Diabetes Disease Management in a Community-Based Setting

GREGORY D. BERG, PHD[1], AND SANDEEP WADHWA, MD, MBA[2]

[1]Senior Research Scientist, McKesson Corp.; [2]Vice President, Population Care Management, McKesson Corp., and Clinical Assistant Professor of Medicine, University of Colorado Health Sciences Center

ABSTRACT

Purpose. The medical cost of diabetes in the United States in 1997 was at least $98 billion. This study illustrates the behavioral change and medical-care utilization impact that occurs in a community-based setting of a diabetes disease-management program that is applied to program participants in a health insurance plan's health maintenance organization and preferred provider organization.

Design. A historical control comparison of diabetes-management participants.

Methodology. One hundred twenty-seven identified diabetes patients are followed from baseline through 1 year. Differences in behavior are compared at program intake and at a 6-month reassessment. Differences in medical-service utilization are compared in the baseline year and the year subsequent to program enrollment. Poisson multivariate-regression models are estimated for counts of inpatient, emergency department, physician evaluation and management, and facility visits, while also controlling for potential confounders.

Principal findings. Behaviors improved between program intake and the 6-month reassessment. From patient reports, the number of participants having a hemoglobin A_{1c} test increased by 44.9 percent ($p<.001$), and there was a 53.2-percent decrease in symptoms of hyperglycemia ($p=.002$). From medical claims after program enrollment, a drop occurred during the program year in every dimension of medical-service utilization. Regression results show that inpatient admissions decreased by 391 ($p<.001$) per 1,000 for each group, while controlling for age, length of membership, and the number of comorbid claims for congestive heart failure. In the analysis of costs that were pre- and post-enrollment, which included disease-management program costs, a 4.34:1 return on investment was calculated.

Conclusion. The diabetes program provides patients with comprehensive information and counseling relative to practicing self-management of diabetes through a number of integrated program components. This study strongly suggests that the implementation of such a program is associated with positive behavioral change and, thus, with substantial reduction in medical-service utilization. In addition, the intervention resulted in a net decrease in direct medical costs.

Author correspondence:

Gregory D. Berg, PhD
McKesson Corp.
335 Interlocken Parkway
Broomfield, CO 80021
E-mail: Greg.Berg@McKesson.com
Phone: 303-926-6208
Fax: 303-466-5949

Author Contributions: Dr. Berg had full access to all the data in this study and takes responsibility for the integrity of the data and accuracy of the data analysis. Dr. Wadhwa provided study supervision and medical expertise.

This study was funded by McKesson Corp.

This paper has undergone peer review by appropriate members of MANAGED CARE's Editorial Advisory Board.

INTRODUCTION

Approximately 10.3-million people in the United States have been diagnosed with diabetes mellitus, a serious, life-long disorder that remains, as yet, without a cure. An additional 5.4-million people have diabetes but are unaware that they have the disease.[1] Individuals with diabetes are at higher risk of heart disease, stroke, high blood pressure, blindness, kidney disease, nervous-system disease, amputations, dental disease, and complications of pregnancy,[1,2] resulting in diabetes mellitus being ranked as the seventh leading cause of death in the United States.[3]

The long-term complications of diabetes, particularly when poorly managed — as with the elderly,[4] give rise to grave financial as well as human consequences. The number of health care services directed toward diabetes patients is high,[5,6] with a large portion of that figure representing inpatient hospital care.[7] The cost of diabetes was estimated at $98.2 billion in 1997.[8]

Diabetes disease management has been shown to save money and improve outcomes in opt-in programs sponsored by health maintenance organizations,[9] resulting in significant short-term improvements in glycemic control in the treatment population.[10] Furthermore, the integration of individualized goals with educational surveillance reduces risk factors in diabetes patients and thus reduces diabetes complications.[11]

The McKesson Health Solutions (MHS) Diabetes CareEnhance program specifically targets diabetes and

its associated conditions by aggressively monitoring and educating members about cardiovascular risk control, glycemic control, and microvascular risk control. The program has an intense focus on aggressive lipid management, appropriate aspirin use, beta-blocker use for diabetes patients with a history of coronary artery disease, and control of blood pressure, in addition to glucose control and preventive testing. Rather than showing results from participants who were recruited in a clinic or hospital setting, this study shows community-based program effects for diabetes patients in an HMO and a PPO.

This diabetes-management program was developed to address some of the most serious challenges facing health care providers, health plans, and employers seeking to improve diabetes management. Through an individualized approach to patient monitoring, education, and counseling, the CareEnhance Diabetes program seeks to improve patients' self-management practices and enhance communication with their providers, while improving clinical outcomes and quality of life, as well as reduce treatment costs associated with diabetes.

MHS developed this telephone-based, RN-delivered diabetes program to directly address the challenge of improving quality while decreasing cost that faces health care providers, health plans, and employers. A team of physicians, nurses, and nurse practitioners with extensive experience in diabetes developed the Diabetes CareEnhance program, which follows the most current clinical practice recommendations outlined in the national guidelines of the American Diabetes Association.[12]

Specially trained registered nurses monitor, educate, and provide telephonic case-management services for members with diabetes. On program enrollment, an RN conducts a comprehensive assessment of a program participant. Each participant is assigned a diabetes-severity level, which ranges from 1 (stable) to 3 (high risk). MHS provides a customized self-management plan for each participant. Interventions vary according to the member's risk profile and individual need. The interventions include written materials, informal and formal education, participant ability to contact the nurses with symptoms and concerns, and regular communication with participant physicians. The customized nature of the program is an important feature, because program goals involve enabling behavioral changes that lead to reduced medical-service utilization.

Interventions are most concentrated in the first 3 months of the program. Thereafter, regular reinforcement of the core training is provided and compliance is assessed.

METHODS

Study design. The diabetes program began to identify diabetes patients in January 2000 from an HMO and PPO health plan. Registered nurses called the members who were identified as having diabetes and asked if they were interested in enrolling in the program. For those who agreed to participate, MHS provided a customized self-management intervention plan that varied according to individual needs and risk profiles. The plan included written materials, informal and formal education, instructions on how to contact the nurses with symptoms and concerns, and encouragement to communicate regularly with participating physicians. Once members were enrolled in the program, nurses conducted a telephonic survey at 6 and 12 months to assess each participant's knowledge, behavior, and health status relative to their diabetic conditions.

The improvement in patient knowledge, behavior, and health status relative to diabetes was expected to lead to changes in their medical-service utilization. Six months after the program was implemented, a comparison of initial interview responses and 6-month interview responses on behavioral and lifestyle changes was conducted. A change in behavior and lifestyle is believed to affect medical-service utilization. Twelve months after the program was implemented, a medical-claims-based historical comparison study was conducted to reveal any changes in medical-service utilization for inpatient (IP), emergency department (ED), physician office (MD), and outpatient facility (FA) services.

Study population. The study group included members whose conditions were identified by the health plan as most severe. In addition, all study participants were: health plan members for 12 months prior to their enrollment and for at least 6 months subsequent to their enrollment; not listed with "deceased" or "does not have condition" on the diabetes program report; had at least 3 months of diabetes-program participation.

This selection process resulted in a total of 127 study participants. The requirements were chosen to provide a fair representation of medical-service utilization at baseline and during the program. The health plan referred members for participation if the member had diabetes and a hospitalization in the past year.

Historical control. Changes in behavior and lifestyle were compared at program intake and at 6 months after intake. Behavioral changes were compared at program intake and 6 months after intake for sugar, microvascular, and macrovascular variables. The program was designed to measure whether changes would result in reductions in medical-service utilization, which were compared during the baseline year and the year following program enrollment.

Since each program participant had a different enrollment date during the period from February 2000 through August 2000, a unique pre-

program period and a program period were established for each participant, e.g., a member who enrolled on April 15, 2000 would have a preprogram period that was the year prior — April 15, 1999 to April 14, 2000, with the corresponding program period from April 15, 2000 to April 14, 2001, or to the date when that member disenrolled in the plan if that occurred prior to April 14, 2001.

If the member disenrolled from the diabetes program but remained in the health plan, the time period after disenrollment was still included in the program evaluation period, up to 1 year. This time period was included because behaviors and lifestyle changes made during program participation were expected to carry over to later dates. Medical-service utilization rates were reported as annualized rates. If the member disenrolled from the health plan before 1 year of diabetes-program participation, no medical claims were available and utilization rates were then annualized. Changes in behavior and lifestyle variables observed at 6 months were expected to lead to changes in medical-service utilization during the year following program enrollment.

Multivariate-regression analysis. Multivariate-regression analysis was performed to account for possible confounders. The list of possible confounders included age group, comorbidities, and the amount of time the member was a health plan member. Four regression models were estimated — one for each type of utilization, including inpatient, emergency department, physician visits, and other visits, which are mostly facility visits.

The dependent variable was the number of visits that occurred in either the pre- or post-enrollment periods. This dependent variable is a count variable (0,1,2,…) rather than continuous, which means that ordinary least squares (OLS) statistical-regression analysis is not appropriate.[13,14] OLS is an appropriate statistical-regression technique when the dependent variable is continuous. Therefore, in this case we selected the Poisson regression technique, which is an appropriate statistical-regression technique when the dependent variable is a count variable. Poisson models also account for possible confounders. For each participant in the study , we calculated the actual number of visits in the 12-month period prior to enrollment and the actual number of visits in the 6- to 12-months after intake during which the member was in the health plan. Explanatory variables were a pre/post dummy variable, an age-group dummy variable, the number of congestive heart failure claims that the member had while with the health plan, the post-enrollment number of days that the member was with the health plan (6–12 months), and the post-enrollment number of days squared.

RESULTS

Membership. The total number of members who met the study criteria was 127. To be considered a study participant, the member must have been enrolled with the health plan for at least 1 year prior to enrollment, must have been enrolled with the health plan for at least 6 months subsequent to enrollment, and must have participated in the diabetes program for at least 3 months. The average length of participation in the diabetes program was 8.43 months for the 127 study participants.

Changes in sugars, microvascular, and macrovascular variables. The evaluation period was from intake to the point at which each individual's 6-month reassessment was conducted. Although the study population was 127, not all participants completed a 6-month evaluation. Six-month evaluations were not performed for the 20 study participants who were not able to be located for the interview. The claims for these 20 study participants were included in the medical-service utilization analysis.

Table 1 shows measures of sugar, microvascular, and macrovascular variables at program intake and at the 6-month reassessment.

P-values were calculated using the McNemar test for all categorical variables, and the Wilcoxon signed-rank test for paired data was used for hemoglobin A_{1c} values.

Statistically significant improvements in sugar variables were noted for symptoms of hyperglycemia during the 2-week periods prior to patient interview and for hemoglobin A_{1c} testing during the year prior to patient interview. Members experienced a 53.2-percent decrease in symptoms of hyperglycemia (p=.002) and the number of members with a hemoglobin A_{1c} test during the prior year increased by 44.9 percent (p<.001).

Statistically significant improvements for microvascular variables were noted for those members who performed a daily foot exam and for those members who had a prescription for an ACE inhibitor. The number of individuals who had daily foot exams increased by 20.6 percent (p=.001), while the number of prescriptions for ACE inhibitors showed an increase of 34.2 percent (p=.003).

Statistically significant improvements for macrovascular variables were noted for members who took aspirin and for members with a diastolic blood pressure below 80. Members who took aspirin daily increased by 29.2 percent (p=.001); members who reported that their most recent diastolic blood pressure was below 80 increased by 34.7 percent (p=.003).

The observed improvements in behavior and lifestyle variables between the intake and the 6-month reassessment are expected to lead to improvements in medical-service uti-

TABLE 1 Behavioral and lifestyle changes

Measure	Intake	6 months	Difference (%)	*p*-value	n
Sugars					
Use glucose meter daily	67.6%	74.5%	10.2	.127	102
Symptoms of hypoglycemia in past 2 weeks	28.0%	27.1%	–3.2	.858	107
Symptoms of hyperglycemia in past 2 weeks	28.0%	13.1%	–53.2	.002	107
Hemoglobin A_{1c} test	56.1%	81.3%	44.9	.000	107
Hemoglobin A_{1c} value	5.38	4.83	–10.2	.250	13
Microvascular					
Foot exam	72.9%	87.9%	20.6	.001	107
Dilated eye exam	69.2%	69.2%	0.0	1.000	107
Kidney function test	57.0%	67.3%	18.1	.093	107
Prescription for ACE inhibitor	50.0%	67.1%	34.2	.003	70
Macrovascular					
Prescription for beta blocker	60.0%	66.7%	11.2	.317	15
Takes aspirin	38.3%	49.5%	29.2	.001	107
Follows a low-salt diet	52.8%	62.5%	18.4	.194	72
Body mass index <30	40.2%	40.2%	0.0	1.000	107
Systolic blood pressure ≤130	63.4%	65.9%	3.9	.763	41
Diastolic blood pressure ≤80	63.4%	85.4%	34.7	.003	41

A *p*-value ≤.05 indicates statistical significance at the 5-percent level.

lization in the year following a member's diabetes program enrollment.

Changes in medical-service utilization. The evaluation period for calculating utilization rates includes the full year of claims before enrollment, and 6 to 12 months of claims after enrollment, which depends on the length of member enrollment in the health plan. Because all study participants were members of the health plan for a full year before enrolling, no annual adjustment was needed for preprogram rates. The number of members in the program evaluation period was 127.

Table 2 shows annualized number of visits, annualized utilization rates, and the percentage change between the preprogram and program evaluation periods for inpatient admissions, emergency department visits, physician visits, and facility visits. The *p*-values are from the Wilcoxon signed-rank test for paired data.

For inpatient admissions, members had a 23.7-percent reduction (*p*=.027) in the post-enrollment period. Such high utilization of inpatient services is due to the health plan's selection of patients with the most severe cases of diabetes. As such, the reduction in the post-enrollment period could be influenced heavily by regression to the mean.

TABLE 2 Changes in medical-service utilization

		Annualized utilization rate/1,000	Utilization reduction
Inpatient	Pre-enrollment	1,110	–23.7%
	Post-enrollment	847	(*p*=.027)
Emergency department	Pre-enrollment	457	–5.7%
	Post-enrollment	431	(*p*=.109)
MD	Pre-enrollment	9,850	–8.2%
	Post-enrollment	9,043	(*p*=.057)
Facility	Pre-enrollment	8,685	–15.7%
	Post-enrollment	7,321	(*p*=.012)

A *p*-value ≤.05 indicates statistical significance at the 5-percent level.

For emergency department visits, physician office visits, and facility visits, members experienced reductions in utilization of 5.7 percent (*p*=.109), 8.2 percent (*p*=.057), and 15.7 percent (*p*=.012), respectively, in the post-enrollment period.

In all types of medical-service utilization, the post-enrollment period is associated with a drop in utilization. The medical-service utilization rates support the claim that observed behavior and lifestyle changes after 6 months of program participation led to observed reductions in medical-service utilization in the year following enrollment. Utilization changes (Table 2) yielded a total savings of $214,486, and program costs totaled $49,429. Given the change that occurred in medical-service utilization

and disease-management program costs, a return on investment of 4.34:1 was calculated.

Multivariate-regression analysis. Multivariate-regression analysis was estimated by a Poisson model, which accounts for the count nature of the dependent variable and allows for control of potential confounding variables. The dependent variable is the number of visits that occurred in either the pre- or post-enrollment periods. Explanatory variables are a pre-enrollment/post-enrollment dummy variable, an age-group dummy variable, the number of CHF claims the member had while with the health plan, the post-enrollment number of days the member was with the health plan (6–12 months), and the post-enrollment number of days squared. Tables 3 and 4 show the Poisson regression analysis results for each type of visit.

Tables 3 and 4 show that the coefficient in the post-enrollment period is negative for all measures of utilization, with statistical significance occurring at $p<.001$, except for ED utilization. What this means is that the number of visits in the post-enrollment period, controlling for confounding variables, is less than the number of visits in the pre-enrollment period. The Poisson multivariate-regression results support the claim that observed behavior and lifestyle changes after 6 months of program participation led to observed reductions in medical-service utilization in the year following enrollment.

TABLE 3 Poisson multivariate-regression results — inpatient admissions and emergency department visits

	IP		ED	
Explanatory variables	Coefficient	*p*-value	Coefficient	*p*-value
Intercept	–1.139	.466	–0.289	.850
Pre-enrollment period	baseline	—	baseline	—
Post-enrollment period	–0.391	.000	–0.070	.554
Age <65	baseline	—	baseline	—
Age ≥65	–0.013	.906	–0.227	.179
Health plan enrollment (days)	0.011	.354	–0.0400	.003
Health plan enrollment squared	0.0000	.531	0.0001	.085
Number of comorbid CHF claims	0.025	.001	0.006	.048

A p-value ≤.05 indicates statistical significance at the 5-percent level.

TABLE 4 Poisson multivariate-regression results — MD and facility visits

	MD		Facility	
Explanatory variables	Coefficient	*p*-value	Coefficient	*p*-value
Intercept	–3.127	.530	7.748	.064
Pre–enrollment period	baseline	—	baseline	—
Post-enrollment period	–2.960	.000	–3.110	.000
Age <65	baseline	—	baseline	—
Age ≥65	1.284	.006	–0.613	.128
Health plan enrollment (days)	0.076	.048	–0.004	.906
Health plan enrollment squared	–0.0001	.109	0.0000	.760
Number of comorbid CHF claims	0.081	.000	0.070	.000

A p-value ≤.05 indicates statistical significance at the 5-percent level.

DISCUSSION

The current study has investigated behavior and lifestyle changes for 127 diabetes-program participants at the initial interview and at 6 months following the initial interview for sugar, microvascular, and macrovascular variables. Improvements in diabetes self-management, symptoms, and medication management were noted between the initial and 6-month follow-up interviews. Reductions in the number of hospitalizations also were noted in the year following the start of the diabetes program. Presumably, the improvements in self-management and medical management contributed to the reduced utilization of high-cost medical services. Medical-service utilization for members was compared to baseline utilization along four dimensions: hospital inpatient, emergency department, physician visits, and outpatient facility visits. Hospitalization and facility visits were lower and statistically significant. Emergency department and office visits were lower but not statistically significant.

There are several inherent biases associated with pre-enrollment and post-enrollment (historical control study) design evaluations. Patients included in this analysis voluntarily participated in the program and, furthermore, elected to participate for at least 3 months and up to 1 year.

Such members may be predisposed to improving their self-management skills. This may suggest that the difference in outcomes is not attributable to the diabetes program but to the motivation levels among those who elect to enroll in a diabetes-management program, which is then enabled by the diabetes program. Clearly, however, if the diabetes program had not been available, members would not have had this opportunity to focus their motivation to manage their condition better.

Another bias inherent to this design is regression to the mean. The study participants were high users of medical services, as denoted by their high baseline inpatient-admission rates. High medical-service usage

members may return to mean utilization over time, given the natural history of their condition. The health plan selected the most severe diabetes patients for recommendation to the diabetes program. As such, without a similar comparison group, this study may suffer from regression to the mean where patients cycle in and out of high-severity status. Without a comparison group, the degree of regression to the mean cannot be known. Nevertheless, unlike other chronic diseases such as asthma, diabetes is a progressive disease. Therefore, regression to the mean is not as likely to play a highly attributive role relative to the results of the study.

Though the sample size of 127 is not large, the statistical model demonstrates many significant findings. The 3-month minimum participation exclusion was designed to include patients who did complete the core curriculum but who may not have participated in the full-year intervention.

The highly positive return on investment points to the effect of intervention in a population of diabetes patients who are high users of health care services. It will be of further interest to extend these results to moderate and mild populations, as well, to determine the associated return on investment. Yet the ability to show a return on investment in 1 year for any group of diabetes patients is of great interest, particularly given the dearth of published results demonstrating this finding in a population of diabetes patients. The fact that the model emphasized macrovascular-risk reduction may account for the rapid return on the investment. Moreover, it is of interest to evaluate the duration of behavior change and reductions in utilization for periods greater than 1 year. All these limitations must be considered in light of the findings of a decrease in utilization and high return on investment.

The diabetes program has provided comprehensive information and counseling about diabetes self-management practices through a number of integrated program components. The current study strongly suggests that implementation of such a program is associated with improvements in behavior and lifestyle variables, leading to substantial reductions in medical-service utilization when administered in a community-based setting.

REFERENCES

1. Centers for Disease Control and Prevention (CDC). National Diabetes Fact Sheet. 1998. Available at «http://www.cdc.gov/diabetes/pubs/pdf/bw_eng.pdf» Accessed February 21, 2002.
2. de Grauw WJ, van de Lisdonk EH, van den Hoogen HJ, van Weel C. Cardiovascular morbidity and mortality in type 2 diabetic patients: A 22 year historical cohort study in Dutch general practice. *Diabetic Medicine.* 1995;12(2):117–122.
3. Centers for Disease Control and Prevention (CDC). National Vital Statistics System. 1999. Available at «http://www.cdc.gov/diabetes/statistics/survl99/chap3/table1.htm» Accessed February 21, 2002.
4. Weiner JP, Parente ST, Garnick DW, Fowles J, Lawthers AG, Palmer RH. Variation in office-based quality: A claims-based profile of care provided to Medicare patients with diabetes. *JAMA.* 1995;273:1503–1508.
5. Janes GR. Ambulatory care for diabetes. In: Harris MI, Cowie CC, Stern MP, Boyko EJ, Reiber GE, Bennet PH, eds. *Diabetes in America.* 2nd ed. Washington: U.S. Department of Health and Human Services, National Institutes of Health; 1995: DHHS publication no. (NIH) 95–1468.
6. Aubert RE, Geiss LS, Ballard DJ, Cocanougher B, Herman WH. Diabetes-related hospitalization and hospital utilization. In: Harris MI, Cowie CC, Stern MP, Boyko EJ, Reiber GE, Bennet PH, eds. *Diabetes in America.* 2nd ed. Washington: U.S. Department of Health and Human Services, National Institutes of Health; 1995: DHHS publication no. (NIH) 95–1468.
7. America Diabetes Association. *Direct and indirect costs of diabetes in the United States in 1992.* Alexandria, Va.: American Diabetes Association, 1993.
8. American Diabetes Association (ADA). Economic consequences of diabetes mellitus in the United States in 1997. *Diabetes Care.* 1998:269–309.
9. Sidorov J, Shull R, Tomcavage J, Girolami S, Lawton N, Harris R. Does diabetes disease management save money and improve outcomes? *Diabetes Care.* 2002;25:684–689.
10. Sidorov J, Gabbay R, Harris R, et al. Disease management for diabetes mellitus: Impact on hemoglobin A_{1c}. *Am J Managed Care.* 2000;6:1217–1226.
11. Olivarius NF, Beck-Nielsen H, Andreasen AH, Horder M, Pedersen PA. Randomized controlled trial of structured personal care of type 2 diabetes mellitus. *Br Med J.* 2001; 323:970–975.
12. American Diabetes Association (ADA). Clinical Practice Recommendations. 2001. Available at «http://journal.diabetes.org/CareSup1Jan01.htm» Accessed February 21, 2002.
13. Greene W. *Econometric analysis.* 4th ed. New Jersey: Prentice Hall: 2000:931.
14. Rothman KJ, Greenland S. *Modern Epidemiology* 2nd ed. Philadelphia: Lippincott Williams & Wilkins: 1998:404–405.