COMPARATIVE RESEARCH

Use of Glycosylated Hemoglobin Testing Among Patients with Diabetes Mellitus

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OBJECTIVE:
To estimate the likelihood of the use of glycosylated hemoglobin testing (HbA1c) among a cohort of patients with diabetes mellitus in a managed care setting.

DESIGN:
A retrospective, cross-sectional analysis of managed care claims data obtained from the private business claims (PBC) files of the Hawaii Medical Service Association for the calendar year 1995. A probit model was used to estimate the probability of the dependent variable (HbA1c). Independent variables specified in the model included age, gender, presence of common comorbidities, use of insulin and oral anti-diabetic agents, and type of insurance plan. The probit model was run for an n of 6,841 patients.

SETTING:
Health insurer in the state of Hawaii. Includes managed care and indemnity products.

PATIENTS:
6,841 patients under 65 years old were identified by paid claims with ICD-9-CM codes of 250.xx.

PARTICIPANTS:
Not applicable.

INTERVENTION:
Not applicable.

MAIN OUTCOME MEASURES:
Use of HbA1c testing.

RESULTS:
Age and gender are not statistically significant as predictors of HbA1c testing. Patients with multiple comorbid conditions, hyperlipidemia, and multiple cardiovascular comorbidities have a higher probability of receiving HbA1c testing relative to the diabetic population with no comorbidities. Patients receiving services under an HMO plan and patients on polypharmacy (oral agents plus insulin) are more likely to receive an HbA1c test. The model demonstrated an explanatory power of 64.05%.

CONCLUSION:
Patients with greater clinical involvement were found to be more likely to receive HbA1c testing over patients with less disease involvement. Patients enrolled in an HMO plan are more likely to receive HbA1c testing relative to patients enrolled in fee-for-service (FFS) plans. Finally, the probit model demonstrated a high level of explanatory power. This is an important criterion if we are to place some level of confidence in claims data for: a) obtaining baseline information; b) planning purposes; and c) periodic evaluation of diabetes care interventions.

KEYWORDS:
Diabetes mellitus, Managed care, Glucose monitoring, Predictive modeling

J Managed Care Pharm 1997; 3:691-696

Current estimates suggest that diabetes affects around 16 million people in the United States. Diabetes imposes a significant economic and social burden on patients and health care providers, not only in terms of managing the disease but also in treating its associated complications and comorbidities. Increasingly, efforts to manage and monitor chronic diseases such as diabetes mellitus involve a partnership among the patient, the provider community, and the patients' extended family and community.

The issue addressed here is whether glycosylated hemoglobin testing (HbA1c), as coded in a managed care organization's claims data files, provides useful information on glucose monitoring. Glucose monitoring is of particular interest since evidence from the Diabetes Control and
Complications Trial (DCCT) suggests that tight glucose control among patients with insulin dependent diabetes mellitus (IDDM) results in fewer complications. Current standards of medical care for patients with diabetes mellitus include regular HbAlc testing, regardless of diabetic disease type. The use of HbAlc as part of a routine management and maintenance program for the diabetic patient provides the patient and provider with a relatively accurate long-term index of the patient's glycohemoglobin and therapeutic efficacy.

The purpose of this study is to estimate the likelihood of the use of HbAlc among a cohort of patients with diabetes mellitus. Here, the presence of HbAlc testing is viewed as a process measure for disease monitoring. This study also evaluates the explanatory power, sensitivity, and specificity of a probit model making use of claims data to estimate the use of HbAlc testing in a managed care organization.

BACKGROUND

Figures indicate that in 1992 the direct health care costs associated with diabetes in the United States were in excess of $45 billion dollars and that indirect costs (those associated with productivity loss borne by patients and families and premature mortality) comprise an additional $47 billion. Of the estimated 16 million people in the United States with diabetes, approximately 12 million (90% to 95%) have non-insulin-dependent diabetes mellitus (NIDDM).

As noted, results of the DCCT revealed that tight glucose control in IDDM patients results in fewer complications. The results of that trial may or may not be generalized to NIDDM patients. An ongoing trial, the United Kingdom Prospective Diabetes Study (UKPDS), is following 5,102 NIDDM patients over 11 years. Reports based on nine years of data indicate that tight glucose control with either insulin, sulfonylurea, or metformin yield improved fasting plasma glucose levels and HbAlc levels compared to diet alone. However, there is evidence of deterioration of glucose control in all arms of the trial. This is due most likely to progressive beta-cell function deterioration. The question remains, however, about whether early and aggressive pharmacotherapy in patients with NIDDM can delay the onset of complications.

Based principally on the DCCT results, the American Diabetes Association (ADA) recommends that most individuals with diabetes should strive to achieve and maintain blood glucose levels as close to normal as possible. Unfortunately, there is no well-controlled study that suggests an appropriate testing protocol for HbAlc. Therefore, the ADA bases its recommendation on expert opinion and suggests testing at least one or two times per year in stable patients and quarterly in poorly-controlled patients.

In exploring the predicted use of HbAlc testing among patients with diabetes in a managed care setting, it is important to first establish baseline information on current practice. One step in this process includes the analysis of readily available data, specifically claims data from the managed care organization.

Even though these data lack detailed clinical information, there is useful information on the extent to which patients with diabetes receive basic services for their condition. Basic resource utilization patterns may be captured for many services and procedures as well as outpatient pharmaceuticals.

The ADA consensus statement on the treatment of patients with diabetes provides a framework for recommended treatment and includes the use of relevant services and procedures commonly found in claims data. These include, for example, laboratory screening and monitoring such as HbAlc testing, pharmacotherapy, provider visits, health education, and eye examinations. Table 1 summarizes the treatment alternatives identified in the consensus statement for patients with NIDDM.

The mere presence of HbAlc testing may be an important process measure for successful diabetic management, irrespective of practice guidelines or patient management philosophy. While there are other useful measures such as fasting plasma glucose (FPG), it was decided that HbAlc was readily identifiable in the data and would serve as a practical case in point. Furthermore, the accrediting organization for managed care organizations, the National Committee for Quality Assurance (NCQA), promotes the use of Health Plan Employer Data Information Set (HEDIS) performance measures. HEDIS includes two diabetic-related measures. One measure focuses on eye exams for people with diabetes. The second measure, under testing, focuses on the percentage of diabetic patients receiving at least two glycohemoglobin levels during the year.

Table 1. Principal Treatment Alternatives

<table>
<thead>
<tr>
<th>Principal Treatment Options</th>
<th>Other Procedures / Preventive Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nonpharmacological therapy</strong></td>
<td>Screening programs: blood sugar, urine, and glucose tolerance testing</td>
</tr>
<tr>
<td>• Diet</td>
<td></td>
</tr>
<tr>
<td>• Exercise</td>
<td></td>
</tr>
<tr>
<td>• Education</td>
<td></td>
</tr>
<tr>
<td><strong>Monotherapy</strong></td>
<td>Tight glucose monitoring and control</td>
</tr>
<tr>
<td>• Sulfonylurea</td>
<td>Glycosylated hemoglobin measures (HbAlc)</td>
</tr>
<tr>
<td>• Biguanide</td>
<td></td>
</tr>
<tr>
<td>• Alpha-glucosidase inhibitors</td>
<td></td>
</tr>
<tr>
<td>• Insulin</td>
<td></td>
</tr>
<tr>
<td><strong>Combination therapy</strong></td>
<td>Insulin pump (IDDM)</td>
</tr>
<tr>
<td>• Sulfonylurea + biguanide</td>
<td>Other preventive procedures such as regular eye exams, foot care, dental screening</td>
</tr>
<tr>
<td>• Sulfonylurea + insulin</td>
<td></td>
</tr>
<tr>
<td>• Sulfonylurea + alpha-glucosidase inhibitor</td>
<td></td>
</tr>
<tr>
<td>• Other combinations of these (less frequent and less studied)</td>
<td></td>
</tr>
</tbody>
</table>
Table 2. Demographic/Clinical Summary of the Study Cohort: HMSA, CY 1995

<table>
<thead>
<tr>
<th>Disease Type</th>
<th>% of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antidiabetic Pharmacotherapy</td>
<td></td>
</tr>
<tr>
<td>Receiving oral agents only</td>
<td>39.18</td>
</tr>
<tr>
<td>Receiving insulin only</td>
<td>11.30</td>
</tr>
<tr>
<td>Receiving oral + insulin agents</td>
<td>5.80</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comorbidities</th>
<th>% of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>With hypertension</td>
<td>16.20</td>
</tr>
<tr>
<td>With hyperlipidemia</td>
<td>14.30</td>
</tr>
<tr>
<td>With cardiovascular disease</td>
<td>1.29</td>
</tr>
<tr>
<td>With congestive heart failure</td>
<td>0.16</td>
</tr>
<tr>
<td>With multiple cardiovascular comorbidity</td>
<td>36.19</td>
</tr>
<tr>
<td>With renal disease</td>
<td>0.36</td>
</tr>
<tr>
<td>With neurologic comorbidity</td>
<td>0.22</td>
</tr>
<tr>
<td>With retinopathy and diabetic eye disease</td>
<td>1.18</td>
</tr>
<tr>
<td>With any combination of comorbidities</td>
<td>12.45</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Benefit Plan Characteristics</th>
<th>% of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>In an HMO benefit plan option</td>
<td>7.82</td>
</tr>
<tr>
<td>In a fee-for-service benefit plan option</td>
<td>90.06</td>
</tr>
<tr>
<td>Switched plans or mixed HMO/FFS</td>
<td>2.12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Selected Services Characteristics</th>
<th>% of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received dialysis service</td>
<td>1.23</td>
</tr>
<tr>
<td>Received at least one HbA1c</td>
<td>45.97</td>
</tr>
<tr>
<td>Received at least one eye examination</td>
<td>33.23</td>
</tr>
</tbody>
</table>

distinguishes IDDM and NIDDM patients by the fifth digit. If the fifth digit was missing in the data and pharmacotherapy markers could not confirm diabetes type, the patient was defined as unclassified.

The predictive model specified in the next section of the study considers variables related to patient demographics, the presence of common comorbidities, use of insulin and oral antidiabetic agents, screening characteristics, disease type, and type of health benefit plan for the study sample. To gain a sense of the resource consumption profile of the study population, Table 2 summarizes disease type, selected services, selected common comorbidities, antidiabetic pharmacotherapy, and benefit plan type. Summary information was generated after a complete review of the 1995 claims history for all identified patients. Comorbidities were identified through ICD-9 codes. Of note is that 46% of the cohort studied had at least one HbA1c test. For those patients who were recorded as having received an HbA1c, the average annual number of tests per patient was 2.3.

METHODS

The Probit Model

As stated earlier, the main purpose of this article is to determine the probability that a patient with diabetes, with a given set of attributes, will obtain HbA1c testing. The dependent variable (y) in our model involves two choices, namely whether the patient receives an HbA1c test (1 = yes; 0 = no) in 1995. The independent variables are either in the form of a continuous variable (age) or a set of binary variables (presence or absence of comorbidities, antidiabetic pharmacotherapy, and benefit plan type). In such instances, regressing the dependent variable on the explanatory variables and using a common ordinary least square (OLS) method does not guarantee that the values of the dependent variable fall within the (0, 1) interval. Thus, a special technique is required to translate the values of independent variables to a probability measure which is restricted, by definition, within an (0, 1) interval.

One approach to solving this problem is to use a cumulative probability function because the range of any cumulative density function is the (0, 1) interval. A probit model, frequently used for like models of qualitative choice, specifies the cumulative normal probability function such that \( P_i = F(\alpha + \beta x_i) \), where \( P_i \) is the probability that the \( j \)-th patient receives an HbA1c test (the dependent variable assumes the value of one), \( F \) is the cumulative density function, and \( \alpha \) and \( \beta \) are parameters associated with the independent variables \( x_i \) in the model. This form of representation of the model guarantees that the values of the dependent variable lie within the (0, 1) interval. From the probit specification we can say that \( F^\prime (P) = Z_i = \alpha + \beta x_i \), and hence, the complete regression model for the probit could be written as \( F^\prime (P) = Z_i = \alpha + \beta x_i + u \), where \( Z \) is the theoretical continuous index determined by a set of
independent variables X, and u is the error term associated with the regression equation. As discussed earlier, the left-hand side of the regression model has a set of ones and zeros (dummy variables), depending on whether or not a patient in the data was monitored with an HbA1c test; the right-hand side of the equation has a number of explanatory variables, both patient and health care delivery system variables, which are being used to determine the explanatory power of the dependent variable under consideration.

The Probit Model

The probit model for this study has been specified as follows:

\[ F^*(P_i) = \Phi (\beta_0 + \beta_1 \text{AGE} + \beta_2 \text{SEX} + \beta_3 \text{INSUL} + \beta_4 \text{ORAL} + \beta_5 \text{INSORAL} + \beta_6 \text{CARDHTN} + \beta_7 \text{CARDLIP} + \beta_8 \text{CARDVAS} + \beta_9 \text{CARDCHF} + \beta_{10} \text{CARDMIX} + \beta_{11} \text{RENAL} + \beta_{12} \text{NEURO} + \beta_{13} \text{EYE} + \beta_{14} \text{MIXED} + \beta_{15} \text{HMO} + \beta_{16} \text{FFSHMO} + u) \]

where:

- \( P_i \) = probability that the patient j has an HbA1c test;
- \( F^* \) = the inverse of the cumulative normal distribution function;
- \( \text{AGE} \) = age in years (continuous variable);
- \( \text{SEX} \) = gender (male = 1, female = 0);
- \( \text{INSUL} \) = receiving insulin therapy (yes = 1, no = 0);
- \( \text{ORAL} \) = receiving oral antidiabetic agents only (yes = 1, no = 0);
- \( \text{INSORAL} \) = receiving insulin and oral therapy: sequentially or concurrently (yes = 1, no = 0);
- \( \text{CARDHTN} \) = patient identified with hypertension as the only comorbidity (yes = 1, no = 0);
- \( \text{CARDLIP} \) = patient identified with hyperlipidemia as the only comorbidity (yes = 1, no = 0);
- \( \text{CARDVAS} \) = patient identified with CAD or CVD as the only comorbidity (yes = 1, no = 0);
- \( \text{CARDCHF} \) = patient identified with CHF as the only comorbidity (yes = 1, no = 0);
- \( \text{CARDMIX} \) = patient identified with multiple cardiovascular comorbidity (yes = 1, no = 0);
- \( \text{RENAL} \) = patient identified with renal disease as the only comorbidity (yes = 1, no = 0);
- \( \text{NEURO} \) = patient identified with neurologic comorbidity as the only comorbidity (yes = 1, no = 0);
- \( \text{EYE} \) = patient identified with ophthalmic disease as the only comorbidity (yes = 1, no = 0);
- \( \text{MIXED} \) = patient identified with any combination of comorbidity groups listed above (yes = 1, no = 0);
- \( \text{HMO} \) = patient on an HMO service benefit plan (yes = 1, no = 0);
- \( \text{FFSHMO} \) = patient on combination HMO and fee-for-service plans or switched plans in the year (yes = 1, no = 0);
- \( \beta_0, \ldots, \beta_{16} \) = regression slope coefficients;
- \( \alpha \) = intercept term; and
- \( u \) = error term associated with the model.

Some salient features of this regression model are as follows. First, it incorporates nine mutually-exclusive comorbid groups with "no comorbidity" as the reference variable. Similarly, three distinct antidiabetic pharmacotherapy options have been included in the model with "no antidiabetic medicine" as the reference variable in the drug category. Third, patients in this data set are identified as belonging to either a health maintenance organization (HMO) plan, or a fee-for-service (FFS) indemnity-type insurance plan, or both. The variables HMO and FFSHMO have been considered in the model with FFS as the reference variable. It is worth noting that these reference variables are excluded from the model in order to prevent perfect collinearity in the regression equation. Last, patient age is the only continuous variable in the model; all other variables are binary variables coded as 0 or 1 depending on the specification schedule under consideration.

RESULTS

Table 3 shows the estimated coefficients of this model. Among 16 explanatory variables, a total of seven variables show significant association with the dependent variable. These are the pharmacotherapy variables (INSUL, ORAL, and INSORAL), presence of hyperlipidemia (CARDLIP), presence of more than one cardiovascular comorbidity (CARDMIX), presence of any combination of all of the commonly-observed comorbidities associated with diabetes (MIXED), and the HMO variable. Moreover, all of these variables have a positive effect on the probability of receiving an HbA1c test, as depicted by the sign of the regression coefficients. Among other personal characteristic variables, age, sex, and a majority of the comorbidities do not have any explanatory power in this model.

Since the coefficient associated with the variable HMO is positive and significant, and the reference variable is the presence of a fee-for-service benefit plan, it could be stated that patients enrolled in a managed care benefit plan have a higher probability of receiving an HbA1c test than patients who are under an FFS plan. On the other hand, the estimated coefficient associated with FFSHMO (i.e., patients who switched plans or have mixed benefit plan options in the period of time under consideration), fails to explain any change in the probability of HbA1c testing.

Goodness-of-fit Measures for the Probit Model

In contrast to the OLS regression modeling method, a qualitative dependent variable model like probit does not permit the calculation of any unique goodness-of-fit measure (R). However, several research methodologist have proposed various ways to compute R square in the probit model based on maximum likelihood estimation procedure. Intuitively, the best way to measure goodness of fit is by calculating a prediction success table for the regression analysis. Table 4 calculates the actual versus predicted probability of receiving an HbA1c test based on the probit results.
Table 3. Probit Model Results: Estimated Regression Coefficients, Diabetes Patients, HMSA CY 1995

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Coefficients</th>
<th>t-stat</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE</td>
<td>0.0011</td>
<td>0.70</td>
</tr>
<tr>
<td>SEX</td>
<td>0.0253</td>
<td>0.79</td>
</tr>
<tr>
<td>INSUL</td>
<td>0.7578*</td>
<td>14.06</td>
</tr>
<tr>
<td>ORAL</td>
<td>0.6915*</td>
<td>19.72</td>
</tr>
<tr>
<td>INSORAL</td>
<td>1.1357*</td>
<td>15.74</td>
</tr>
<tr>
<td>CARDHTN</td>
<td>0.0963</td>
<td>1.70</td>
</tr>
<tr>
<td>CARDLIP</td>
<td>0.3785*</td>
<td>6.57</td>
</tr>
<tr>
<td>CARDVAS</td>
<td>-0.2122</td>
<td>-1.40</td>
</tr>
<tr>
<td>CARDCHF</td>
<td>-0.0904</td>
<td>-0.22</td>
</tr>
<tr>
<td>CARDMIX</td>
<td>0.3324*</td>
<td>6.69</td>
</tr>
<tr>
<td>RENAL</td>
<td>-0.4249</td>
<td>-1.47</td>
</tr>
<tr>
<td>NEURO</td>
<td>-0.2138</td>
<td>-0.61</td>
</tr>
<tr>
<td>EYE</td>
<td>0.1027</td>
<td>0.69</td>
</tr>
<tr>
<td>MIXED</td>
<td>0.2635*</td>
<td>4.22</td>
</tr>
<tr>
<td>HMO</td>
<td>0.1231*</td>
<td>2.10</td>
</tr>
<tr>
<td>FFSHMO</td>
<td>0.1154</td>
<td>0.05</td>
</tr>
<tr>
<td>CONSTANT</td>
<td>-0.8342*</td>
<td>-10.42</td>
</tr>
</tbody>
</table>

* significant at the alpha level of 0.05, n = 6,841

Sensitivity of the probit model is the probability of predicting an HbA1c test given the number of patients actually having undergone the testing procedure. On the other hand, specificity of the regression model is the probability of predicting no testing, given that no such events actually happened. In other words, of those patients who had an HbA1c test, this model successfully allocates 64.17% of the patients into the right category; the model also correctly predicts almost 63.96% of those who did not go through any such testing in that particular year. Considering that we are dealing with a microlevel (individual patient) data set with expected noise, the results show significant predictive power of 64.05% for the probit model. Table 4 also shows that among the 6,841 patients identified with diabetes mellitus, 3,145 had an HbA1c test performed.

HMO Enrollees and the Probability of HbA1c Test: An Example

As mentioned earlier, the regression model predicts that a patient enrolled in an HMO plan has a higher probability of receiving an HbA1c test than a patient enrolled in a PFS plan. The question yet to be answered is the extent or magnitude of this difference, as predicted by the model. Assume that two female patients identified with diabetes mellitus have similar personal and clinical characteristics (age = 50, taking oral antidiabetic medication, and suffering from hyperlipidemia as the only comorbidity). The only difference is that one patient, "N," is enrolled in an HMO and the other patient, "M," is under an FFS benefit plan. The model could be written as follows:

For patient N: F(0) = 0.4139, and for patient M: F(0) = 0.2908.

Note that the difference between the values of the index functions is equal to the coefficient associated with the HMO variable (βHMO). From the above relationship, we can write that for patient N: Pn = F(0.4139) and for patient M: Pm = F(0.2908).

Since F is the cumulative standard normal distribution function, and by using the cumulative distribution table, the probabilities may easily be compared. These are approximately 0.659 and 0.614 for patient N and patient M, respectively. Hence, N, enrolled in an HMO, has 4.5% higher probability of receiving HbA1c testing compared to M, who has the same characteristics but is under an FFS benefit plan.

DISCUSSION

Results indicate that age and gender are not statistically significant as predictors of HbA1c testing. Significant and higher probabilities of HbA1c testing are associated with patients who are: a) on insulin and insulin plus oral antidiabetic agents; b) having hyperlipidemia, multiple cardiovascular comorbidities, and multiple mixed comorbidities; and c) receiving services under a managed care plan. Even though we expect to see a greater frequency of HbA1c testing in the...
unstable and involved patient it is less clear why patients in a
managed care plan have a higher probability of receiving the
test. While the magnitude of the difference in the illustrative
example with patients M and N may not be great, it does pro-
vide guidance into the decisions and planning for a justifiable
and reasoned intervention plan to improve and evaluate glu-
cose monitoring in the future. Further, the case example raises
the following question: Given a baseline analysis, what are
reasonable expected rates of testing between groups of pa-
tients and the study population as a whole?

From a disease management perspective, the results of
this study have potential application in that the study identi-
fies 1,332 patients who are predicted to be undergoing HbA1c
testing, but in actuality, as recorded in the data, they are not
(see Table 4). Although it is not possible to discern the exact
reason for this discrepancy, one potential concern is that these
patients may have not been managing their disease properly.
It will thus be important to probe this further with a prospective
study design.

Limitations

One concern that may limit the value of this study relates
to the accuracy of claims data. In a recent study on the accu-
ragy of diagnostic coding, Worth and Mytinger examined claims
submitted to the HMSA.11 The investigators found 96% coding
accuracy for hospital claims and 62% coding accuracy for
physician claims. Following a feedback loop intervention,
physician coding improved markedly to 94% accuracy. There-
fore, these data, while limited in clinical information such as
disease onset and disease involvement, may be useful for base-
line and periodic aggregate analyses.

One underlying intent of the present study was to
demonstrate the usefulness of claims data for questions related
to chronic disease management. The findings may be used for
decision making in planning and monitoring disease interven-
tions to improve health outcomes and evaluate costs. This par-
ticular health plan is preparing to add an enhanced diabetes
care program to its existing general diabetes education activi-
ties. Also, the findings are helpful for preparing useful and
important future studies.

Another concern is that this model does not provide any
information on actual glucose control. It merely tells us the
likelihood of receiving a test and some of the characteristics
of that future predicted population.

Finally, and perhaps most important, the model does not
indicate the degree to which testing resulted in changes in dia-
betes management and/or improved glucose control. However,
armed with the information provided herein, the next phase of
investigation could target a more focused analysis of re-
source consumption and clinical outcome.

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