

Effect of Drug Therapy on HEDIS Measurements of HbA_{1c} Control In Diabetes Patients

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INTRODUCTION

The National Committee for Quality Assurance (NCQA 2008) collects data from over 90 percent of the health plans in the United States to evaluate and report health plan performance with respect to quality of care and service. The tool that NCQA uses to collect this data is the Health Plan Employer Data and Information Set (HEDIS) (NCQA 2007, NCQA 2005). HEDIS addresses a wide range of important health care states, including comprehensive diabetes care. Comprehensive diabetes care data collected by HEDIS and reported annually by NCQA are used by employers, providers, and consumers to compare health plans' care

Key Words: HEDIS, diabetes care, analog insulin, human insulin

Disclosure

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ABSTRACT

The purpose of this study was to corroborate an earlier study that explored the relationship between a health plan's Health Plan Employer Data and Information Set (HEDIS) score for glycolated hemoglobin (HbA_{1c}) control in diabetes patients and its utilization of insulin and oral diabetes products. Prescription volumes were tracked for four categories of diabetes drug therapy: analog insulin, human insulin, single-source brand oral products, and multisource generic oral products, for calendar years 2005 and 2006. The prescription shares of each of the four drug categories for each health plan were matched to the health plan's HEDIS measurements of HbA_{1c} control for each year. Univariate and multivariate regression analysis was performed between the health plan's HbA_{1c}-based HEDIS score and its prescription share of each drug category. A favorable and statistically significant ($p < 0.01$) relationship was found between plan HbA_{1c} HEDIS score and plan prescription share of analog insulin in both 2005 and 2006. The correlation between HEDIS scores and human insulin was not statistically significant. Unfavorable relationships were found between HEDIS scores and both the single-source brand (statistically significant) and the multisource generic oral category prescription shares (not significant). These results corroborate the relationships found in our earlier study, although a cause and effect relationship cannot be confirmed.

for their diabetic patient populations.

Although results for individual plans vary greatly, nationally, nearly 30 percent of patients with diabetes who are enrolled in commercial health plans have poor control of their disease, as defined by glycolated hemoglobin (HbA_{1c}) levels >9 percent (NCQA 2007). There has been a continual improvement in the percentages of patients in poor diabetic control from a high of 42.5 percent in 2000 to 29.6 percent in 2006, the most recent year for which data is available. Recently, NCQA has added a new measure of performance with respect to diabetes. "Good HbA_{1c}

Control" will report the percentage of patients with diabetes with HbA_{1c} <7 percent. The most recent NCQA report stated that 41.8 percent of the population with diabetes is reported to be within good control as defined by this new measure (NCQA 2007).

Attempts have been made to correlate disease management, adherence, and preventative care programs with improvements in diabetes HEDIS scores. While some of these studies have shown an improvement in HEDIS scores, others have demonstrated inconsistent results (Sidorov 2002, Bramley 2006, Quenan 2000).

In 2007, we reported a correlation

between high use of certain medications with better diabetes HEDIS scores. For the first time, the relationship between utilization of specific classes of medications and declining rates of patients in poor diabetes control was demonstrated (Weiss 2007). That study examined the relationship among health plans of HEDIS-measured HbA_{1c} control and the prescription share of four categories of diabetes products: analog insulin, human insulin, branded oral products, and generic oral products. We reported a strong positive relationship between better HEDIS scores and higher analog insulin prescription share ($P < 0.0001$).

The purpose of the current study was to investigate whether these results could be corroborated with a more robust and recent data set.

METHODS

To identify the level of HbA_{1c} control for a given health plan, this study used the HEDIS measurement “percent of diabetes patients having poor HbA_{1c} control” as reported in the NCQA Quality Compass product (NCQA 2008). These measurements were matched to the plan’s prescription share (based on prescription volume) in each calendar year for four groupings of antidiabetic products: (1) analog insulin, (2) human insulin, (3) single-source branded oral products, and (4) multisource generic oral products. A health plan was included in the study for 2004 or 2005, provided the plan had a valid HbA_{1c} “poor control” HEDIS measurement and at least 2,000 total diabetes prescriptions in that year.

Prescription volume for each product group was reported by IMS HealthCare (Plymouth Meeting, Pa.) for individual health plans in its PlanTrak report. Analog insulins included the insulin lispro, insulin aspart, and insulin glargine product lines. Human insulin included the insulin isophane (Humulin) and human insulin isophane suspension (Novolin) product lines. Branded and

generic oral products consisted of all single source and multisource oral products respectively captured in the IMS prescription database. The prescription share of each of the four drug classes was calculated based on all prescription diabetes products in the PlanTrak database. Therefore, the prescription shares of the four classes within each health plan totaled 100 percent.

ANALYSIS

Univariate (simple) and multivariate regression analysis was performed between the health plan’s (HbA_{1c})-based HEDIS score and its prescription share of each drug category. The effect of plan size and region of the United States was also explored via multivariate regression. In order to assess the effect of copayments on HEDIS score we matched HEDIS score to the percentage of diabetes prescriptions in the lowest copayment tier in each plan and performed a linear regression across health plans to determine the relationship between HEDIS score and percentage of diabetes prescriptions with the lowest copayment.

RESULTS

A total of 194 eligible health plans were identified for 2005, and 211 health plans were identified for 2006. Table 1 summarizes the prescription volume from eligible plans for each

year. The total diabetes prescription volume for eligible plans was about 21.2 million in 2005 and about 24.5 million in 2006. Combined branded and multisource generic oral products represented slightly more than two thirds of total diabetes prescriptions (68 percent and 68.1 percent for 2005 and 2006, respectively). Analog insulin prescription share increased from 20.7 percent in 2005 to 23 percent in 2006, while human insulin share decreased from 11.3 percent to 8.9 percent during the same time period. The oral multisource generic market share increased slightly from 48.1 percent in 2005 to 49.4 percent in 2006, while branded oral market share decreased from 19.8 percent in 2005 to 18.6 percent in 2006. The mean HEDIS score for percentage of patients with diabetes enrolled in eligible plans who were not in control improved from 29.6 percent \pm 7.7 in 2005 to 28.8 percent \pm 7.13 in 2006 ($P = NS$).

A statistically significant correlation ($p = 0.002$ and < 0.001 , respectively) was seen between higher analog insulin prescription shares and better (i.e., lower percentage of patients with HbA_{1c} level > 9 percent) HEDIS scores among health plans in both 2005 and 2006 (Table 2). That is, a higher analog insulin prescription share was associated with a lower (fewer patients with HbA_{1c} level > 9 percent) HEDIS score. The slope

TABLE 1
Summary of prescription volume and share for eligible plans

	2005 N = 194 plans		2006 N = 211 plans	
	TRx volume	TRx share	TRx volume	TRx share
Analog insulin	4,404,688	20.7%	5,651,117	23.0%
Human insulin	2,395,031	11.3%	2,182,978	8.9%
Total insulin	6,799,719	32.0%	7,834,095	31.9%
Brand orals	4,211,152	19.8%	4,573,738	18.6%
Generic orals	10,223,185	48.1%	12,127,876	49.4%
Total orals	14,434,337	68.0%	16,701,614	68.1%
Total	21,234,056	100.0%	24,535,709	100.0%

TRx = Total prescriptions (new and refill); N = number of plans in analysis

TABLE 2**Simple linear regression models of HEDIS score with analog insulin, human insulin, branded oral, and generic oral prescription share**

Drug Class	Correlation with HEDIS 2005 (N = 194)*			Correlation with HEDIS 2006 (N = 211)*		
	Model coefficient	P value [†]	Model coefficient	P value [†]		
Analog insulin share	-0.22	0.002	-0.30	< .001		
Human insulin share	-0.09	0.197	-0.10	0.128		
OAD share (brand)	0.22	0.002	0.326	< .001		
OAD share (generic)	0.07	0.321	0.12	0.090		

*A negative correlation value indicates a favorable correlation between HbA_{1c} control and prescription share (i.e., higher prescription share is associated with a lower HbA_{1c} "poor control" score)

[†]t test OAD = oral antidiabetic drug

(model coefficient in Table 3) of the linear regression line was -0.319 in 2005 and -0.424 in 2006. The slope in 2006 indicates that a 10-share-point increase in analog insulin utilization was associated with a 4.2 percentage point decline in the "poor control" HEDIS score (i.e., is associated with an improvement in HbA_{1c} control). Linear regression analysis using human insulin share as the independent variable showed a favorable correlation between human insulin share and improvement of "poor control" in both years. However, the relationship was not as strong as the analog insulin relationship (model coefficient = -0.218 in 2005 and -0.257 in 2006) and not statistically significant in either year.

Linear regression analysis using either branded oral product share or multisource generic oral share as the independent variable showed a posi-

tive correlation between poorer (i.e., higher percentage of patients with HbA_{1c} level > 9 percent) HEDIS scores and higher oral product prescription share. This unfavorable correlation was statistically significant in the case of branded oral product prescription share in 2005 and 2006 (p = 0.002 and p < 0.001, respectively). The unfavorable correlation was not significant for generic oral agents in either year.

To further compare the effect of product group prescription share on HEDIS score, a multivariate regression was conducted for each year with analog insulin share, human insulin share, and branded oral share as independent variables (Table 3). Since the four categories total 100 percent, the generic oral value is completely dependent on the values of the other three shares and was dropped from the model. The multivariate regression clearly discriminated between

the effect of analog and human insulin prescription share, with higher analog insulin utilization continuing to be statistically significantly associated in both 2005 and 2006 (p = 0.004 and p = 0.013, respectively) with better HEDIS scores. Higher human insulin utilization was not associated with better HEDIS scores. Branded oral share continued to be associated with poorer HEDIS scores at a statistically significant level (p = 0.011 and p = 0.002 in 2005 and 2006, respectively).

Evaluation of plan enrollment and location in the multiple regression analysis revealed that only two U.S. regions reached statistical significance (South Atlantic/Central and Mountain) with both regions unfavorably correlated to HEDIS scores (Table 4). However the effects were small compared to the product prescription shares. The inclusion of plan enroll-

TABLE 3**Multivariate regression analysis of HEDIS score with analog insulin, human insulin, and branded oral prescription share**

Drug class	HEDIS 2005 (N = 194)*		HEDIS 2006 (N = 211)*	
	model coefficient	P value [†]	model coefficient	P value [†]
Analog insulin share	-0.302	0.004	-0.258	0.013
Human insulin share	0.010	0.961	0.156	0.427
OAD share (brand)	0.363	0.011	0.492	0.002

*A negative model coefficient indicates a favorable correlation between HbA_{1c} control and prescription share. Model statistics: r²=0.091, p<0.001, F-test (year 2005); r²=0.141, p<0.001, F-test (year 2006).

[†]t test OAD = oral antidiabetic drug

TABLE 4**Multivariate regression analysis of HEDIS score with analog insulin, human insulin, and brand oral prescription share; plan enrollment; and plan location**

Drug class, enrollment, location	Correlation with HEDIS 2005 (N = 194)*		Correlation with HEDIS 2006 (N = 211)*	
		P value [†]		P value [†]
Analog insulin share	-0.263	0.02	-0.288	0.01
Human insulin share	0.148	0.48	0.298	0.15
OAD share (brand)	0.429	0.01	0.491	0.00
Small enrollment	-0.010	0.50	-0.003	0.82
Medium enrollment	-0.002	0.91	-0.011	0.39
Large enrollment	-0.013	0.47	-0.006	0.71
East north central	-0.007	0.65	-0.006	0.64
South Atlantic/Central	0.035	0.02	0.032	0.01
Mountain	0.040	0.02	0.036	0.02
Pacific	0.011	0.67	0.002	0.94

Small enrollment = 100,000 to 249,999; medium enrollment = 250,000 to 749,999; large enrollment \geq 750,000

Enrollments under 100,000, northeast and mid-Atlantic used as reference and not included in model

*A negative model coefficient indicates a favorable correlation between HbA_{1c} control and prescription share. Model statistics: $r^2=0.161$, $p<0.001$, F-test (year 2005); $r^2=0.207$, $p<0.001$, F-test (year 2006).

[†]t test

OAD = oral antidiabetic drug

ment and location in the multiple regression model increased the unfavorable effect of human insulin with respect to analog insulin.

The linear regression with percentage of diabetes prescriptions on the lowest copayment tier as the independent variable showed a small nonsignificant effect (Table 5). For 2005, a higher percentage of prescriptions in the lowest copay tier was associated with a better (lower) HEDIS score. The slope was -11.3, indicating a 1.1 percentage point drop in HEDIS score for a 10-share-point increase in prescriptions in the lowest copay tier ($p = 0.06$). In 2006, this relationship diminished to a slope of -7.4.

DISCUSSION

These results of this study corroborate those reported in the earlier study (years 2004 and 2005), which used more limited prescription volume information (Weiss 2007). A strong relationship between better (lower) HEDIS scores for HbA_{1c} control and higher analog insulin prescription share was demonstrated by both the univariate and multivariate regression analyses for 2005 and 2006. Human insulin share showed a favorable relationship to HEDIS scores in the univariate analysis in both years but without statistical significance. The multivariate analysis attributed the improvement in HEDIS scores to analog insulin only,

with human insulin showing a slight (nonsignificant) unfavorable effect on HEDIS scores in both years. The inclusion of plan enrollment and location in the multiple regression analysis resulted in a further differentiation between analog and human insulin, with human insulin showing a greater unfavorable impact, although still not reaching statistical significance. Both the univariate and multivariate regressions demonstrated an unfavorable relationship between oral product shares and HEDIS scores. The relationship was much more pronounced for the brand oral products, with higher brand oral market shares in health plans associated with statistically sig-

TABLE 5**Results of univariate (simple) regression between HEDIS score and percentage of diabetes prescriptions in lowest copayment tier**

	Mean percent of diabetes prescriptions by copayment tier			Slope	p-value
	Tier 1	Tier 2	Tier 3		
2005	68.4%	30.7%	0.9%	-11.3	0.06
2006	70.5%	28.2%	1.3%	-7.4	0.18

Percentages are based on prescriptions for products with known copayment tiers

nificantly poorer HbA_{1c} control. One interpretation for this result is that patients and physicians may be attempting to avoid insulin therapy by using a variety of newer oral agents.

The lack of a relationship between HEDIS score and percentage of diabetes prescriptions in the lowest copay tier may be due to the fact that the copay tier status was missing for many products. The initial assumption was that a higher percentage of prescriptions in the lowest copay tier might result in better patient compliance and therefore better HbA_{1c} control. Although this proved to be the case directionally, the results did not reach statistical significance. We calculated the percentage of prescriptions in the lowest copay tier based only on the product prescriptions for which a copay tier was known.

Although the results clearly indicate that higher utilization of analog insulin is associated with greater HbA_{1c} control in diabetes patients in commercial health plans, an association does not imply a cause-and-effect relationship. Drug therapy is only one factor in the management of diabetes. Comprehensive diabetes care may also entail enrollment in disease management programs, improved adherence to published treatment guidelines, and other factors such as diet and exercise.

A potential confounding factor could be the proportion of Type 1 diabetes patients in a health plan. These patients would raise the ratio of insulin to oral medications, but not necessarily the analog portion. While Type 1 patients would be expected to be more adherent to their regimens, they might not show any better control than Type 2 patients because of the volatility of their glucose levels. Type 1 patients represent only 5 percent to 10 percent of diabetes patients, and therefore the impact on the correlation between insulin utilization and improved HEDIS scores is likely to be small. Also, there is no reason to expect significant fluctua-

tions in the portion of Type 1 and Type 2 patients among health plans. Therefore, the proportion of Type 1 patients would not be expected to be a significant factor in these results.

No data were available in this study to determine concomitant use of insulin and oral products, or among products within a drug class. The prescription share analysis assumes patients are on monotherapy, although concomitant use would not invalidate the findings regarding the relationship between HEDIS scores and analog insulin prescription share.

The new NCQA measure of percentage of patients with diabetes with good HbA_{1c} control (<7 percent) will provide the first data point to corroborate the results of the current and prior studies using a direct measure of good control (NCQA 2006). A future study might perform analyses similar to those conducted here, but using both performance measures over time.

As new medications to treat diabetes enter the market, future studies must account for their effect on diabetes performance measures. Thus, a future study might correlate only the newer agents with HEDIS results.

Future studies might also explore the causes of the correlations between better NCQA/HEDIS performance scores in diabetes and specific drug classes and agents. Areas to explore might include disease severity, patient population statistics, and plan interventions such as disease and medication management programs.

CONCLUSIONS

Data from this study corroborate an earlier study performed by the authors that indicate a statistically significant correlation between higher utilization of analog insulins and lower percentages of health plan members with diabetes who are not in glycemic control, as defined by HbA_{1c} levels >9 percent. Human insulin showed either a weaker positive effect (univariate analysis) or a negative effect (multivariate analysis) on

HbA_{1c} levels. Studies should be conducted to confirm these findings with more data points, compare them with new standards-of-care measures, and longitudinally track the effect of new medications on diabetes care as measured by HEDIS.

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