pressure; CABG, coronary artery bypass graft; CAD, coronary artery disease; CHF, congestive heart failure; CSME, clinically significant macular edema; CVA, cerebrovascular accident; CVD, cardiovascular disease; DKA, diabetic ketoacidosis; HbA<sub>1c</sub>, glycosylated hemoglobin; HTN, hypertension; LDL, low-density lipoprotein cholesterol level; LVH, left ventricular hypertrophy; MI, myocardial infarction; NIVS, noninvasive vascular studies; NPDR, nonproliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy; PTCA, percutaneous transluminal coronary angioplasty; and PVD, peripheral vascular disease.

medications paid for by the insurer and patient copayments. These categories have been used widely in previous research<sup>4,5</sup> to estimate healthcare costs and resource utilization.

**Data Analysis**

Data are reported as mean ± SE except as noted. Analysis of variance with a Bonferroni correction was used to detect differences in continuous demographic variables (age and duration) within each of the 6 disease-related categories, and  $\chi^2$  was used for differences in the categorical variable (sex). Because of the nonnormal distributions of the cost data and the different numbers of patients in each stratification category, differences in costs for the stratification levels within each of the 6 disease-related categories were analyzed in relation to the median cost of the total group using the median test.<sup>6</sup> Pearson correlation coefficients (Spearman  $r_{sp}$  when distribution assumptions were violated) were estimated to detect associations between continuous variables. Data were entered into a database (Access; Microsoft Corp, Redmond, Wash) and analyzed using statistical software (SAS Version 6.12; SAS Institute Inc, Cary, NC). Glycosylated hemoglobin (HbA<sub>1c</sub>) concentration was measured using the high-performance liquid chromatography ion capture method (Tosoh Medics Inc, San Francisco, Calif). The nondiabetic reference range is 4.0% to 6.0%. Using the 6 risk severity categories as individual predictors, we

used logistic regression to estimate odds ratios for being in the group representing the top 10% of costs vs the group representing the lower 90% of costs.

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**RESULTS**

Of the 508 patients in the study population, 68% had type 1 diabetes mellitus and 32% had type 2 diabetes mellitus. The mean patient age was 41.8 ± 10 years, and 55% of patients were males. The characteristics of the sample are summarized in **Table 2**. As expected, patients with type 1 diabetes mellitus were younger than those with type 2 diabetes mellitus; they also had a longer duration of diabetes mellitus and were less obese. Among patients with type 1 diabetes mellitus, the numbers of male and female patients were roughly equal, whereas the type 2 diabetes mellitus group had a higher proportion of male patients. The average medical care costs of the 2 groups were similar. The mean HbA<sub>1c</sub> level of the patient population was similar for patients with both types of diabetes mellitus.

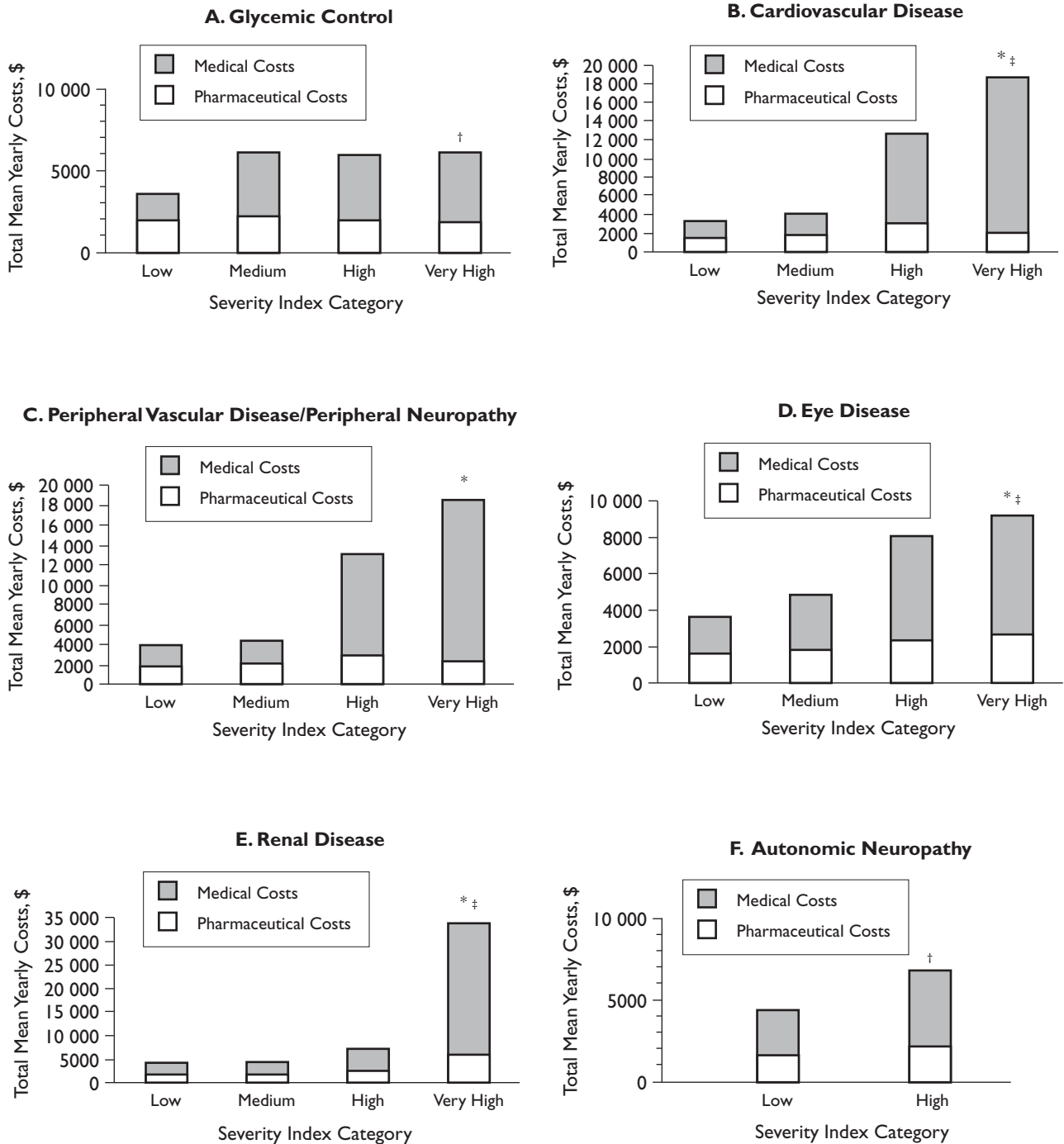
The mean medical and pharmacy costs are shown according to individual risk categories in the **Figure**. Medical care expenses increased progressively with severity of illness related to the major comorbidities of diabetes mellitus and were substantially higher for the smaller number of patients in the high- and very high-risk categories (Figure B-F). There was no sta-

**Table 2.** Characteristics of the Diabetic Patient Study Population

	Type 1 Diabetes Mellitus (n = 347)	Type 2 Diabetes Mellitus (n = 161)	Total (n = 508)
Age, mean ± SE, y	41.8 ± 0.6	52.5 ± 0.8	45.2 ± 0.5
Duration of diabetes mellitus, mean ± SE, y	22.8 ± 0.6	11.3 ± 0.6	19.2 ± 0.5
Females, %	47.8	37.3	45.5
Body mass index, mean ± SE, kg/m <sup>2</sup>	26.8 ± 0.3	33.4 ± 0.6	29.2 ± 0.4
Blood pressure, mean ± SE, mm Hg	124/73	131/76	127/74
Glycosylated hemoglobin, mean ± SE, %	8.35 ± 0.08	8.23 ± 0.13	8.28 ± 0.07
Insulin-treated patients, No. (%)	344 (99)	90 (56)	434 (84)
Patients taking oral hypoglycemic agents, No. (%)	3 (1)	98 (61)	101 (20)
Patients receiving intensive insulin therapy, No. (%)	62 (18)	2 (1)	64 (13)
Total yearly cost, mean ± SE, \$	5486 ± 471	5267 ± 717	5416 ± 393
Medical care cost, mean ± SE, \$	3664 ± 442	3286 ± 688	3544 ± 372
Pharmacy cost, mean ± SE, \$	1880 ± 95	1987 ± 121	1905 ± 75

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**Figure.** Mean Yearly Medical and Pharmaceutical Costs for Patients With Diabetes Mellitus in 6 Risk Stratification Categories



\* $P < .001$  associated with median test for medical costs (median for total sample, \$891).

† $P < .05$  for pharmaceutical cost trends.

\* $P < .001$  associated with median test for pharmaceutical costs (median for total sample, \$1506).

**Table 3.** Impact of Number of High- or Very High-Risk Categories on Cost

	No. of High- or Very High-Risk Categories per Patient*					
	0 (n = 169)	1 (n = 166)	2 (n = 109)	3 (n = 46)	4 (n = 14)	5 (n = 4)
Total cost, mean (median), \$	3243 (2255)	3887 (2273)	5946 (3600)	11 871 (5908)	19 312 (10 900)	23 379 (15 630)
Medical cost, mean (median), \$	1649 (604)	2275 (678)	3871 (1773)	9355 (3578)	16 344 (7744)	16 906 (8137)
Pharmaceutical cost, mean (median), \$	1649 (1393)	1665 (1333)	2108 (1614)	2517 (2015)	2967 (2716)	6474 (5849)
Glycosylated hemoglobin, mean (median), %	7.22 (7.3)	8.73 (8.6)	8.68 (8.6)	9.25 (9.0)	8.79 (8.8)	9.25 (9.5)

\*Does not include the autonomic neuropathy category.

tistically significant difference detected between the total costs or medical care costs for patients in the different glycemic control stratification levels; however, pharmaceutical costs were slightly lower for patients at higher risk related to glycemic control (Figure A.)

Patients at low risk on average were 4 to 12 years younger and had a diabetes mellitus duration for 4 to 15 years less than those at highest levels ( $F = 2.59$ - $25.95$ ;  $P = .05$  to  $<.0001$ ). Men had higher peripheral vascular disease and autonomic neuropathy severity stratification levels than women ( $\chi^2 = 13$ ;  $P < .005$ ; Fisher exact test,  $P < .001$ ). No consistent relationship existed between level of glycemic control ( $HbA_{1c}$ ) and risk stratification level in any of the 5 risk categories related to the comorbidities associated with diabetes mellitus.

If a patient was at high or very high risk in one category it did not necessarily mean that the patient was at high risk in other categories as well. Patients who were at very high risk in multiple categories had progressively higher costs ( $r_{sp} = 0.34$ ;  $P < .0001$ ). Patients at very high risk in multiple categories also tended to have worse glycemic control, as measured by mean  $HbA_{1c}$  level ( $r_{sp} = 0.47$ ;  $P < .0001$ ). The same trend toward higher costs and worse glycemic control was found in patients who were classified as being high risk or very high risk in multiple categories (Table 3). Similarly patients identified as having few or no high- or very-high-risk levels in multiple categories had low pharmaceutical and medical costs. The autonomic neuropathy category was eliminated from this portion of the analysis because, unlike the other categories, the lack of detailed data related to this category in the medical records allowed only 2 rather than 4 levels of sever-

ity to be identified (Table 1).

Sixteen study patients were pregnant during the study. Pregnancy was a high-cost factor, with mean total yearly costs for these patients of  $\$12\,016 \pm \$1694$ , of which medical care expenses averaged  $\$10\,364 \pm \$1842$  and pharmaceutical expenses were  $\$2707 \pm \$792$ . The costs measured in the 1-year study varied according to the timing of the pregnancy. Only 8 pregnant women were delivered of infants during the 12-month study. Thus, the costs reported here do not represent the full costs of pregnancy. For the 8 pregnant patients delivered of babies during the study, mean medical expenses were  $\$16\,263 \pm \$1184$ , and pharmacy costs were  $\$1930 \pm \$332$ . The 8 pregnant patients who were not delivered of infants during the data collection period incurred much lower mean expenses (medical:  $\$4465 \pm \$1792$ ; pharmacy:  $\$3485 \pm \$1552$ ). Expenses were not associated with risk categories in these patients. The medical and pharmaceutical cost data presented for the entire patient population include the pregnant patients.

The presence of depression, as identified by diagnosis in the medical record, was another factor found to be associated with markedly increased expenses (Table 4). Patients with depression were more likely to be female (Fisher exact test,  $P < .001$ ), but depression was not associated with age, duration of diabetes mellitus,  $HbA_{1c}$  level, insulin, or form of diabetes mellitus therapy. The incidence of depression was associated with an increased cardiac risk level ( $\chi^2 = 9.9$ ;  $P < .02$ ) but not with disease severity in any other stratification category.

Univariate analysis of medical care costs for the total patient population indicated that a relatively small percentage of patients accounted for a major

**Table 4.** Characteristics of Patients With Depression

	Depression (n = 92)	No Depression (n = 416)
Age, mean $\pm$ SE, y	46.0 $\pm$ 1.1	45.0 $\pm$ 0.6
Diabetes mellitus duration, mean $\pm$ SE, y	21.1 $\pm$ 1.2	18.7 $\pm$ 0.6
Glycosylated hemoglobin, mean $\pm$ SE, %	8.4 $\pm$ 0.2	8.3 $\pm$ 0.1
Female, No. (%)	62 (67)	167 (40)
Total cost, mean $\pm$ SE, \$	8061 $\pm$ 1327	4832 $\pm$ 375
Medical cost, mean $\pm$ SE, \$	5613 $\pm$ 1312	3086 $\pm$ 347
Pharmaceutical cost, mean $\pm$ SE, \$	2459 $\pm$ 165	1784 $\pm$ 83

proportion of the medical care costs in this capitated patient population. The 10% of patients with the highest yearly medical costs represented 60% of the total costs of this capitated group, and the 5% of patients with the highest costs represented 44% of the medical costs. The 10% high-cost patients were more likely to have higher risk scores in categories related to comorbidities of diabetes mellitus other than autonomic neuropathy compared with the total population. (See **Table 5** for odds ratios; pregnant women were excluded from this analysis.) For example, for each step increase in cardiovascular risk level, patients are 3.4 times more likely to be among the top 10% in costs. The logistic regression model accurately predicted the cost category 82% of the time (highest 10% versus lowest 90%).

## DISCUSSION

Effective utilization of risk stratification to manage patients is possible. Diabetes mellitus, with its comorbidities, places an enormous economic burden on the US economy; results of various studies<sup>1,7,8</sup> have shown per-patient costs to be as much as 2 to 3.5 times those of the normal population, representing nearly 15% of national healthcare expenditures. However, a wide range of levels of severity of illness exists in the population of patients with diabetes mellitus. Patients with high and very high severity of illness related to the major comorbidities of diabetes mellitus, such as cardiovascular disease, peripheral neuropathy and vascular disease, and eye and renal disease, are associated with markedly excess costs. Similar to the findings in our patient population, evaluation of a large population with diabetes melli-

tus in the Kaiser Permanente system indicated that 20% of the patients accounted for 79% of the excess costs of care in 1995.<sup>9</sup> The outpatient diagnoses and laboratory results that were important predictors of future microvascular or metabolic complication events in that study were present as clinical data elements in our risk stratification system. These predictors include HbA<sub>1c</sub> level greater than 10%, key outpatient microvascular and macrovascular diagnoses, congestive heart failure, chronic renal insufficiency, and recent inpatient and emergency department visits for metabolic events.

Any attempt to evaluate quality and cost effectiveness of care in a population of patients with diabetes mellitus needs to take into account the severity of illness and adjust for associated risk.<sup>3</sup> It is important to note that this study reflects the patient care costs incurred under one insurer, thus limiting its ability to be generalized to others. However, the per-patient healthcare costs of the population studied herein were similar to those in HMO populations cited by Rubin et al<sup>10</sup> and lower than those cited in other primary care, managed care settings<sup>11,12</sup> despite the fact that the populations had extremely high proportions of individuals (1) with type 1 diabetes mellitus, (2) treated with insulin, and (3) with multiple complications.

Other studies have attempted case-mix adjustment of patients with diabetes mellitus using diagnostic codes from hospital discharge administrative data, and some of the codes have been correlated with hospital length of stay.<sup>13</sup> However, these diagnostic categories have not been helpful in analysis of outpatient resource utilization and identification of candidates for case management. They also do not address the majority of patients not recently hospitalized. The risk stratification system described in this article assigns levels of severity based on outpatient medical records and laboratory data exclusively. Data collected at the point of regular interaction with the patient can be especially helpful because they reflect the actions of the provider, such as examination of the foot, and the behaviors of the patient, such as smoking and efforts to stop. This information is not usually accessible in administrative data. The commonly accepted performance measures for the management of adult

diabetes mellitus rely to a large extent on outpatient medical record data.<sup>14-16</sup>

Models of cost of care in the treatment of diabetes mellitus suggest that improved glycemic control can lead to a decrease in the economic burden of diabetes mellitus<sup>17</sup> by ameliorating or preventing long-term complications of the disease, which are expensive to treat.<sup>18-21</sup> The association between improved glucose control and reduced cost has been confirmed in studies in the managed care setting.<sup>22,23</sup> As shown in Figure A, for patients in poor glycemic control risk stratification levels, pharmaceutical costs were slightly lower. We do not have a breakdown of the specific pharmaceuticals used, and we cannot address whether poorly controlled patients underused pharmaceuticals to control glucose levels. Unlike the study by Gilmer et al,<sup>17</sup> this study was not longitudinal. The studies cited earlier suggest that cost savings related to prevention of complications may manifest themselves several years after initiation of better glycemic control, perhaps within 1 to 2 years of intervention.<sup>8</sup>

The effect of improved glycemic control on reducing costs may reflect reduced burden of symptoms and improved functionality as much as reduction in long-term complications.<sup>24</sup> Expenses directly related to the long-term complications of diabetes mellitus represent at least 26% of total healthcare expenditures for the disease, and they contribute to the higher expenditures for treatment of general medical conditions for patients with diabetes mellitus, representing approximately 56% of the total. For example, a patient with long-standing diabetes mellitus admitted to the hospital for acute cholecystitis may have increased complications of surgery and increased length of stay than a patient without diabetes mellitus.

Other studies have shown that risk stratification of patients with diabetes mellitus in a managed care environment can aid in the targeting of interventions to improve outcomes, but these studies did not investigate costs.<sup>25</sup> Risk stratification systems have been particularly useful for management of patients with cardiovascular risk factors and established cardiac disease.<sup>26,27</sup> In the diabetic population studied herein, patients at very high risk for cardiovascular disease also had very high costs.

Although the diabetes mellitus severity index described here was devised primarily as a tool to aid in the clinical management of patients by identify-

**Table 5.** Odds of High-Cost Patients Being in Higher-Risk Categories

Risk Category	Odds Ratio (95% Confidence Interval)	P
Glycemic control	1.4 (1.1-2.0)	.02
Cardiovascular disease	3.4 (1.7-6.7)	.0004
PVD/peripheral neuropathy	2.5 (1.5-4.2)	.0004
Eye disease	1.4 (1.0-1.9)	.03
Renal disease	1.6 (1.1-2.4)	.01
Autonomic neuropathy	0.9 (0.6-1.4)	.8

PVD = peripheral vascular disease.

ing individuals for specific care pathways and quality improvement interventions, it has also proven useful as a predictor of medical expenses and has enabled us to identify high-risk patients for more intensive case management to reduce costs. For example, high- and very high-risk patients in the categories described here are all selected for follow-up by the case manager, who performs an educational needs assessment. The case manager identifies patients who require more intensive educational programs or referral for specialized dietary intervention, foot care, or cardiovascular prevention or rehabilitation programs. It is clear, as shown in Table 3, that patients identified as being at high or very high risk in multiple categories have substantially increased medical and pharmaceutical costs. Because care of these patients, especially their inpatient hospitalization costs, represents a significant portion of the overall costs of the program, targeted interventions that reduce the need for future hospitalizations can have a major impact on medical care costs.

Two other clinical elements, pregnancy and depression, were outside of the framework of the stratification system and yet were relevant to diabetes mellitus. These diagnoses were also correlated with very high medical expenses. The first, pregnancy, is associated with multiple complications in diabetes mellitus and increased risks to the fetus and mother.<sup>28</sup> However, in the population with diabetes mellitus in this study, the inclusion of pregnant patients in the total had a minimal effect on the mean medical expenses for the total patient population in any of the risk categories. The presence of depression was another high-cost indicator, as documented previously in a study<sup>29</sup> of patients with diabetes mellitus with respect to primary, ambulatory, and total healthcare costs. This fact is not surprising



given the close association of depression with worse glycemic control, problems with diet and medication adherence, and comorbidities in patients with diabetes mellitus.

In this selected population of patients with diabetes mellitus, followed as primary care patients in a diabetes center, we showed that key clinical indicators can be identified from outpatient medical records that correlate with markedly increased medical care costs. In addition to the major macrovascular and microvascular complications commonly associated with diabetes mellitus, other indicators of high cost were depression and pregnancy. Use of a clinical database such as this can help care providers and case managers develop targeted interventions and new approaches to care for high-risk, high-cost patients within the population of patients with diabetes mellitus. The population studied in this research had a much higher proportion of individuals who were treated with insulin or who had type 1 diabetes mellitus than the general population. Studies are under way to assess the applicability of this stratification system to the larger population of patients with diabetes mellitus, which might be expected to have a much smaller proportion of insulin-treated individuals and a lower incidence of complications.

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