The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program

Carole W. Cranor, Barry A. Bunting, and Dale B. Christensen

Objective: To assess the persistence of outcomes for up to 5 years following the initiation of community-based pharmaceutical care services (PCS) for patients with diabetes. **Design:** Quasi-experimental, longitudinal pre–post cohort study. **Setting:** Twelve community pharmacies in Asheville, N.C. **Patients and Other Participants:** Patients with diabetes covered by self-insured employers' health plans. Community pharmacists trained in a diabetes certificate program and reimbursed for PCS. **Interventions:** Education by certified diabetes educators, long-term community pharmacist follow-up using scheduled consultations, clinical assessment, goal setting, monitoring, and collaborative drug therapy management with physicians. **Main Outcome Measures:** Changes in glycosylated hemoglobin (A1c) and serum lipid concentrations and changes in diabetes-related and total medical utilization and costs over time. **Results:** Mean A1c decreased at all follow-ups, with more than 50% of patients demonstrating improvements at each time. The number of patients with optimal A1c values (< 7 %) also increased at each follow-up. More than 50% showed improvements in lipid levels at every measurement. Multivariate logistic regressions suggested that patients with higher baseline A1c values or higher baseline costs were most likely to improve or have lower costs, respectively. Costs shifted from inpatient and outpatient physician services to prescriptions, which increased significantly at every follow-up. Total mean direct medical costs decreased by $1,200 to $1,872 per patient per year compared with baseline. Days of sick time decreased every year (1997–2001) for one employer group, with estimated increases in productivity estimated at $18,000 annually. **Conclusion:** Patients with diabetes who received ongoing PCS maintained improvement in A1c over time, and employers experienced a decline in mean total direct medical costs.

Keywords: Asheville Project, pharmaceutical care, diabetes, quality of life, health care costs, health outcomes.

J Am Pharm Assoc. 2003;43:173–84.

Research has demonstrated that educational interventions by health care providers help patients with diabetes make the behavioral changes needed to improve glycemic control[1,2] and that ade-

Carole W. Cranor, PhD, is pharmacoeconomist, PPD Development, Inc., Morrisville, N.C. At the time of the study she was a graduate student at the University of North Carolina–Chapel Hill. Barry A. Bunting, PharmD, is clinical manager of community pharmacy services, Diabetes and Health Education Center, Mission–St. Joseph's Health System, Asheville, N.C.. Dale B. Christensen, PhD, is Mescal S. Ferguson Professor and chairman, Division of Pharmaceutical Policy and Evaluative Sciences, School of Pharmacy, University of North Carolina–Chapel Hill.

Correspondence: Carole W. Cranor, PhD, Health Outcomes and Marketing Research, PPD Development, Inc., 3900 Paramount Parkway, Morrisville, NC 27560. Fax: 919-654-8570. E-mail: carole.cranor@ rtp.ppdi.com.

quate metabolic control reduces diabetes-related morbidity and mortality.[3] However, a recent meta-analysis revealed that such improvements in glycemic control tend to decline within 3 months after the educational intervention ceases.[2] Because patients visit pharmacies more than any other health care setting,[4] pharmacists are well placed to reinforce and maintain the effectiveness of such interventions through expanded pharmaceutical care services (PCS) to patients with diabetes. As PCS become more prevalent, interest in their long-term effectiveness is expected to increase as well. The study described here is unique in that it is the first to assess, for periods as long as 5 years, the clinical and economic outcomes of community pharmacy-based PCS in patients with diabetes.

Objectives

This research was part of a larger study, the purpose of which was to assess the clinical, economic, and humanistic outcomes of

PCS provided for two employer groups of patients with diabetes in 12 community pharmacies in Asheville, N.C. The specific objectives of the larger study, known as the Asheville Project were to assess the short-term outcomes after the first 7 to 9 months of PCS,[5] to evaluate the effect of PCS interventions on these short-term outcomes when controlling for other factors,[6] and to assess the persistence of outcomes after up to 5 years of PCS.

In this article, we address the third objective, building on the results of two previous quasi-experimental, pre–post cohort-with-comparison group analyses (see pages 149 and 160 of this issue of *JAPhA*) that addressed the first two objectives by evaluating the short-term outcomes of PCS for patients with diabetes.[5,6] In the accompanying articles, we describe how we assessed potential threats to internal validity by comparing the experiences of patients in the first group to receive PCS interventions with those of patients in the second group, who enrolled later.[5,6] That analysis provided justification for combining the groups, thus increasing sample size and analytical power. In the earlier studies we used bivariate and multivariate methods to demonstrate that patients with diabetes who participated in the Asheville Project experienced improvement in glycosylated hemoglobin (A1c) concentrations and improved satisfaction with pharmacy services, without incurring increases in direct health care costs. The earlier multivariate analyses suggested that characteristics associated with the employer group affected certain outcomes; thus, in this analysis we also controlled for group effects using similar logistic regression methods.[6]

Methods

Setting

The setting for this study was Asheville, N.C. Two employers offered their employees with diabetes an identical health care ben-efit, described as an employer-sponsored wellness program. City of Asheville employees (group 1) began enrolling in March 1997, whereas employees of the Mission–St. Joseph's Health System (MSJ) (group 2) began in March 1999. The unique components of the program were PCS provided by community pharmacists who were reimbursed for their cognitive services, the availability of a diabetes education center (DEC) that employed certified diabetes educators, and patient participation incentives, including a home blood glucose monitor and waiver of co-payments for all diabetes drugs and supplies. All of the participating pharmacists received focused diabetes education training. The patients and pharmacists were not required to adhere to a specific protocol. Rather, PCS were incorporated into the usual care process. All patients provided informed consent before starting the program.

This study was approved by the Institutional Review Boards of MSJ and the University of North Carolina–Chapel Hill (UNC) School of Medicine and the UNC Hospitals Committee on the Protection of the Rights of Human Subjects.

Intervention

The PCS benefit consisted of consultation with a community-based pharmacist. Patients were provided the opportunity to meet with pharmacists at no cost to set and monitor treatment goals and to receive diabetes education, home glucose meter training, and information about adherence to their regimen. Pharmacists also performed physical assessments of patients' feet, skin, blood pressure, and weight. Appropriate lipid management was a key component of the educational intervention. In addition, pharmacists referred patients to their physician or the DEC, as needed. As an incentive to participate, patients received a free home blood glucose monitor and a waiver of co-payments for diabetes-specific drugs and supplies.

Table 1. Baseline Characteristics for Patients Remaining in the Clinical Cohort at Each Follow-up

| Baseline Characteristic | Baseline n = 187[b] | Follow-up[a] | | | | | | |
		1 n = 136[c]	2 n = 81[c]	3 n = 55[c]	4 n = 39[c]	5 n = 26[c]	6 n = 16[c]	7 n = 11[c]
Age, years								
Median	48.0	48.0	49.0	50.0	50.0	49.0	53.5	54.0
Mean ± SD	47.7 ± 11.1	48.8 ± 10.7	49.3 ± 11.1	50.3 ± 9.4	50.5 ± 8.7	49.8 ± 8.6	52.1 ± 4.8	52.5 4.6
Min, Max	17, 80	17, 80	17, 80	23, 80	23, 71	23, 64	44, 60	44, 59
Males, no. (%)	91 (49)	71 (52)	46 (57)	34 (61)	24 (62)	18 (69)	10 (63)	7 (64)
White, no. (%)	155 (83)	115 (85)	69 (85)	49 (89)	34 (87)	22 (85)	13 (81)	10 (91)
Type 1 diabetes, no. (%)	50 (27)	33 (24)	21 (26)	12 (22)	5 (13)	3 (12)	1 (6)	1 (9)
Baseline A1c (%)[d]								
Median	7.5	7.6	7.4	7.2	7.1	7.2	7.0	8.0
Mean ± SD	7.8 ± 1.9	7.9 ± 2.1	7.7 ± 2.0	7.7 ± 2.1	7.7 ± 2.3	8.0 ± 2.6	8.0 ± 2.8	7.9 ± 1.9

A1c = glycosylated hemoglobin; SD = standard deviation.
[a]Follow-up periods defined as 6-month intervals following baseline.
[b]No. of patients with at least one pharmaceutical care visit preceded by a baseline A1c before December 31, 2001. Note: At the time of this study, some patients did not have a follow-up A1c reported due to insufficient time in the cohort.
[c]No. of patients with both baseline and follow-up A1c values at each time.
[d]4.4%–6.4% is expected range in people without diabetes; target range for people with diabetes is < 7.0%.

Design

This was a quasi-experimental, longitudinal, pre–post cohort-with-comparison group study. Subjects were City of Asheville or MSJ employees with diabetes who accepted their employer's offer of an additional health care benefit at no charge. The PCS providers were community pharmacists who had received certificate training in diabetes care. Further details regarding setting, participants, and interventions are provided elsewhere.[5,6]

Inclusion Criteria

Patients were assigned to a clinical cohort and/or an economic cohort based on their available baseline data. Patients who enrolled in the program between March 1997 and December 2001 were eligible for inclusion if they had at least one PCS visit and if data were available on the patient's baseline A1c concentration within 6 months before any intervention (clinical cohort) and/or health care costs documented by insurance and prescription claims for at least 6 months preceding their enrollment in the study (economic cohort).

Study Timeline

The patients began enrolling in March 1997, and the last patients enrolled in December 2001. The cohort baseline year was defined as the year preceding enrollment. For example, patients who enrolled in March 1997 were assigned 1996 as their baseline year. Patients who met the inclusion criteria were followed through December 2001 provided they continued to participate and their data were available.

Outcome Definitions

The clinical outcomes assessed in this study were changes from pre-PCS (baseline) values for A1c, low-density lipoprotein cholesterol (LDL-C), and high-density lipoprotein cholesterol (HDL-C). For the bivariate analyses, these changes were expressed as the median and mean changes over time. For the analyses in which the proportion or number of patients with improved clinical outcomes was assessed and in the multivariate analyses, any improvement over baseline was defined as improvement. Optimal values were based on the American Diabetes Association (ADA) guidelines.[7] Specifically, optimal A1c was defined as A1c less than 7%; optimal LDL-C was less than 100 mg/dL; and optimal HDL-C was greater than 45 mg/dL for men or greater than 55 mg/dL for women.

To determine the economic outcomes of the PCS project, we looked at change in direct medical costs during the same time periods. For the bivariate assessments of median and mean change from baseline (continuous variables), we compared the actual decrease or increase in dollar value. For the analyses in which the proportion or number of patients with decreased costs was assessed and in the multivariate regression, we defined a decrease in cost as at least a 10% decrease over baseline. Given the inherently skewed distribution of cost data, we considered a reduction

Table 2. Patients With A1c Reports at Each Follow-up Time by Baseline Year[a]

Cohort Baseline Year	Baseline No. (%)[c]	Follow-up[b]						
		1 No. (%)[c]	2 No. (%)[c]	3 No. (%)[c]	4 No. (%)[c]	5 No. (%)[c]	6 No. (%)[c]	7 No. (%)[c]
1996	37 (27.2)	37 (27.2)	35 (43.2)	30 (54.5)	27 (69.2)	22 (84.6)	16 (100)	11
1997	11 (8.1)	11 (8.1)	10 (12.3)	7 (12.7)	5 (12.8)	2 (7.7)	0	NA
1998	24 (17.6)	24 (17.6)	17 (21.0)	13 (23.6)	7 (17.9)	2 (7.7)	NA	NA
1999	31 (22.8)	31 (22.8)	16 (19.8)	5 (9.1)	NA	NA	NA	NA
2000	20 (14.7)	20 (14.7)	3 (3.7)	NA	NA	NA	NA	NA
2001	13 (9.6)	13 (9.6)	NA	NA	NA	NA	NA	NA
All years total	136	136	81	55	39	26	16	11
All years: cohort-eligible[d]	136	136	134	122	113	108	103	99
Not eligible: left employment or dropped insurance[e]	NA	NA	4 (2.9)	3 (2.2)	2 (1.6)	0	0	0
Not eligible: inadequate time in cohort at designated follow-up[e]	NA	NA	22 (16.2)	7 (5.2)	7 (5.7)	5 (4.4)	5 (4.6)	4 (3.9)
Not eligible: expired[e]	NA	NA	0	2 (1.5)	0	0	0	0
Eligible: no data reported for period[e]	NA	NA	29 (21.3)	15 (11.2)	6 (4.9)	8 (7.1)	4 (4.6)	1 (0.97)

A1c = glycosylated hemoglobin; NA = not applicable.
[a]Inclusion criteria: Each patient must have a baseline A1c and at least one follow-up A1c. Baseline A1c must have been obtained within 6 months prior to the first PCS visit.
[b]Follow-up periods defined as 6-month intervals following baseline.
[c]No. = the number of laboratory values reported at each time; % = % of all years total.
[d]Cohort eligible = all years total – not eligible from prior period.
[e]Denominator for percentages = n from previous all years: cohort eligible (lagged).

of at least 10% from baseline to be meaningful from the payers' perspective. Direct medical costs were defined as the amount paid by the employer (as the payer) for physician visits, hospitalization, emergency department visits, laboratory tests, prescription drugs and diabetes supplies, cognitive PCS, MSJ DEC fees, and co-payment waivers. Change in the number of sick days missed from work was also assessed for group 1, but this information was not available for group 2.

Finally, patients were asked questions pre- and post-PCS regarding their adherence to national diabetes care guidelines. Specifically, we asked patients to report the frequency of their A1c

determinations and foot exams, and whether they currently used an angiotensin-converting enzyme inhibitor (ACEI) and self-tested their blood glucose concentrations.

Data Sources

Demographic data were obtained from the patients during an initial baseline interview and from medical records. Clinical data were gathered from patients' laboratory reports. Data regarding direct costs of care were obtained from patients' medical records, insurance and prescription claims, and employer records.[5]

Table 3. Changes Over Time in A1c Concentrations

Time of Measurement (n)	Baseline A1c (%)[a] Median Mean ± SD	Follow-up A1c (%)[a] Median Mean ± SD	Change From Baseline A1c (%)[b] Median Mean ± SD	P[c]	Patients Improved No. (%)
1st follow-up[d] (136)	7.6 7.9 ± 2.1	6.6 6.8 ± 1.3	−0.8 −1.1 ± 1.9	< .0001	102 (75.0)
2nd follow-up (81)	7.4 7.7 ± 2.0	6.5 6.7 ± 1.3	−0.7 −1.1 ± 1.9	< .0001	56 (69.1)
3rd follow-up (55)	7.2 7.7 ± 2.1	6.8 6.9 ± 1.1	−0.5 −0.9 ± 2.0	.002	37 (67.3)
4th follow-up (39)	7.1 7.7 ± 2.3	6.8 6.9 ± 1.2	−0.4 −0.8 ± 2.3	.07[e]	23 (59.0)
5th follow-up (26)	7.2 8.0 ± 2.6	6.9 7.1 ± 1.2	−0.4 −0.9 ± 2.7	0.26[e]	15 (57.7)
6th follow-up (16)	7.0 8.0 ± 2.8	6.7 6.8 ± 0.9	−0.8 −1.2 ± 2.8	.13[e]	11 (68.8)
7th follow-up (11)	8.0 7.9 ± 1.9	6.8 6.8 ± 0.8	−1.0 −1.1 ± 1.7	.05	9 (81.8)

A1c = glycosylated hemoglobin; SD = standard deviation.
[a]Expected range in people without diabetes is 4.4%–6.4%; target range for people with diabetes is < 7.0%.
[b]Follow-up minus baseline (a negative number indicates improvement over baseline).
[c]Wilcoxon signed rank test for paired data (H0: difference = 0). Unadjusted P values are shown. Using the Bonferroni adjustment for 7 tests, the significant P value would be .007 under the assumption that the critical value of P = .05 for only one test of significance.
[d]Follow-up periods defined as 6-month intervals following baseline.
[e]Power to detect a difference of 10% or more < .60.

Table 4. Number of Patients With Optimal A1c at Each Follow-up[a]

Time of Measurement (n)	Baseline A1c No. (%)	Follow-up A1c No. (%)	Change From Baseline[b] No. (% Change)	P[c]
1st follow-up[d] (136)	52 (38.2)	85 (62.5)	33 (24.3)	< .0001
2nd follow-up (81)	32 (39.5)	54 (66.7)	22 (27.2)	.0001
3rd follow-up (55)	23 (41.8)	33 (60.0)	10 (18.2)	.02
4th follow-up (39)	18 (46.2)	21 (53.8)	3 (7.7)	.44[e]
5th follow-up (26)	12 (46.2)	14 (53.9)	2 (7.7)	.53[e]
6th follow-up (16)	8 (50.0)	10 (62.5)	2 (12.5)	.41[e]
7th follow-up (11)	5 (45.5)	7 (63.6)	2 (18.2)	.32[e]

A1c = glycosylated hemoglobin.
[a]Optimal value < 7%.
[b]Follow-up minus baseline.
[c]McNemar χ^2 (H0: change = 0). Unadjusted P values are shown. Using the Bonferroni adjustment for 7 tests, the significant P value would be .007 under the assumption that the critical value of P = .05 for only one test of significance.
[d]Follow-up periods defined as 6-month intervals following baseline.
[e]Power to detect a difference of 10% or more < .50.

Information on patient self-care behaviors was obtained from the aforementioned questionnaires.

Data Measurement

In this intention-to-treat (ITT) study, all patients were required to have at least one PCS visit. All patients who met the inclusion criteria and had at least one PCS intervention were included in subsequent follow-up analyses whenever possible. ITT patients were analyzed with their original cohort based on their original baseline year. Patients who had missing clinical or PCS data were included if they had complete insurance claims data for the study period. Imputation was not used for missing clinical data, although, as described below, we used it to annualize claims data for patients with an employment history of less than 12 months but at least 6 months. Enrollment in the program was ongoing during the 5 years assessed in this analysis, and this evaluation reflected real-life (rather than research protocol-driven) health care services delivery. PCS visits were scheduled on an individual basis to meet the needs of each patient but did not occur at rigidly defined time intervals. Patients' A1c, LDL-C, and HDL-C concentrations were thus measured at baseline and approximately every 6 months thereafter.

Direct medical costs were recorded throughout each patient's

Table 5. Changes Over Time in LDL-C Concentrations

Time of Measurement (n)	Baseline LDL-C (mg/dL)[a] Median Mean ± SD	Change From Baseline LDL-C (mg/dL)[b] Median Mean ± SD	P[c]	Patients Improved No. (%)
1st follow-up[d] (122)	110 116 ± 37.9	−2.5 −4.2 ± 32.2	.13[e]	65 (53.3)
2nd follow-up (70)	110 115 ± 38.5	−4.5 −6.5 ± 34.8	.16[e]	38 (54.3)
3rd follow-up (43)	108 109 ± 39.0	−7 −9.3 ± 30.3	.05[e]	26 (60.5)
4th follow-up (29)	104 105 ± 44.2	−5 −6.4 ± 32.7	.41[e]	17 (58.6)
5th follow-up (19)	106 112 ± 44.8	−5 −3.2 ± 36.1	.72[e]	10 (52.6)
6th follow-up (12)	106 103 ± 53.5	−0.5 −8.3 ± 43.7	.53[e]	6 (50.0)
7th follow-up (9)	104 94 ± 58.5	−18 −6.4 ± 43.5	.37[e]	6 (66.7)

LDL-C = low-density lipoprotein cholesterol; SD = standard deviation.
[a]Optimal value < 100 mg/dL.
[b]Follow-up minus baseline (a negative number indicates improvement over baseline).
[c]Wilcoxon signed rank for paired data (H0: difference = 0). Unadjusted P values are shown. Using the Bonferroni adjustment for 7 tests, the significant P value would be .007 under the assumption that the critical value of P = .05 for only one test of significance.
[d]Follow-up periods defined as 6-month intervals following baseline.
[e]Power to detect a difference of 10% or more < .50.

Table 6. Number of Patients With Optimal LDL-C at Each Follow-up[a]

Time of Measurement (n)	Baseline LDL-C No. (%)	Follow-Up LDL-C No. (%)	Change From Baseline[b] No. (% Change)	P[c]
1st follow-up[d] (122)	44 (36.1)	47 (38.5)	3 (2.4)	.61[e]
2nd follow-up (70)	25 (35.7)	31 (44.2)	6 (8.5)	.20[e]
3rd follow-up (43)	16 (37.2)	25 (58.1)	9 (20.9)	.02
4th follow-up (29)	13 (44.8)	16 (55.2)	3 (10.4)	.26[e]
5th follow-up (19)	6 (31.6)	9 (47.4)	3 (15.8)	.18[e]
6th follow-up (12)	4 (33.3)	6 (50.0)	2 (16.7)	.32[e]
7th follow-up (9)	4 (44.4)	4 (44.4)	0	NA

LDL-C = low-density lipoprotein cholesterol; NA = not applicable.
[a]Optimal value < 100 mg/dL.
[b]Follow-up minus baseline.
[c]McNemar χ^2 (H0: change = 0). Unadjusted P values are shown. Using the Bonferroni adjustment for 7 tests, the significant P value would be .007 under the assumption that the critical value of P = .05 for only one test of significance.
[d]Follow-up periods defined as 6-month intervals following baseline.
[e]Power to detect a difference of 10% or more < .50.

participation in the project. A minimum of 6 months of preintervention insurance claims was required. We converted all costs to costs per patient per year and adjusted to 2001 U.S. dollars using the U.S. Consumer Price Index for Medical Care. If patient cost data were available for at least 6 months but less than a full year, we annualized costs for that year. This adjustment applied to patients who joined the plan at midyear and those who left the plan or study at midyear.

We compared data with baseline values at each follow-up time. At each follow-up point, we reported the number of patients not eligible or lost to follow-up (LTF) and the reason (e.g., disenrolled, insufficient time in cohort, expired, data missing or not available). In some instances, patient data not available for one follow-up period were available for a subsequent period.

We tracked patients by length of time in the program. To assess cohort effects, we examined differences in baseline patient characteristics and differences in pre- to post–follow-up by enrollment year. In the multivariate logistic regression analyses, we also included an indicator variable for baseline year.

Since clinical laboratory values, such as A1c and LDL-C concentrations, could have been determined during any calendar month, we analyzed the reported value that was closest to either of two dates: December 1 and June 1 of each calendar year. Missing LDL-C values were sometimes due to triglyceride concentrations above 400 mg/dL, the maximum value at which the laboratory is able to calculate LDL-C.

We reported patient age as of the study entry date. Baseline data were collected for the 6-month period most closely approximating the enrollment date. In some cases, patients had clinical laborato-

ry data recorded at baseline and follow-up but did not have baseline cost data. In these cases, we included them for the clinical outcome analysis but not the cost outcome analysis. Similarly, patients who had baseline and follow-up cost data but no baseline clinical data were included in the cost analyses but not the clinical analyses.

Data Analysis

For most analyses, we combined data from both groups to create one large cohort. Differences between employer groups were assessed by inclusion of an indicator variable for group in multivariate logistic regressions. Similarly, patient demographics, baseline status, and baseline year were controlled as covariates in the multivariate analyses.

The analyses compared outcomes from the pre-PCS baseline to each available follow-up date using nonparametric statistics for paired data. For continuous data, we used the Wilcoxon signed rank test, and for counts, we used the McNemar χ^2 test. Because multiple comparisons were involved, we adjusted the critical P value for statistical tests accordingly under the assumption that a critical value of P is .05 for only one test of significance. The most conservative of the adjustment methods is the Bonferroni correction. Our major end points for comparison were 1-year follow-ups from baseline, although we displayed 6-month follow-ups as well. Using this most conservative correction, the equivalent critical P value is .01 for five follow-up comparison time periods. If all seven follow-up measures were considered, the equivalent critical P value would be .007. We did not use repeated measures analysis

Table 7. Changes Over Time in HDL-C Concentrations

Time of Measurement (n)	Baseline HDL-C (mg/dL)[a] Median Mean ± SD	Change From Baseline HDL-C (mg/dL)[b] Median Mean ± SD	P[c]	Patients Improved No. (%)
1st follow-up[d] (124)	44.5 46 ± 13	1 1.10 ± 7.9	.05[e]	69 (55.7)
2nd follow-up (72)	44.5 46 ± 14	2 1.5 ± 7.8	.08[e]	41 (56.9)
3rd follow-up (46)	43 46 ± 16	2.5 1.9 ± 8.0	.04	27 (58.7)
4th follow-up (30)	44.5 46 ± 16	1 1 ± 7.8	.27[e]	16 (53.3)
5th follow-up (20)	44.5 48 ± 17	5 3.3 ± 11.4	.07[e]	15 (75.0)
6th follow-up (10)	47 46 ± 17	3.5 5.0 ± 6.8	.05[e]	7 (70.0)
7th follow-up (10)	44 46 ± 17	1.5 0.5 ± 6.9	.28[e]	6 (60.0)

HDL-C = high-density lipoprotein cholesterol; SD = standard deviation.
[a]Optimal value > 55 mg/dL for women and > 45 mg/dL for men.
[b]Follow-up minus baseline (a positive number indicates improvement over baseline).
[c]Wilcoxon signed rank test for paired data (H0: difference = 0). Unadjusted P values are shown. Using the Bonferroni adjustment for 7 tests, the significant P value would be .007 under the assumption that the critical value of P = .05 for only one test of significance.
[d]Follow-up periods defined as 6-month intervals following baseline.
[e]Power to detect a difference of 10% or more < .50.

of variance because of the varying cohort size and composition at each follow-up time period.

Results

This section summarizes patients' baseline characteristics, and the clinical and economic outcomes for the cohort over the course of the study.

Patients' Baseline Characteristics

Overall, 194 patients met the inclusion criteria of at least one PCS visit and data on baseline A1c within 6 months before any intervention (clinical cohort) and/or health care costs documented by insurance and prescription claims for at least 6 months preceding their enrollment in the study (economic cohort). Of those, 187 were eligible for the clinical cohort, 164 for the economic cohort, and 157 for both the economic and clinical cohorts.

Table 1 summarizes the baseline characteristics of the members of the clinical cohort remaining at each follow-up time period. All patients with a baseline A1c measurement obtained by December 31, 2001, are included in this table. Baseline demographic characteristics (age, sex, and race) did not differ substantially over time, with a few exceptions. Mean baseline age increased slightly for patients remaining at the later follow-up times. The proportion of patients with type 1 diabetes decreased from 27% at baseline to 12% at the fifth follow-up. Mean baseline A1c values for patients still in the study at the fifth, sixth, and seventh follow-up periods were slightly higher than the baseline mean for the entire clinical cohort.

Table 2 summarizes the number of patients with A1c reports at each follow-up by patient baseline year, including reasons why patients were LTF or no longer eligible at each follow-up. Patients accounted for in Table 2 had a baseline A1c and at least one fol-low-up A1c before December 31, 2001. The sample size for the baseline is thus smaller in this table than in Table 1. There were 136 patients in the cohort who met the inclusion criteria. The sample size decreased over time as more patients were LTF or became ineligible for additional follow-up due to later enrollment. Overall, among patients who were LTF because they were no longer eligible, 2 had died, 9 left employment, and 50 late enrollees were not in the study long enough to have follow-up A1c data at every measurement. Over the course of the study, 63 patients were considered eligible for the cohort but did not have A1c data reported.

Clinical Outcomes

Table 3 summarizes the change in A1c from baseline at each follow-up for patients remaining in the program. Mean A1c decreased (i.e., improved) at every follow-up. Additionally, at every follow-up, 57.7% to 81.8% of patients were improved, compared with baseline. Further, the number of patients with optimal A1c values (i.e., A1c < 7%)[8] increased (see Table 4). At the first follow-up, 24.3% more patients had optimal A1c values, and increases of 27.2% and 18.2% were noted at the second and third follow-ups, respectively.

Mean LDL-C decreased (improved) at every follow-up, although the magnitude of the change was small (see Table 5). The percentage of patients with improved LDL-C values was 50.0% to 66.7% at each follow-up. Table 6 summarizes the percentage of patients who achieved optimal LDL-C (< 100 mg/dL)[8] values at each time. At the first six follow-ups the percentage of patients with optimal LDL-C increased, with a range from 2.4% to 20.9% increase over baseline.

Tables 7 and 8 summarize the HDL-C values over time. Mean HDL-C increased (improved) at every follow-up. Similar to LDL-C outcomes, 53.3% to 75.0% of patients experienced improved HDL-C at every measurement. We also observed an increase in the number of patients achieving optimal HDL-C[8] values at each time.

Table 8. Number of Patients With Optimal HDL-C at Each Follow-up[a]

Time of Measurement (n)	Baseline HDL-C No. (%)	Follow-up HDL-C No. (%)	Change From Baseline[b] No. (% Change)	P[c]
1st follow-up[d] (124)	37 (29.8)	42 (33.9)	5 (4.0)	.28[e]
2nd follow-up (72)	19 (26.4)	25 (34.7)	6 (8.3)	.11[e]
3rd follow-up (46)	12 (26.1)	17 (37.0)	5 (10.9)	.06[e]
4th follow-up (30)	7 (23.3)	12 (40.0)	5 (16.7)	.06[e]
5th follow-up (20)	5 (25.0)	8 (40.0)	3 (15.0)	.18[e]
6th follow-up (10)	1 (10.0)	6 (60.0)	5 (50.0)	.03
7th follow-up (10)	2 (20.0)	3 (30.0)	1 (10.0)	.56[e]

HDL-C = high-density lipoprotein cholesterol.
[a]Optimal value > 55 mg/dL for women and > 45 mg/dL for men.
[b]Follow-up minus baseline.
[c]McNemar χ^2 (H0: change = 0). Unadjusted P values are shown. Using the Bonferroni adjustment for 7 tests, the significant P value would be .007 under the assumption that the critical value of $P = .05$ for only one test of significance.
[d]Follow-up periods defined as 6-month intervals following baseline.
[e]Power to detect a difference of 10% or more < .50.

Finally, Figure 1 demonstrates the percentage of patients at each follow-up who achieved A1c, LDL-C, and HDL-C concentrations in the optimal range.

Economic Outcomes

Economic outcomes are reported by calendar year (January through December) for the baseline year and each follow-up year (see Tables 9 and 10, Figure 2). All costs are in U.S. dollars adjusted to the year 2001. Costs are defined as the amount paid per patient per year (PPPY) by the employers as the primary insurers (payers' perspective). Costs from insurance claims included physician visits, hospitalizations, emergency department visits, and laboratory tests. Prescription costs included prescription drugs and supplies, and are categorized as diabetes-specific drugs and supplies, drugs and supplies for other diagnoses, and drugs and supplies for all diagnoses. Costs for PCS reimbursement and prescription co-payment waivers could not be accurately disaggregated for several reasons. Initially, due to the uniqueness of the program, PCS reimbursement record keeping was inconsistent. During later years, the service fees for PCS visits were included in group 2's insurance claims and group 1's prescription claims. Both employers changed third party providers during the study, resulting in variations in the structure of the claims data that made it impossible to accurately estimate the proportion of costs attributable to co-payment waivers for PCS and diabetes prescriptions and supplies. Thus, it was not possible to extract the PCS-specific claims for either employer group.

The amount paid PPPY for insurance claims was lower than baseline in each follow-up year, with more than one-half of patients experiencing a decline of 10% or more in most years. In contrast, the cost of prescriptions increased every year compared with baseline. The mean insurance cost PPPY decreased by $2,704, $3,609, $3,908, $5,480, and $6,502 in the first through fifth follow-up years, respectively (see Table 10). This contrasted with the mean total prescription costs, which increased by $656, $1,487, $1,932, $1,942, and $2,188 PPPY for the same years ($P <$ .0001). In every follow-up year, the increases in the diabetes-specific prescription costs accounted for more than 60% of the total increase in prescription costs. Overall, despite the increase in prescription costs, total mean direct medical costs PPPY decreased every year compared with baseline (Figure 2).

Mean number of days of sick time used for group 1 decreased at every follow-up year, compared with baseline. Data were available for 37 patients for the years 1996 through 2001. During the baseline year the mean number of sick days was 12.6 days PPPY. There was a mean decrease of 6.6, 4.1, 5.3, 4.9, and 6.2 days PPPY in each subsequent year (data not shown). The group 1 employer has estimated the value of increased productivity to be $18,000 per year.

Table 9. Direct Medical Costs per Patient per Year Over Time

Time of Measurement[a] (n)	Insurance Claims[b] Median (Min, Max) Mean ± SD	Prescription Claims: Total[b] Median (Min, Max) Mean ± SD	Prescription Claims: Diabetes[b] Median (Min, Max) Mean ± SD	Prescription Claims: All Other Diagnoses[b] Median (Min, Max) Mean ± SD	Total Costs: All Diagnoses[b] Median (Min, Max) Mean ± SD
Baseline year (164), $	1,359 (0, 65,226) 6,096 ± 11,479	762 (0, 8,896) 1,153 ± 1,271	323 (0, 3,257) 488 ± 595	313 (0, 8,697) 666 ± 1,024	2,863 (0, 65,985) 7,082 ± 11,410
1st follow-up year (155), $	1,315 (0, 44,499) 3,596 ± 6,308	1,319 (0, 6,444) 1,614 ± 1,461	520 (0, 4,140) 889 ± 981	349 (0, 5,330) 724 ± 919	3,292 (0, 47,110) 5,210 ± 6,771
2nd follow-up year (116), $	1,325 (0, 32,771) 3,492 ± 5,532	2,132 (0, 8,613) 2,335 ± 1,641	1,224 (0, 5,505) 1,440 ± 1,115	474 (0, 4,468) 894 ± 1,062	3,635 (0, 35,603) 5,843 ± 6,052
3rd follow-up year (74), $	1,163 (0, 36,598) 3,283 ± 5,958	2,453 (0, 12,411) 2,599 ± 1,989	1,453 (0, 5,051) 1,572 ± 1,143	714 (0, 7,931) 1,027 ± 1,279	4,257 (0, 37,795) 5,882 ± 6,555
4th follow-up year (43), $	996 (0, 40,172) 2,815 ± 6,371	2,450 (0, 6,769) 2,579 ± 1,816	1,340 (0, 4,412) 1,409 ± 1,099	613 (0, 4,930) 1,170 ± 1,257	3,941 (0, 43,485) 5,394 ± 6,916
5th follow-up year (28), $	577 (0, 15,130) 1,584 ± 2,995	2,958 (0, 8,691) 3,095 ± 1,776	1,716 (0, 3,211) 1,702 ± 884	1,263 (0, 6,069) 1,393 ± 1,283	3,871 (0, $15,130) 4,651 ± 3,131

SD = standard deviation.
[a]Inclusion criteria: Each patient must have at least one pharmaceutical care services (PCS) visit before December 31, 2001, and a baseline cost and at least one follow-up cost. Cost data must be available for at least 6 months of the baseline year and 6 months of the follow-up year. Follow-up periods are defined as calendar years (January–December) with baseline year equaling the year immediately preceding the first PCS visit. If less than 12 months but at least 6 months of cost data were available, costs were annualized for that 12-month calendar year.
[b]All costs are adjusted to U.S. 2001 dollars. Insurance claims include physician office visits, hospitalizations, emergency department visits, and laboratory tests. The PCS visits are included in outpatient insurance claims for group 2 (Mission–St. Joseph's Health System). Prescription claims include prescriptions and supplies filled. The PCS visits are included in the prescription claims for group 1 (City of Asheville).

Multivariate Logistic Regression Outcomes

Logistic regressions were used to assess the effects of covariates on the probability that outcomes improved after PCS. Specifically, two outcomes were evaluated: the probability that A1c improved by any amount at each follow-up and the probability that total costs decreased by 10% or more at each follow-up compared with baseline. The regression models were similar to those reported in a companion article in this issue of *JAPhA*.[6] We used the following model to assess factors related to the probability that each outcome improved:

Probability ($Y_i = 1$ = outcome improved) = $\beta_0 + \beta_i X_i = \beta_0 +$
β_1*Baseline value of the outcome being assessed + β_2*Age +
β_3*Sex + β_4*Race + β_5*Type 1 Diabetes + β_6*Group + β_7*Baseline Year.

In the above regression model, Y_i = the probability that the outcome of interest improved, β_0 = the constant (similar to the inter-cept in ordinary least squares regressions [OLS]), β_i = a vector of regression coefficients, and X_i = a vector of explanatory independent variables.

Because the sample sizes decreased with each subsequent follow-up, regressions were run on only the first four (of seven) follow-up A1c measurements. Stepwise regressions were used initially if the number of predictor variables exceeded 10% of the sample size.[9] In all four regressions, only the baseline value of A1c was statistically significant. The baseline A1c coefficient (β_1) was positive and significant in all regressions, indicating that for every one unit increase in baseline A1c (with all else constant), there was a higher probability that A1c would be improved (lower) at follow-up. The results for each follow-up are as follows:

- First follow-up: $\beta_1 = 0.59$; $P < .001$; odds ratio (OR), 1.81; 95% confidence interval (CI), 1.31–2.52; n = 136.
- Second follow-up: $\beta_1 = 0.78$; $P = .001$; OR, 2.19; 95% CI, 1.36–3.52; n = 81.

Table 10. Change From Baseline in Direct Medical Costs Over Time

| Follow-up Time (n)[a]	Insurance Claims		Prescription Claims Total		Prescription Claims Diabetes		Total Claims All Diagnoses	
	Change $ PPPY[b]	≥ 10% Cost Decrease No. (%)	Change $ PPPY[b]	≥ 10% Cost Decrease No. (%)	Change $ PPPY[b]	≥ 10% Cost Decrease No. (%)	Change $ PPPY[b]	≥ 10% Cost Decrease No.(%)
1st follow-up (138)								
Median	–$90	66 (47.8)	$520	36 (26.3)	$218	35 (25.6)	$380	55 (40.2)
Mean ± SD	–$2,704 ± $13,056	—	$656 ± $1,199	—	$408 ± $828	—	–$1828 ± $12,898	—
P[c]	.19[d]	—	<.0001	—	<.0001	—	.57[d]	—
2nd follow-up (104)								
Median	–$235	64 (61.5)	$1,395	9 (8.7)	$863	10 (9.6)	$882	31 (30.0)
Mean ± SD	–$3,609 ± $13,665	—	$1,487 ± $1,419	—	$989 ± $1,023	—	–$1,883 ± $13,590	—
P[c]	.02	—	< .0001	—	< .0001	—	.11[d]	—
3rd follow-up (66)								
Median	–$378	39 (59.1)	$2,122	9 (13.9)	$1,199	5 (7.7)	$764	20 (30.8)
Mean ± SD	–$3,908 ± $14,963	—	$1,932 ± $1,865	—	$1,234 ± $1,176	—	–$1,622 ± $14,971	—
P[c]	.10[d]	—	< .0001	—	< .0001	—	.20[d]	—
4th follow-up (39)								
Median	–$367	22 (56.4)	$1,795	5 (13.2)	$1,195	5 (13.2)	$1,938	12 (31.6)
Mean ± SD	–$5,480 ± $16,519	—	$1,942 ± $1,777	—	$1,177 ± $1,196	—	–$2,808 ± $16,314	—
P[c]	.12[d]	—	< .0001	—	< .0001	—	.38[d]	—
5th follow-up (27)								
Median	–$329	15 (55.6)	$2,158	1 (4.0)	$1,066	2 (8.0)	$1,395	8 (30.8)
Mean ± SD	–$6,502 ± $17,244	—	$2,188 ± $1,431	—	$1,326 ± $1,918	—	–$3,356 ± $12,866	—
P[c]	.14[d]	—	< .0001	—	< .0001	—	.25[d]	—

PPPY = per patient per year; SD = standard deviation.
[a]Inclusion criteria: Each patient must have at least one pharmaceutical care services (PCS) visit before December 31, 2001 and a baseline cost and at least one follow-up cost. Cost data must be available for at least 6 months of the baseline year and 6 months of the follow-up year. Follow-up periods are defined as calendar years (January–December) with baseline year equaling the year immediately preceding the first PCS visit. If less than 12 months but at least 6 months of cost data were available, costs were annualized for that 12-month calendar year.
[b]Follow-up minus baseline: (negative number means costs decreased). All costs are adjusted to U.S. 2001 dollars. Insurance claims include physician office visits, hospitalizations, emergency department visits, and laboratory tests. The PCS visits are included in outpatient insurance claims for group 2 (Mission–St. Joseph's Health System). Prescription claims include prescriptions and supplies filled. The PCS visits are included in the prescription claims for group 1 (City of Asheville).
[c]Wilcoxon signed rank test for paired data (HO: baseline = follow-up). Unadjusted P values are shown. Using the Bonferroni adjustment for 5 tests, the significant P value would be .01 under the assumption that the critical value of P = .05 for only one test of significance.
[d]Power to detect a difference of 10% or more < .50.

Figure 1. Percentage of Lab Values[a] in Optimal Range Over Time
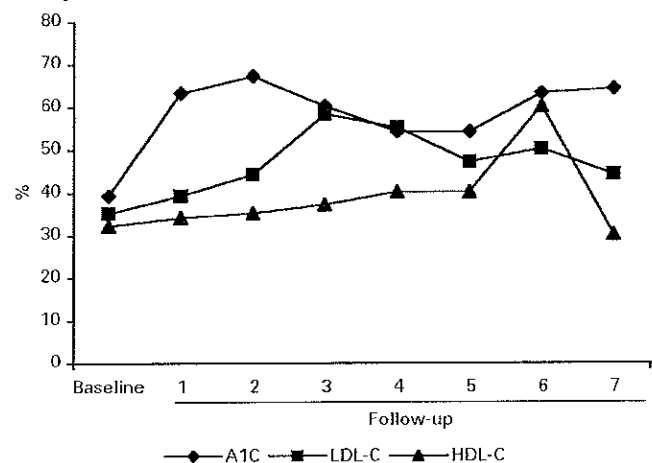
A1c = glycosylated hemoglobin; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol.
[a]Optimal values: A1c < 7.0%; LDL-C < 100 mg/dL; HDL-C > 55 mg/dL for women, > 45 mg/dL for men.

- Third follow-up: β_1 = 0.90; P = .006; OR, 2.46; 95% CI, 1.29–4.66; n = 55.
- Fourth follow-up: β_1 = 1.46; P = .004; OR, 4.29; 95% CI, 1.59–11.53, n = 39.

Sample sizes limited regression analyses to the first four (of five) follow-up cost measurements. The results of the logistic regressions of the probability that total costs decreased by 10% from baseline were similar in that the baseline costs (β_1) were significant ($P \leq .001$) in the regressions for the first 3 follow-up years. However, the coefficients were of small magnitude, with β_1 values < 0.001 and ORs = 1.00. During the first follow-up year, patients with type 1 diabetes were less likely than those with type 2 diabetes to see a 10% decrease in costs (β_5 = −1.55; P = .03; OR, 0.21; 95% CI, 0.05–0.84; n = 137), but no similar relationship was seen in later follow-up years.

Patient-Reported Outcomes

Patients' responses to questions about their diabetes care before entering the program and at their latest post-PCS follow-up indicated substantial improvement in their adherence to four behaviors targeted by the ADA guidelines (A1c and foot exam in last 6 months, self-testing of blood glucose, and use of ACEIs).[7,8] Among the 50 responders, the percentage reporting having had an A1c measurement in the last 6 months increased by 18%, and the percentage of patients reporting having had a foot exam increased by 43%. The number of patients taking an ACEI increased by 38%, and the number performing self-testing of blood sugar increased by 29% (Figure 3).

Discussion

One of the common problems with demonstration projects is that any effect that is demonstrated may be transient. This study is one of the few of its kind to examine long-term effects of PCS on A1c concentrations, lipids, and direct medical costs. We examined cohorts of patients over time, regardless of when they entered the study. By the end of 2001, about 67% of the eligible patients who knew they had diabetes had enrolled in the PCS program. We noted minor differences in the composition of the cohort over time, and relatively few patients were LTF because they specifically dropped out of the program. Among patients who were LTF, one-half had become ineligible for later follow-ups because they joined the cohort during a later baseline year, left employment, or died. Had we continued this study over a longer time, we would expect the number of patients in the later follow-up periods to have been larger due to the continued participation of those who joined in the later years.

This analysis shows that improvement in A1c concentrations, the primary clinical variable, persisted over time. Of particular note is that at every follow-up, more than 50% of patients experienced improvement over baseline. Further, at all follow-ups we observed an increase in the number of patients with optimal A1c values (i.e., A1c < 7 %), with increases as high as 27.2% at the first three follow-ups (Table 4). Since research has established that any improvement in A1c is beneficial, reduces the risks of complications, and prolongs life, all of the improvements noted above were considered clinically important.[3,8,10]

The results of the multivariate logistic regressions suggest that the patients with higher baseline A1c values were the most likely to improve at each follow-up. Similar results are noted in our companion article[6] and reported elsewhere.[11] As in the original study, we cannot rule out regression to the mean as the reason we observed these improvements. However, this study demonstrated that the improvements persisted for as long as 5 years among patients who remained eligible for the later follow-up measurements. The finding that patients with more poorly controlled A1c maintained their improvement serves to strengthen the evidence for the effectiveness of the pharmacists' interventions.

The other clinical outcomes, LDL-C and HDL-C concentrations, while not the primary focus of this intervention, also improved but not substantially (Tables 5–8). In a recently published report of a study of another community pharmacy-based diabetes management program, Nau and Ponte[12] reported statistically significant improvement in total cholesterol and LDL-C following 6 months of pharmacist interventions. Because patients with diabetes are at increased risk for cardiovascular disease, future PCS programs should emphasize the importance of improving lipids as well as A1c.

Analyses of insurance and prescription claims indicated that mean total amount paid for all diagnoses decreased at each follow-up year. Most of the decrease in total costs was accounted for by a shift from insurance claims for emergency department, inpatient,

Figure 2. Direct Medical Costs Over Time

Insurance claims   Diabetes prescriptions   Other prescriptions
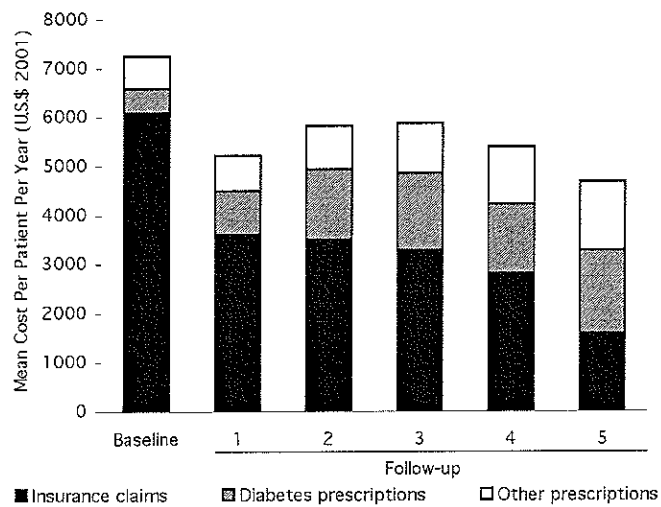
and physician office visits to prescription claims. Mean costs for insurance claims decreased by $2,704 PPPY in the first follow-up year and by $6,502 PPPY in the fifth follow-up year (Table 10). During the same periods, mean prescription costs increased significantly, by $656 to $2,188 PPPY, with diabetes-related prescriptions accounting for more than half of the increase. Logistic regression suggested that in the first year of the program patients with type 1 diabetes were less likely than those with type 2 diabetes to see a 10% decrease in total medical costs. The payers realized decreases in total direct medical costs that ranged from $1,622 to $3,356 PPPY.

Although it was not possible to correlate the patient-reported improvements in self-care with specific interventions or outcomes, the percentage of patients reporting improvement increased for all four target behaviors. These and other aspects of patient-reported care, although not the primary focus of this study, deserve additional study, especially with respect to comparisons with other care models.

In general, the findings of this study support what was anecdotally stated by patients themselves. That is, in addition to the support of community pharmacists, the use of financial incentives (waived prescription co-payments and 100% coverage of diabetes education) and support from employers and the medical community were positive factors in improving clinical and economic outcomes among patients with diabetes.

Collaboration between providers and employers was an important element in the success of this community-based project. After we informed the physicians that their patients were voluntarily participating in an employer-sponsored wellness program, we asked them to share their treatment goals with the patient's pharmacist. This sharing of information enabled the pharmacists to reinforce the physicians' goals during PCS visits. Additionally, the pharmacists provided brief written summaries of their PCS

encounters, observations, and recommendations to the physicians.

Other studies have demonstrated that appropriate patient training and monitoring result in improved A1c concentrations and reduced costs, and that a sustained reduction in A1c among adult patients with diabetes is associated with cost savings within 1 to 2 years of improvement.[2,13] Ours is the first long-term study to demonstrate these effects following the interventions of community pharmacists.

As a result of the clinical improvements and financial savings associated with this program, both employers have made it a permanent part of their health plan benefit. This indicates that from the employers' perspective, the savings more than offset the costs of the benefit.

Limitations

This longitudinal analysis of patients with diabetes is subject to the limitations that are typical of nonrandomized, real-world studies with no control group. These limitations are discussed in depth in a companion article in this issue of *JAPhA*.[5] Limitations specific to this study hinge on missing and/or unreported clinical data, resulting in diminished cohort sizes over time, and in limitations in the level of detail of claims data available for use in economic assessments. Neither providers nor patients followed a specific protocol or documentation format, which limited our ability to describe the specific PCS interventions or relate them to patient outcomes. Irons et al.[14] reported similar problems resulting from incomplete documentation of services by practitioners. As discussed in detail in the Economic Outcomes section, costs for PCS reimbursement and prescription co-payment waivers could not be accurately estimated. Additionally, for patients who were employed or left employment at midyear, cost data were annualized if at least 6 months of claims data were available for the year. This technique was used for nine patients (three patients in their pre-PCS year, two patients in their final year, and two in their pre-PCS and final years), but we did not evaluate its validity. In our earlier studies we computed actual costs per patient per month using claims data for only the months of actual interventions.[5,6] Due to claims structure limitations, making such an adjustment was not possible in the study described here.

Conclusion

Patients with diabetes receiving PCS in community pharmacies in this study maintained clinically meaningful improvements in their A1c concentrations over time, and third party payers experienced an overall decline in mean total direct medical costs during each year of follow-up. Patients at higher risk because of elevated A1c concentrations were the most likely to experience improvement in A1c following PCS. There was an increase in the number of patients reporting adherence to ADA-targeted behaviors

Figure 3. Patient-Reported Behaviors Over Time

Figure 4. Patient-Reported Behaviors Over Time
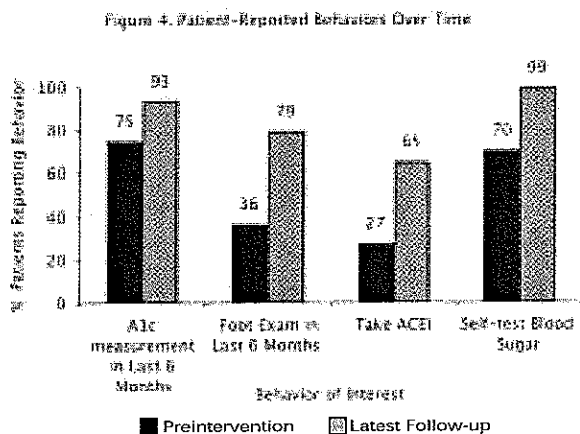
A1c = glycosylated hemoglobin; ACEI = angiotensin-converting enzyme inhibitor.

regarding receiving A1c tests, performing foot exams, using ACEIs, and performing self-testing of blood glucose. As a result of the clinical improvements and financial savings associated with this PCS program, the participating employers have made it a permanent part of their health plan benefit.

References

1. Johnson JA. Self-efficacy theory as a framework for community pharmacy–based diabetes education programs. *Diabetes Educ.* 1996;22:237–41.

2. Norris SL, Lau J, Smith SJ, et al. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes Care.* 2002;25:1159–71.

3. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group. *N Engl J Med.* 1993;329:977–86.

4. U.S. Bureau of Health Professions. *Report on Health Professional Accessibility.* Washington, DC: Government Printing Office; 1996.

5. Cranor CW, Christensen DB. The Asheville Project: short-term outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc.* 2003;43:149–59.

6. Cranor CW, Christensen DB. The Asheville Project: factors associated with outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc.* 2003;43:160–72.

7. American Diabetes Association. American Diabetes Association: clinical practice recommendations 2002. *Diabetes Care.* 2002;25:1–139.

8. American Diabetes Association. Standards of medical care for patients with diabetes mellitus (position statement). *Diabetes Care.* 2002;25:S33–49.

9. Rothman KJ, Greenland S. *Modern Epidemiology.* Philadelphia, Pa: Lippincott-Raven; 1998:406.

10. American Diabetes Association. Implications of the Diabetes Control and Complications Trial. *Diabetes Care.* 2002;25:S25–7.

11. Hirsch IB, Goldberg HI, Ellsworth A, et al. A multifaceted intervention in support of diabetes treatment guidelines: a cont trial. *Diabetes Res Clin Pract.* 2002;58:27–36.

12. Nau DP, Ponte CD. Effects of a community pharmacist-based diabetes patient-management program on intermediate clinical outcome measures. *J Manage Care Pharm.* 2002;8(1):48–53.

13. Wagner EH, Sandhu N, Newton KM, et al. Effect of improved glycemic control on health care costs and utilization. *JAMA.* 2001;285:182–9.

14. Irons BK, Lenz RJ, Anderson SL, et al. A retrospective cohort analysis of the clinical effectiveness of a physician–pharmacist collaborative drug therapy management diabetes clinic. *Pharmacotherapy.* 2002;22:1294–1300.