Cost Outcomes of Diabetes Education in a Specialized Community Pharmacy

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Diabetes mellitus is a chronic metabolic disease with multiple complications, resulting in progressive health and economic burdens. In the United States in 2002, the total estimated cost for diabetes was $132 billion: $92 billion for direct medical costs and $40 billion for indirect costs related to lost productivity.[1,2] The annual cost increased to $174 billion in 2007[2,3] and accumulated to $218 billion when costs were added for undiagnosed diabetes, prediabetes, and gestational diabetes.[4] Parallel to the cost increase, the age-adjusted incidence of diabetes increased 90% from 4.8 per 1000 in 1995-1997 to 9.1 in 2005-2007.[5]

These alarming numbers indicate the urgent need for interventions to manage the impact of this progressive, costly disease. Despite the availability of several effective medications, healthcare costs continue to grow as the prevalence of the disease increases. Several studies have reported the rate of diabetes medication adherence to be as low as 36% to 54%.[6] Therefore, patient education and disease management are the primary approaches to improve adherence and compliance with treatments predicted to have successful clinical and economic outcomes.

Several intervention models have been based on patient education and disease management; most are run by healthcare providers,[7-9] and pharmacists in particular.[10-16] However, with the exception of a few reports,[18,19] the outcomes were measured for short periods of time.[7-15,17-21] Not fully addressed were longer intervals (≥3 years) during which clinical and medical cost outcomes for the same group of patients were measured.

In this retrospective pilot study, a clinically trained pharmacist in a community specialty pharmacy provided individualized diabetes education and a long-term disease management program for 3 consecutive years. The pharmacist provided the service to members of a self-funded health benefits plan. Clinical and medical cost outcomes were measured and evaluated.

ABSTRACT

Objective: To investigate clinical outcomes and medical costs resulting from a comprehensive diabetes education and management service offered in a specialized community pharmacy.

Study Design: Cost-effectiveness analysis.

Methods: A diabetes education and management service was offered to patients in a self-insured health plan. A community-based clinical pharmacist provided one-on-one comprehensive education sessions. Outcome measures included clinical data and total costs of medical and prescription claims before and during the 3-year intervention period. Data were collected for a cost comparison group over the same time period.

Results: In the intervention group (n = 22), mean glycosylated hemoglobin decreased from 8.9% ± 2.2% to 6.78% ± 0.9% (-2.2 percentage points, *P* <.001). Participants' mean lipid profile improved; triglyceride levels decreased (64 ± 78 mg/dL, *P* = .002), high-density lipoprotein cholesterol increased (8 ± 6 mg/dL, *P* = .020), and total and low-density lipoprotein cholesterol decreased (179.2 ± 24.1 mg/dL [*P* = .243] and 105.8 ± 21.5 mg/dL [*P* = .220], respectively). Mean antibiotic utilization declined from 3.2 to 1.4 incidents per year (*P* = .057). Fourteen patients lost between 5 and 37 pounds. Mean insurance costs decreased by $3033 ± $1549, with decreased medical and physician costs and increased prescription costs. Costs increased in the comparison group by $11,960 ± $10,927, with increased medical and physician costs and decreased prescription costs.

Conclusion: Comprehensive diabetes education and management in a specialized community pharmacy resulted in improved clinical outcomes and decreased medical costs. Future plans include testing in a randomized controlled study.

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PRACTICAL IMPLICATIONS

This study of diabetes management in a specialized community pharmacy examined clinical and economic outcomes over a 3-year period.

- Glycosylated hemoglobin decreased from 8.9% ± 2.2% to 6.78% ± 0.95, and control was sustained for more than 2 years.
- Patient lipid profiles and weight improved, and the incidence of infection declined 65%.
- The total cost per patient decreased 35% compared with baseline, for savings of $177,213 for 22 patients over 3 years.

METHODS

An employer group contracted with a community specialty pharmacy for provision of patient education and diabetes disease management by a clinical pharmacist. The employer sent out letters to all the members of its third-party plan regardless of their disease state. The employer had no access to patients' diagnosis, as required by the patient information confidentiality agreement. Participation in the diabetes program was voluntary, and patients were given an incentive of a copayment waiver on the diabetes medications and blood-glucose testing supplies. Thirty-six patients were enrolled in 2005-2007 at different times.

In 2008, data were collected on 22 patients (intervention group) who continued in the program for 3 consecutive years, 2005-2007; data from 2004 served for the baseline (before intervention) comparison. Data were not included for 14 patients who enrolled but were managed for fewer than 3 years due to late enrollment (3 patients), loss of job or retirement (2 patients), relocation (2 patients), poor compliance with the program (4 patients), or a new diagnosis of cancer, HIV, or accident (3 patients). Data included total medical costs and clinical outcomes for the intervention group. Medical costs included hospital admissions (inpatient and outpatient), emergency department visits, physical therapy, diagnostic testing, and any other expenses incurred by the health plan for each patient. Physician visit costs included all costs incurred during the patient's visits. Medication cost and filling dates were collected for diabetes and hypertension drugs, lipid-lowering agents, antibiotics, and any additional medications combined as "other medications."

Clinical data were obtained from physician office laboratory results, and copies of results were voluntarily provided by the patient to the pharmacist as part of the service outcome measures. Physician laboratory results were used to maintain an appropriate comparison with baseline data and to keep constant test references for each laboratory. To prevent bias, patients' physician clinical data were used rather than pharmacy testing equipment. Clinical data obtained from the physician's office included glycosylated hemoglobin (A1C), cholesterol/lipid profile, and weight. Blood pressure and other laboratory values were not collected for the study because of inconsistency among providers' practices.

Data were collected from the same employer health plan for another 46 patients with a primary diagnosis of type 2 diabetes, whose age and ethnicity were comparable to those of the intervention group and who had similar baseline costs in 2004. Data included costs paid by the health plan as described above; these patients served as the cost comparison group. However, clinical data were not available, as patients in this group did not enroll in the pharmacist's education service. This study was approved by the University of Tennessee Institutional Review Board, and data were collected according to its guidelines.

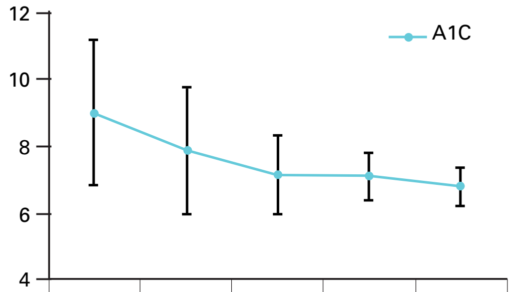
Patients received individualized, 1-hour sessions with the pharmacist, who maintained patient privacy by using consultation rooms at multiple pharmacy locations. The education curriculum was tailored to the patient, based on the pharmacist's evaluation of the medical history obtained from the patient, the pharmaceutical profile, and lab values. Each patient's lifestyle (exercise, food choices, health literacy) was evaluated in the initial visit and reassessed in each follow-up visit. The pharmacist collaborated with physicians on modifying therapy for each patient's optimal treatment plan.

The pharmacist intervention was based on patient education methodology that uses a socioecological or multilevel model to accommodate patients' different health literacy levels. The pharmacist, who had a background in academic and clinical research focused on chronic diseases and therapeutic management, applied standard diabetes patient education (diabetes pathophysiology, food choices, carbohydrate count, and physical activities recommendations) and therapeutic management guidance as recommended by the American Association of Diabetes Educators, the American Diabetes Association, the American Association of Endocrinologists, and evidence-based translational research on diabetes and obesity management.[22-31]

Statistical Analyses

Statistical analysis was done by an independent statistician and epidemiologist who had no access to any

Figure 1. **Changes in A1C Over 3 Years[a]**



	2005(0)	1	2	3	4
A1C	8.99	7.87	7.15	7.1	6.78

A1C indicates glycosylated hemoglobin.

[a] 2005 (0): Zero point of the initial A1C average for 22 patients at start year of 2005. Data points 1 and 2 were measured throughout 2006, and data points 3 and 4 were measured throughout 2007. *P* <.001 for all points versus zero point.

identifying patient information. The average age of the 22 patients in the intervention group was 57 ± 7.44 years, and 13 (59%) were female; 15 (68%) were Caucasian and 7 (32%) were African American. In the cost comparison group (n = 46), the average age was 57 ± 9 years, and 25 (54%) were female; 36 (78%) were Caucasian and 10 (22%) were African American. The cost comparison and intervention groups were not significantly different with respect to age, sex, or ethnicity.

All statistical analyses were performed using SAS software (Version 9.1, SAS Institute, Cary, NC). The target variables (medical costs, physician visit costs, diabetes drug costs, hypertension drug costs, lipid-lowering agent costs, antibiotic costs, and the costs of all other medical events) were summed yearly from 2004 through 2007. Because of the repeated measurements over time on the same patients, we were able to estimate the variance associated with an individual over time, as well as the variance associated with any time frame. Like many cost data, the measures were strongly positively skewed. The data were normalized using the natural log SAS PROC MIXED with the repeated measures analysis of variance method to estimate the mean values of each measure, adjusted for age, sex, ethnicity, inflation rate,[32] and baseline measurement. Contrasts were used to estimate the difference between the measure for each year and the baseline of 2004.

RESULTS

Clinical outcome measures of the intervention group included changes in A1C, cholesterol/lipid profile, weight, and use of antibiotics. The mean A1C significantly decreased from 8.99% ± 2.2% to 6.78% ± 0.9% (decrease of 2.21 percentage points, *P* <.001) **(Figure 1)**. The mean A1C decreased from 8.99% to 7.87% in the first 3 to 6 months of the intervention, and that level was maintained or further decreased throughout the program to a controlled level.

Cholesterol/lipid outcome measures were compared before and after pharmacist intervention **(Table 1)**. Data were collected 3 to 6 months prior to enrollment and in the last 3 to 6 months in 2007. Total cholesterol (TC) and low-density lipoprotein cholesterol (LDL-C) levels decreased from baseline to acceptable clinical levels (TC ≤200 mg/dL, LDL-C ≤100 mg/dL). The mean triglyceride level (clinical goal is ≤150 mg/dL) decreased significantly (53 ± 78 mg/dL, *P* = .002). High-density lipoprotein cholesterol (HDL-C, clinical goal is ≥40 mg/dL for men and ≥50 mg/dL for women) level increased significantly (7 ± 6 mg/dL, *P* = .02). The mean cardiovascular risk score (TC/HDL) decreased from 5.8 ± 1.7 to 4.1 ± 0.6.

Over the 3-year intervention period, 14 patients lost between 5 and 37 pounds, 5 patients maintained an acceptable normal weight, and 3 overweight patients had no change in weight (data not shown).

Table 2 presents the economic costs of medical, physician, and medications each year compared with baseline costs in 2004. Medical costs decreased significantly, with 61%, 55%, and 36% decreases in 2005, 2006, and 2007, respectively. Physician-visit costs decreased significantly, with 37%, 21%, and 50% decreases in 2005, 2006, and 2007, respectively. Total drug costs increased significantly every year: 77%, 120%, and 158% in 2005, 2006, and 2007, respectively. The overall average cost per patient per year decreased compared with the baseline cost in 2004: 35%, 21%, and 12% in 2005, 2006, and 2007, respectively.

In the cost comparison group, the total average cost per patient increased from baseline year 2004: $15,505 ± $3816 to $19,109 ± $5992 in 2005, $23,455 ± $6566 in 2006, and $39,831 ± $10,447 in 2007.

Medications were classified according to their therapeutic class: diabetes, hypertension, cholesterol, antibiotics, and other drugs. Costs of diabetes and hypertension drugs increased significantly in 2006 and 2007 compared with 2004. The cost of cholesterol drugs did not change significantly. Antibiotic costs significantly decreased every year compared with baseline. Other drug costs increased significantly in 2006 and 2007 compared with baseline.

Figure 2 presents the change in mean medical costs (2A), physician costs (2B), drug costs (2C), and diabetes medication/supplies (2D) per patient in the intervention group versus the cost comparison group over the 4-year period. Data showed no significant difference in the intervention group versus the cost comparison group

Table 1. Changes in Cholesterol/Lipid Profile Before and After Disease Management Intervention

Lipid Profile (Clinical Reference)	Mean ± SD: Before Intervention	Mean ± SD: After Intervention	P[a] (n = 22)
Total cholesterol <200 mg/dL	206.5 ± 37.6	179.2 ± 24.1	.243
Triglycerides <150 mg/dL	235 ± 65.3	171.3 ± 54.9	.002
LDL-C <100 mg/dL	140.4 ± 45	105.8 ± 21.5	.22
HDL-C >40-60 mg/dL	36.8 ± 6.1	44.8 ± 6.9	.02
Cardiovascular risk factor score	5.8 ± 1.7	4.1 ± 0.6	.21

HDL-C indicates high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol.
[a]$P \leq .05$ indicates statistical significance.

Table 2. Changes in Medical, Physician, and Medication Costs per Year in the Intervention Group

Type of Cost	Mean ± SD Cost, $ (P)[a]: 2004	2005	2006	2007
Medical	7827 ± 2543	3020 ± 1025 (.06)	3487 ± 1446 (.021)	4995 ± 2925 (.003)
Physician visit	3765 ± 829	2387 ± 434 (.03)	2976 ± 594 (.09)	1911 ± 475 (.001)
All drugs	1939 ± 223	3437 ± 462 (<.001)	4270 ± 523 (<.001)	5011 ± 649 (<.001)
Diabetes	785 ± 112	1111 ± 186 (.073)	1923 ± 317 (<.001)	2107 ± 334 (<.001)
Hypertension	456 ± 78	559 ± 102	692 ± 124	814 ± 132
Lipid lowering	363 ± 79	491 ± 118	480 ± 116	531 ± 122
Antibiotics	231 ± 43	131 ± 33	86 ± 25	127 ± 48
Other drugs	233 ± 46	945 ± 243	812 ± 162	1006 ± 190
Total average cost per patient	13,531 ± 3013	8844 ± 528	10,733 ± 651	11,917 ± 1785
Actual total cost per year[b]	297,707	194,569	236,143	262,196
Saving from baseline year (2004)		103,138	61,564	35,511

[a]P value for cost difference compared with baseline value in 2004. $P \leq .05$ indicates statistical significance.
[b]Actual total cost each year as reported by the third-party plan for all the 22 patients combined.

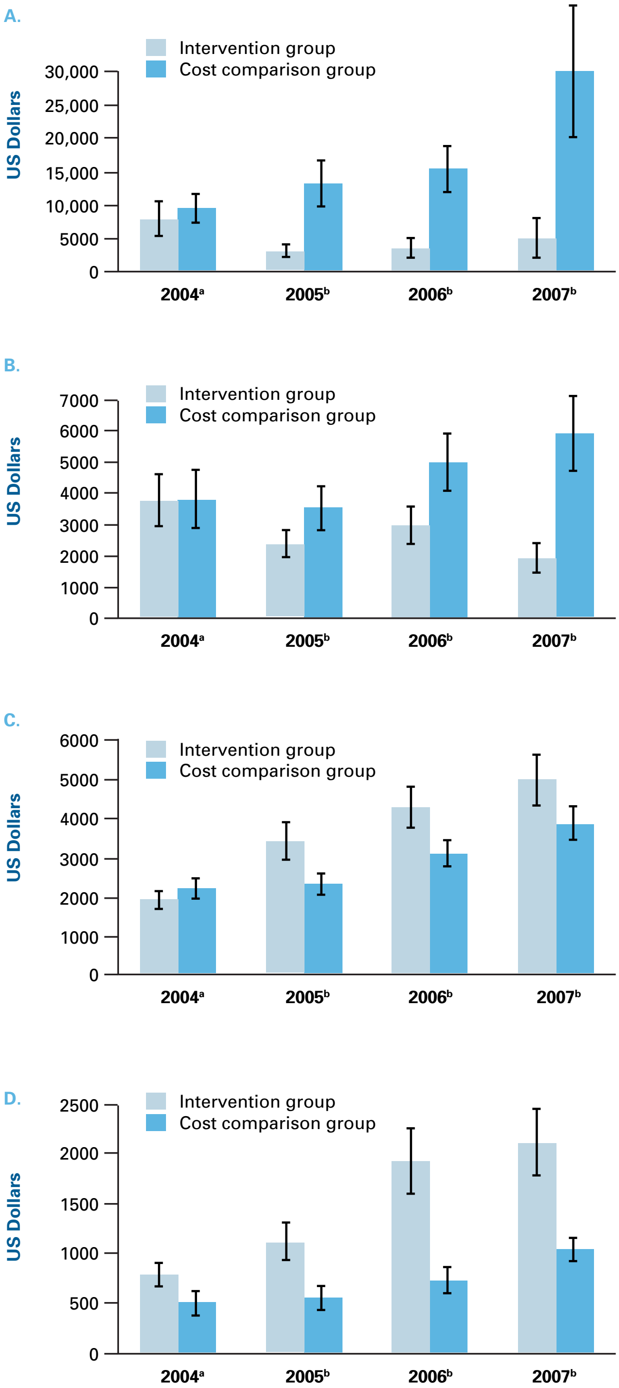
in baseline year 2004 on the 4 outcome measures. Figure 2A shows that mean medical costs in the intervention group significantly decreased from baseline, whereas mean medical costs continued to increase significantly in the cost comparison group in the same period. There also was a significant difference between the 2 groups in each year other than the baseline year.

Figure 2B shows that the cost comparison group had significantly higher costs than the intervention group from 2005 to 2007. Figure 2C shows that the intervention group had significantly more drug utilization than the cost comparison group from 2005 to 2007. Figure 2D shows that the intervention group had significantly higher diabetes medication costs than the comparison group from 2005 to 2007. In the cost comparison group, there was no statistically significant difference in the mean costs of diabetes medication from 2004 to 2006; however, these differences became significant in 2007 compared with 2004.

The cost of hypertension drugs, cholesterol-lowering drugs, and other medications was not statistically different between the intervention group and the cost comparison group (data not shown).

Figure 3 presents the mean antibiotic use each year for the intervention and cost comparison groups over the

Figure 2. Mean Medical Costs (A), Physician Office Visit Costs (B), Total Drug Costs (C), and Costs of Diabetes Drugs and Supplies (D) in the Intervention Group (n = 22) and Cost Comparison Group (n = 46), 2004-2007



[a]No statistically significant difference ($P \geq .05$) between the intervention group and the cost comparison group.

[b]Statistically significant difference ($P \geq .05$) between the intervention group and the cost comparison group.

4-year period. Frequency of antibiotic use was counted per patient per year according to the appearance of antibiotic prescriptions in the pharmacy records, and the means for each group were compared with each other and with the baseline mean. Mean antibiotic use significantly decreased in the intervention group, from 3.2 ± 0.32 (2004) to 2.36 ± 0.4 (2005), 1.64 ± 0.31 (2006), and 1.4 ± 0.28 (2007). However, mean antibiotic use in the cost comparison group increased from 2.8 ± 0.26 (2004) to 3.17 ± 0.32 (2005), 4.26 ± 0.49 (2006), and 4.70 ± 0.49 (2007).

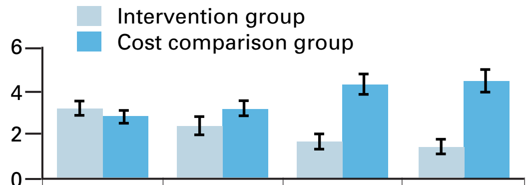
DISCUSSION

The chronic, progressive nature of diabetes creates economic burdens for the healthcare system and negatively affects patients' quality of life. Continuous therapeutic management is required to prevent or delay disease complications. Successful therapeutic management of diabetes by pharmacists has produced positive clinical and economic outcomes, as seen in the Asheville project and similar programs around the country. Five-year outcomes of the Asheville project include the following: A1C decreased by 1.0 percentage point, lipid profile improved in 50% of patients, and cost per patient per year decreased by \$1200 to \$1872.[16] The purpose of our study was to build on and replicate the results of the Asheville study, using 1 pharmacist, a smaller pharmacy system, and significantly fewer resources than were utilized for the Asheville cohort.

We evaluated a diabetes management and education program performed in a community specialty pharmacy by a clinical pharmacist, who provided diabetes therapeutic management along with medication dispensing. The pharmacist was well positioned for this service because of the clinical training received, accessibility to the patients' medication histories, frequent interaction with the patients through counseling on purchased medications (prescription and over-the-counter products), and communication with the patients' healthcare provider(s). Based on pharmacy medication records, the pharmacist developed a strategy to provide diabetes education and a management plan that was constructed following face-to-face interviews. The pharmacist's plan accommodated each patient's health status and health literacy level, and set primary goals to achieve successful clinical and economic outcomes.

In this study, the clinical pharmacist used a socioecological or multilevel model for education to encourage patient compliance with the treatment plan and long-term disease management. The study period of 3 consecutive

Figure 3. **Mean Number of Antibiotic-Utilization Incidents per Patient in the Intervention Group (n = 22) and Cost Comparison Group (n = 46)**



	2004	2005	2006	2007
IG	3.2	2.36	1.64	1.41
CCG	2.8[a]	3.17[a]	4.26[b]	4.4[b]

CCG indicates cost comparison group; IG, intervention group.

[a]No statistically significant difference ($P \geq .05$) between the intervention group and the cost comparison group.

[b]Statistically significant difference ($P \leq .05$) between the intervention group and the cost comparison group.

years was appropriate to evaluate the long-term clinical and cost benefits of the intervention, unlike shorter studies (≤12 months) reported in the literature, with the exception of a few studies like the Asheville project.

Clinical outcomes for the intervention group showed a significant decrease in A1C. Cholesterol/lipid profile measurements showed significant clinical improvement compared with baseline values. Total cholesterol, LDL-C, HDL-C, triglycerides, and cardiovascular risk-factor values reached acceptable clinical goals, despite the fact that differences in TC and LDL-C were not significant. Moreover, because diet modification and regular exercise were essential goals of the program, 14 patients lost weight (5-37 pounds). Five other patients had an acceptable weight, and 3 were overweight with no change.

It has been shown that patients with diabetes are more prone to infection and antibiotic use than patients without diabetes.[33-35] Therefore, we used antibiotic utilization as a measure of diabetes control. The intervention group had significant decreases in antibiotic use: 41% less in 2005, 59% less in 2006, and 65% less in 2007. However, the cost comparison group had significant increases in antibiotic use: 52% in 2006 and 68% in 2007. We chose to compare antibiotic use between groups rather than antibiotic costs because of the variability of medication price for each kind of infection. We speculate that less antibiotic use reflected achievement in long-term glycemic control and successful clinical outcomes.

The intervention group had statistically significant decreases in medical and physician visit costs and a statistically significant increase in medication costs compared with 2004 baseline costs. Medical and physician costs decreased 55% in 2005, 45% in 2006, and 41% in 2007. Medication cost increased 77% in 2005, 120% in 2006, and 158% in 2007. The overall average cost per patient per year decreased 35% in 2005, 21% in 2006, and 12% in 2007.

The decrease in medical costs was associated with a decrease in number of hospitalizations and emergency department visits (69% fewer, data not shown). Similarly, the decreased cost of physician office visits was associated with a decrease in primary care clinic visits; however, visits to an endocrinologist did not change or slightly increased in the second year of intervention because of referrals (data not shown). The management program did not replace physician visits; rather, it may have decreased unnecessary higher-cost visits, which perhaps would have resulted from infection incidents and other symptoms arising from lack of disease education and self-management.

The decrease in physician visit costs may be explained by decreased antibiotic utilization and infections because of better diabetes self-management. This observation is supported by patient-reported health improvement because of understanding diabetes self-management, adherence to the diabetes education program, increased compliance with diabetes medication, and subsequent improvement of A1C. The increase of diabetes medication costs was the result of patient compliance with refills, changes in drug therapy, and increased inflation. One might argue that compliance with diabetes medications might have been the result of the drug copayment waiver as an incentive to participate in the program; however, the waiver was restricted to diabetes medication only and patients in the intervention group were more compliant with all medications (not only the diabetes medication) compared with the cost comparison group. Reaching clinical goals for blood glucose levels and cholesterol/lipid profile was another indication of increased patient education and compliance with all medications to maintain the required therapeutic management of diabetes.

Mean medical and physician visit costs all were higher in the cost comparison group. Medical costs were 4 to 6 times higher in the cost comparison group than in the intervention group, whose costs decreased significantly from baseline. Mean physician visit costs were 1.6 to 3 times higher in the cost comparison group than in the intervention group. Both groups showed an increase in total medication costs, with a slightly higher increase in the intervention group compared with the cost comparison group. The intervention group had significantly higher diabetes medication costs. Costs for hypertension and cholesterol-lowering drugs were slightly higher in the intervention group than in the comparison group; however, the increase did not significantly contribute to the overall increase in the total medication cost. These data indicate that decreased compliance with diabetes medication in the cost comparison group (data not shown) was the underlying cause of the uncontrolled diabetes. This notion is supported by an increased incidence of infection in the cost comparison group.

The total average cost per patient in the cost comparison group continued to increase from $15,505 in 2004 to $19,109, $23,455, and $39,831 over the 3-year period. However, the mean total cost per patient in the intervention group decreased from $13,531 to $8844 in the first year of the intervention, and the mean cost per patient continued to be lower than baseline cost in the following 2 years: $10,733 and $11,917. Actual medical and physician visit costs were much lower than the baseline costs in the intervention group. Despite the increase in medication costs, the program saved $177,213 for 22 patients over the 3-year period, even after subtracting the cost of the pharmacy education service, which was a flat fee per patient per year regardless of the number of interactions with the pharmacist. The difference between the average cost for intervention group patients ($990,615) and the average cost for 22 patients in the comparison group ($2,153,855) was $1,163,240 over the 4-year period, including baseline year costs.

The clinical and cost data combined demonstrate the long-term, significant impact of a diabetes education and management program that can be established in a readily accessible community pharmacy with multiple locations. The study design was unique as it measured clinical outcomes and cost outcomes, including all patient costs incurred by a third-party health plan. Moreover, the study reported the intervention outcomes in the same patient sample for 4 consecutive years. Despite the small sample size, the program showed significant clinical improvement of A1C, lipid profile, and infection incidence, along with total medical cost savings for the employer.

Maintaining disease control for 3 years during the intervention and decreasing medical costs below their baseline levels indicated the sustainability of the program over a long period. This service demonstrated that continued patient interaction with the same pharmacist in a structured disease management program is the key element to sustaining disease control. This program ensured consistent teaching of patients, improved compliance with individual treatment plans, enabled immunization records to be kept current, provided continuous training on disease self-management, and accommodated needs for immediate intervention(s) to maintain clinical goals.

Several limitations of this work should be noted. First, a weakness of design involves the self-selection bias inherent in the way the study subjects were recruited and enrolled. Undoubtedly, those patients who elected to enroll in this disease management program had stronger motivation to comply with and learn techniques for blood sugar management than the average patient with diabetes. This variable could have led to better clinical outcomes. Second, the comparison group was not randomly selected; rather, patients matched on age, sex, disease state, and baseline costs were pulled from the health benefits pool and constituted a convenience group. Also, these patients' clinical outcomes could not be tracked for comparison over time, with the exception of gross costs and utilization patterns. These factors limit the validity of our conclusions about the differences between the intervention and control groups.

Attrition bias must be acknowledged. This was a community-based study of patients followed over a long period of time, which always results in substantial attrition for various reasons such as noncompliance, patients relocating or dropping out of the program, or new diagnoses. We did not follow up with those patients who dropped out over the course of the intervention, which could have resulted in bias toward positive patient outcomes in the absence of a strong control group. Reporting on outcomes of the dropouts (even via an informal phone survey) would strengthen confidence in the clinical outcomes and cost data reported for the intervention group and could serve as a secondary comparison group.

In addition, cost data were biased in that the control group had higher baseline costs that were sustained throughout the study period. Aggregating costs into medicine, physician visit, and emergency department visit categories may have rendered the findings more interpretable and allowed for more meaningful comparisons between the intervention and control groups. Lastly, future studies should be based on randomized controlled trials with a larger patient sample to support the hypothesis that implementing an effective diabetes education program will have significant clinical and cost-saving outcomes in community pharmacy. Follow-up studies should measure improvements in patient behavior, as well as evaluate qualitative patient variables that may impact the clinical outcomes.

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