Clinical and Economic Outcomes of the Cincinnati Pharmacy Coaching Program for Diabetes and Hypertension

The program showed significant improvements in all diabetes and hypertension-related clinical measures

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ABSTRACT

Purpose: Value-based insurance designs (VBID) have been developed by health insurance companies and used by employers to allocate health care resources appropriately and to lower patients' out-of-pocket costs for services related to chronic conditions. The purpose of this study was to evaluate the effect of the Cincinnati Pharmacy Coaching Program (CPCP) on clinical and economic outcomes. The CPCP is a VBID implemented by Anthem Blue Cross & Blue Shield in Ohio. It provided tailored pharmacist-based educational services and financial incentives to participants.

Methods: This was a quasi-experimental pre/post longitudinal study in which patients were identified as they enrolled in the CPCP between Jan. 1, 2008, and Dec. 31, 2009. Patients could participate in a Diabetes Coaching Program (DCP) or a Heart Healthy Coaching Program (HHCP). Control subjects were selected from patients who were invited but did not choose to participate. Control subjects were matched to intervention cohorts using propensity score matching. Clinical (blood pressure, lipid levels, and hemoglobin A_{1c}) and economic (all-cause and disease-attributable) outcomes were evaluated using within-subject (pre-post) and between-subject comparison (intervention-control) design.

Results: A total of 607 patients were enrolled in intervention groups, and 557 control subjects were selected after matching. Significant reductions were found in blood pressure, lipid levels, and hemoglobin A_{1c} after enrollment, and a significantly greater proportion of patients, compared with controls, achieved their clinical goals according to national guidelines in both programs. Hypertension-related cost trends were favorable for HHCP relative to the control cohort. Diabetes-related costs increased for all groups from pre- to post-index, largely driven by office visits and medication costs in the DCP and inpatient/ER visits in the control cohort.

Conclusion: Results showed significant improvements in all diabetes- and hypertension-related clinical measures. This study shows the effect of a comprehensive VBID on the health of patients with chronic disease.

Conflicts/Disclosures

Debra Wertz, Likun Hou, Andrea DeVries, and Mark Cziraky were all employees of HealthCore when this study was conducted. HealthCore received funding from Novartis Pharmaceuticals Corp. for this work.

Leon Dupclay Jr. is employed by Novartis Pharmaceuticals Corp., which funded this research study.

Frannie McGowan is an employee of Kroger Pharmacy. Barry Malinowski is an employee of Anthem Blue Cross & Blue Shield of Ohio.

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INTRODUCTION

Nearly half of all adults in the United States have diabetes, hypertension, or dyslipidemia (Fryer 2010). These chronic conditions are all associated with cardiovascular disease, the leading cause of death in the United States (Murphy 2010). In addition to mortality implications, chronic diseases are major drivers of disease burden and poor quality of life among patients and of overall cost of care among payers (Ramsey 2002, Schappert 2008). Moreover, in 2007, type 2 diabetes accounted for an estimated $116 billion annually in direct costs (ADA 2008) and it is ex-

pected that, in 2010, hypertension will have accounted for nearly $80 billion in direct costs (Lloyd-Jones 2010). As health care costs continue to rise, the need to establish innovative approaches that will improve health care outcomes and deliver long-term cost savings increases.

Over the past decade, disease management programs typically centered on reaching out to patients by way of phone or mail to educate them on their conditions or to remind them of preventive care. Recently, there has been a shift in the payer perspective on what will motivate behavior change in members — for example, use of an actual financial benefit such as a copayment waiver (Chernew 2010, Chernew 2007).

Payers and employer groups are increasingly recognizing that successful management of chronic diseases relies on a combination of engaging patients in their treatment, modifying behavior by removing barriers, and increasing access to care. VBID combines several approaches to manage chronic diseases, including offering financial incentives to health plan members through benefit design and increasing the availability of tools for members to manage their care through education, preventive screenings, and medication therapy management (Chernew 2010, Chernew 2007).

While introduction of these incentives individually can affect outcomes, it is the combination of incentives that has the greatest effect on quality and cost of care.

The CPCP is a comprehensive VBID aimed at improving quality and affordability of diabetes, hypertension, and dyslipidemia-related health care. As part of the CPCP, patients could enroll in 1 of 2 medication therapy management programs, the Diabetes Coaching Program (DCP) for patients with diabetes or the Heart Healthy Coaching Program (HHCP) for patients with hypertension. The CPCP is a collaboration of stakeholders, including two large employer groups (city of Cincinnati and Kroger Co.), a large health plan (Anthem Blue Cross & Blue Shield of Ohio), and a large retail pharmacy chain (Kroger Pharmacy), as well as research collaboration between a large pharmaceutical company (Novartis Pharmaceuticals Corp.) and an independent health outcomes research consulting company (HealthCore).

City of Cincinnati (COC) and Kroger employees who enrolled in the CPCP program received incentives for participation, including coaching on their conditions by trained clinical pharmacists and financial incentives in the form of copayment waivers or reductions and contributions to health savings accounts.

The educational and outreach components of the CPCP are modeled after the Asheville Project in North Carolina (Cranor 2003). In assessments that spanned up to five years after the Asheville Project was implemented, it was found that mean hemoglobin A_{1c} (HbA_{1c}) levels, lipid levels, and blood pressure readings significantly improved at all follow-up visits (Cranor 2003). Positive outcomes have also been reported in other pharmacist-led coaching programs, namely the diabetes Patient Self-Management Program (PSMP) and the Diabetes Ten City Challenge (DTCC) (Garrett 2005, Fera 2009).

Similar to Asheville, the PSMP and the DTCC found improvements in HbA_{1c}, lipid levels, blood pressure readings, and goal attainment. Although cost data from the PSMP and the DTCC were evaluated differently and reporting was variable, it was proposed that the cost of the coaching and preventive services in these programs would be offset by the reduction in long-term cardiovascular complications associated with these diseases.

While the clinical aspects of the CPCP were similar to these other programs, the CPCP program builds on the previous studies by partnering with a large employer, health plan, and retail pharmacy to develop the program and to implement it in a large metropolitan area. In addition to the coaching and copayment waiver incentives offered in previous studies, the current study builds on the financial aspects by providing contributions to patients health savings accounts.

One of the limitations of the previous studies is that there was no control group. The current study addresses this limitation in its research design by incorporating a control group of nonparticipating patients from the same employer group. This study is unique in that it was able to measure change in economic outcomes and medication adherence using a control group of propensity score-matched patients. Because multiple factors affect overall quality and cost of care, the current study sought to evaluate the effect of the CPCP on clinical and economic outcomes.

Similarly to the other studies, this study assessed pre/post changes in HbA_{1c}, lipid levels, and blood pressure readings. In addition to these clinical measures, this study also examined pre/post changes in resource use, cost, adherence, and disease-related therapies for both the intervention and control groups.

METHODS

Intervention

Members with diabetes or hypertension were invited to participate in the CPCP by way of employer and health plan communications. Participation consisted of meeting with community-based pharmacists regularly. The pharmacists provided tailored pharmaceutical care services to participants to help them better understand and manage their conditions.

Depending on the incentives provided by the employer groups, some participants received $100 contribu-

tions to their health savings accounts; copayment waivers or copayment reductions for all medications related to diabetes, hypertension, and dyslipidemia; and regular follow-up visits with clinical pharmacists, including education and monitoring of their clinical outcomes (e.g., adherence, treatment goals, and assessments of their feet, blood pressure, weight, lipid values, and glucose control). There was an annual average value of over $500 to the participating member. Where appropriate, the pharmacist made recommendations regarding dosage and the addition or switching of medication classes.

Study design and data sources

The program started Jan. 1, 2008, with ongoing enrollment through 2008 and 2009. The research study is a pre-post design using clinical information collected as part of the coaching program (laboratory values for HbA_{1c}, lipid levels, and blood pressure readings), data obtained from patient charts, and administrative claims data for both intervention and control groups.

The longitudinal administrative data set consists of integrated medical claims, pharmacy claims, and eligibility files from the HealthCore Integrated Research Database (HIRD). Administrative claims and eligibility data used in the analysis spanned the time period from Jan. 1, 2007, through December 31, 2009, allowing for a full year of baseline claims for each participant. The Kroger Co. also provided pharmacy data for Kroger employees participating in the program. The study database was developed in compliance with Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations. Patient consent and Institutional Review Board approval was obtained to gain access to the patient site-visit information.

Patient selection

Patients were assigned to 1 of 4 cohorts based on their participation or nonparticipation in the CPCP, as well as their specific disease condition, as follows: (1) DCP intervention cohort, (2) HHCP intervention cohort, (3) diabetes control cohort, or (4) hypertension control cohort.

Intervention cohort (DCP or HHCP participants)

The cohort enrolled in the diabetes coaching program included members (employees of COC and Kroger) age 18 or above with at least 1 medical claim with an *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) code 250.XX before program enrollment. The Heart Healthy cohort included members (employees of COC and Kroger) age 18 or above with 1 or more inpatient admissions or ER visits or at least 2 professional office visits with ICD-9 codes for hypertension, identified based on ICD-9 codes of 401.xx–405.xx, 362.11, or 437.2F. For patients enrolled in the pharmacy coaching program, the index date was defined as the date of the first site visit.

Control cohort (nonparticipants)

The control cohort was identified using City of Cincinnati employees with diabetes and/or hypertension who were offered the program but did not participate. They were selected as the comparison group because they were similar in terms of their demographic and socioeconomic factors and were being treated at the same medical centers, presumably by the same physicians. Also, except for the benefits received through the CPCP program, these employees faced the same benefit structure.

Kroger employees who did not choose to participate in the program were not included in the control group because of the lack of access to pharmacy claims data for nonparticipants. The patients were selected using propensity score matching by age, gender, pre-index comorbid indicators (including history of ischemic heart disease, acute myocardial infarction, and other cardiovascular events), and Deyo-Charlson Index scores (DCI) (Charlson 1987, Deyo 1992).The index date for the control cohort was assigned based on the index date of the intervention group.

All patients were required to have a minimum of 12 months of continuous health plan enrollment before and after index date. Potential control group members who did not have a good match in the intervention group were eliminated to avoid introducing bias, while unmatched intervention group subjects were retained to preserve statistical power with different stratifications and clinical outcomes.

STATISTICAL ANALYSIS

Two types of analyses were conducted: (1) within-subject comparison (pre-post design) comparing outcomes before and after enrollment in the program and (2) between-subject comparison of outcomes between the intervention and control cohorts. Statistical differences were assessed using paired t-tests and the McNemar test for categorical variables. An *a priori* 2-tailed level of significance (alpha value) was set at the 0.05 level for all analyses.

Within-subject comparison

Clinical and economic outcomes were measured for program participants by comparing changes from pre-index (before program start date) to post-index. Clinical measures of interest included HbA_{1c} levels, lipid levels, and blood pressure readings. The change was measured in absolute terms (average increase/decrease), and the percentages of participants achieving goal attainment, medication adherence, medication change, and disease-related and all-cause utilization and cost changes were measured.

Medication adherence was measured using proportion of days covered (PDC), defined as the ratio of total days supply of medication dispensed during the period to the total number of days over the 12 months post-index. Medication change was measured by counting the number of distinct medication classes and agents during the 12-month pre- and post-index periods. Disease-related utilization was measured through identification of medical claims containing ICD-9-CM codes for diabetes and hypertension.

The study also measured cardiovascular-related costs based on ICD-9 codes. Total disease-related cost of care was the total allowed by the health plans and consisted of both medical and pharmacy components. The medical component included inpatient, emergency room, and outpatient costs. Disease-related and all-cause utilization were measured by comparing the 12 months pre- and post-index date, with all participants and control members having 2 years of eligibility and claims data available.

Between-subject comparison

Medication adherence, medication change, and disease-related and all-cause utilization and cost changes were measured relative to changes observed in the matched control population. This allowed for a real-world view of changes in expected vs. actual utilization for program participants, compared to using a trend factor or other estimation techniques.

RESULTS

Demographics

Of the initial pool of 845 participants, a final intervention cohort of 607 members was selected after matching to claims data and applying 12 months of pre-index eligibility. The intervention cohort was made up of 344 active employees and 263 retirees. Of the initial pool of 5,217 nonparticipants, a final propensity

TABLE 1
Baseline demographics and clinical characteristics

Patient characteristic	Diabetes			Hypertension		
At least 365 days pre-index eligibility*	**DCP intervention cohort (N=307)**	**Diabetes control cohort (N=274)**	**P values**	**HHCP intervention cohort (N=307)**	**Hypertension control cohort (N=289)**	**P values**
Age mean±SD (median)	59±12 (58)	59±12 (59)	0.758	57±12 (55)	57±12 (55)	0.999
Female N (%)	160 (52.1%)	136 (49.6%)	0.550	179 (58.3%)	167 (57.8%)	0.898
Race, N (%)						
Caucasian	157 (51.1%)	—	—	154 (50.2%)	—	—
African-American	103 (33.6%)	—	—	113 (36.8%)	—	—
Asian	3 (1.0%)	—	—	1 (0.3%)	—	—
Unknown		—	—		—	—
Coaching program						
Duration of program, mean±SD, median	421±278 (447)	—	—	406±263 (414)	—	—
Average # of coaching visits during follow-up	8.1±5.2	—	—	7.2±4.3	—	—
Comorbidities						
Hypertension	167 (54.4%)	153 (55.8%)	0.727	241 (78.5%)	238 (82.4%)	0.237
Diabetes	286 (93.2%)	255 (93.1%)	0.964	13 (4.2%)	8 (2.8%)	0.332
Dyslipidemia	231 (75.2%)	210 (76.7%	0.694	174 (56.7%)	171 (59.1%)	0.538
Any cardiovascular disease	72 (23.5%)	63 (23.0%)	0.896	47 (15.3%)	42 (14.5%)	0.790
Ischemic heart disease	51 (16.6%)	40 (14.6%)	0.505	37 (12.1%)	33 (11.4%)	0.810
Myocardial infarction	10 (3.3%)	13 (4.7%)	0.815	8 (2.6%)	6 (2.1%)	0.670
Stroke	11 (3.6%)	14 (5.1%)	0.365	12 (3.9%)	10 (3.5%)	0.772
Congestive heart failure	14 (4.6%)	13 (4.7%)	0.916	9 (2.9%)	8 (2.8%)	0.905
Deyo-Charlson Comorbidity Index	1.9±1.5	2.0±1.6	0.359	0.5±1.0	0.4±0.8	0.349

*Pre-index defined as 365 days before index date; chi-square test for categorical variables and t-test for continuous variables.

score-matched cohort of 557 members was selected for the control cohort. Fifty patients in the intervention group did not have a good match in the available control subjects, but were retained in the cohort to maximize statistical power, with an overall 92% matched group.

The final study population consisted of 581 diabetic patients (307 in the DCP and 274 in the control population), and 596 Heart Healthy patients (307 in the HHCP and 289 in the control population). Seven patients initially presented with hypertension only and were later diagnosed with diabetes; thus, these patients contributed data to both coaching programs. Mean age was similar for the intervention and control groups for both DCP (59±12 and 59±12, respectively) and HHCP (57±12 and 57±12, respectively). There were no significant differences in chronic disease score or in select comorbid conditions between the intervention and control populations. Race and program duration were available for the intervention cohort (Table 1). The average duration of program participation was 14 months. Active enrollees had an average of 6 pharmacist encounters during the follow-up; retirees had an average of 9.5 encounters.

Medication treatment patterns

Both DCP and HHCP program groups had higher proportions of patients on antihypertensive medications than the control populations at baseline, 83.6% vs. 76.1% for DCP and 89.5% vs. 84.5% for HHCP (Tables 2a and 2b). Statin use was similar at baseline for intervention and control cohorts. Compared to the control cohort, DCP patients had significantly higher usage of metformin (51.4% vs. 40%) and insulin (28% vs. 19.4%).

Despite the higher rate at baseline, the percentage of patients receiving antihypertensive medications post-index increased from baseline for DCP (83.6% to 90.2%) compared to controls (76.1% to 77.2%) — a 7.9% increase compared to 1.4% increase, respectively (p=0.019).

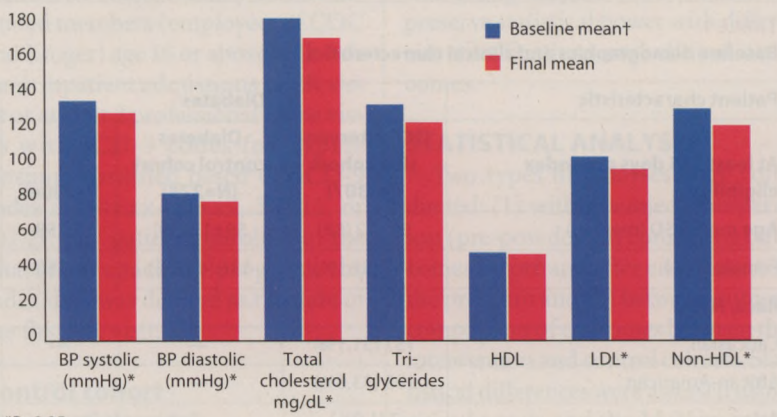
Both program populations also had a significantly greater increase in statin use from baseline compared to controls, 12% increase (62.6% to 70.1%) vs. 1% decrease (65.0% to 64.4%) in DCP and control cohorts, respectively (p=0.021); and 12.8% increase (41.4% to 46.7%) vs. 5.8% (44.6% to 47.2%) increase in the HHCP and control cohorts, respectively (p=0.351).

Similar increases were observed in the percentage of patients receiving antidiabetic medications from baseline to post-index in DCP and control. The overall mean number of antihypertensive classes significantly increased from baseline to post-index in HHCP (2.21 vs. 2.4, p=0.14; no significant differences were observed from baseline to post-index for the control cohorts.

Overall, patients enrolled in the program were more likely to add or change medications during the study period which indicates they were ac-

FIGURE 1A

HHCP clinical measures baseline vs. final post-index: within subject comparison

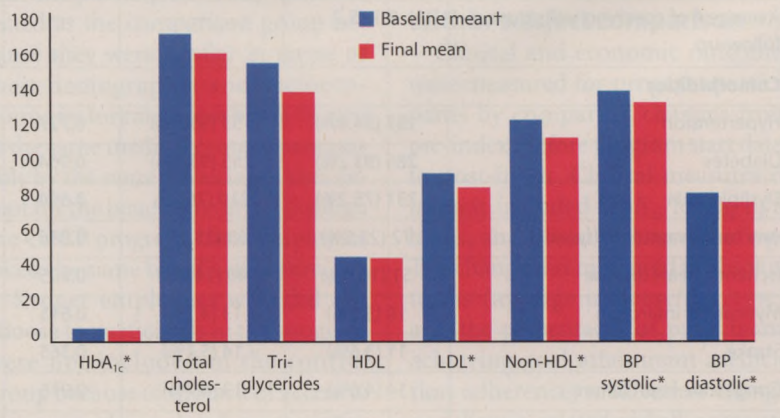


*P<0.05

† Baseline was defined as clinical value obtained on index date or up to 183 days before index date. The latest value was captured for the analysis.

FIGURE 1B

DCP clinical measures baseline vs. final post-index: within subject comparison



*P<0.05

†Baseline was defined as clinical value obtained on index date or up to 183 days before index date.

tively being managed by their health care providers. The same trends were found with dyslipidemia medications in the intervention and control cohorts. No significant differences were observed in antidiabetic medications in either cohort.

Medication adherence rates

Medication adherence rates also increased significantly within the intervention groups. Adherence with antihypertensive medications increased 7.1% in DCP (PDC=0.85 at baseline to 0.91 in follow-up; $p<0.05$), and 11% in HHCP (PDC=0.82 to 0.91; $p<0.05$). There were no significant changes in antihypertensive medication adherence from baseline to post-index for either control cohort. Adherence with statins increased significantly in both DCP (PDC=0.71 at baseline to 0.82 in follow-up, $p<0.05$) and HHCP (PDC=0.76 at baseline to 0.87 at follow-up, $p<0.05$) cohorts.

A significant increase in antidiabetic medication adherence was also found in the DCP from baseline to post-index (PDC=0.78 at baseline

TABLE 2A
Pre-post-index* treatment patterns (Diabetes Coaching Program)

Treatment patterns	DCP intervention cohort (N=214)			Diabetes control cohort (N=180)		
	Pre-index	Post-index	P values	Pre-index	Post-index	P values
Hypertension medications						
All anti-hypertensives	179 (83.6%)	193 (90.2%)	0.002	137 (76.1%	139 (77.2%)	0.019
Beta blocker	62 (29.0%)	67 (31.3%)	0.225	40 (22.2%)	41 (22.8%)	0.621
Calcium channel blocker	50 (23.4%)	62 (29.0%)	0.005	41 (22.8%)	45 (25.0%)	0.287
Angiotensin converting enzyme	83 (38.8%)	96 (44.9%)	0.012	63 (35.0%)	58 (32.2%)	0.013
Angiotensin receptor blocker	37 (17.3)	44 (20.1%)	0.090	27 (15.0%)	26 (14.4%)	0.181
AHY combination	56 (26.2%)	63 (29.4%)	0.090	47 (26.1)	47 (26.1%)	0.194
Diuretics	70 (32.7%)	82 (38.3%)	0.014	46 (25.5%)	49 (27.2%)	0.283
Thiazide diuretic	30 (14.0%)	38 (17.8%)	0.059	19 (10.6%)	21 (11.7%)	0.514
Loop diuretics	37 (17.3%)	39 (18.2%)	0.593	21 (11.7%)	27 (15.0%)	0.243
Dyslipidemia medications						
Statins	134 (62.6%)	150 (70.1%)	0.003	117 (65.0)	116 (64.4%)	0.021
Fenofibrates	30 (14.0%)	29 (13.6%)	0.655	16 (8.9%)	16 (8.9%)	0.836
Zetia	21 (9.8%)	19 (8.9%)	0.317	12 (6.7%)	8 (4.4%)	0.185
Diabetes medications						
All antidiabetic medications	187 (87.4%)	194 (90.7%)	0.020	139 (77.2%)	144 (80.0%)	0.341
Sulfonylureas	78 (36.5%)	73 (34.1%)	0.166	63 (35.0%)	61 (33.9%)	0.637
Metformin	110 (51.4%)	122 (57%)	0.011	72 (40.0%)	73 (40.6%)	0.139
Thiazolidinediones	50 (23.4%)	48 (22.4%)	0.564	42 (23.3%)	39 (21.7%)	0.760
Insulin	60 (28.0%)	65 (30.4%)	0.132	35 (19.4%)	40 (22.2%)	0.657
Proportion of days covered (PDC)						
Antihypertensives	0.85±0.2429	0.91±0.19	0.0002	0.85±0.85	0.85±0.25	0.021
Antidiabetics (excluding insulin)	0.78±0.28	0.86±0.23	0.0002	0.74±0.30	0.76±0.28	0.064
Statins	0.71±0.30	0.82±0.23	0.0001	0.70±0.31	0.78±0.27	0.200
Antihyperlipidemics	0.76±0.29	0.84±0.23	0.0004	0.76±0.28	0.79±0.26	0.134
Total medication classes						
Antidiabetic medication classes	1.81±1.32	1.86±1.25	0.410	1.49±1.27	1.48±1.13	0.516
Antihypertensive medication classes	2.14±1.60	2.44±1.62	<0.0001	1.92±1.66	1.97±1.65	0.031
Antihyperlipidemics	1.01±0.86	1.08±0.83	0.049	0.91±0.75	0.86±0.71	0.026

*Pre-index defined as 365 days before index date; post-index defined as 365 days after index date; chi-square test for categorical variables and t-test for continuous variables.

to 0.86 at follow-up; $p<0.05$). No significant change in adherence with antidiabetic medications was found in the DCP control cohort.

Clinical measures

Blood pressure improved significantly from baseline to follow-up in both program groups. Mean systolic blood pressure (SBP)/diastolic blood pressure (DBP) improved from 136.1/83.5 mmHg at baseline to 129.5/79.3 mmHg at follow-up in HHCP ($p<0.05$), and from 136.1/81.0 mmHg to 130.4/76.3 mmHg in DCP ($p<0.05$) as shown in Figures 1a and 1b. Also, the percentage of patients achieving blood pressure goals improved significantly in both groups (Table 3: bit.ly/yAM7iF). In HHCP, the percentage of patients achieving BP of <140/90 mmHg increased from 52% to 70% ($p<0.05$). In DCP, the percentage of patients achieving BP of <130/80 increased from 25% to 37% ($p<0.05$), as shown in Figure 2.

Similar results were found for LDL and non-HDL cholesterol. Mean LDL cholesterol values improved from

TABLE 2B
Pre-post-index treatment patterns (Heart Healthy Coaching Program)

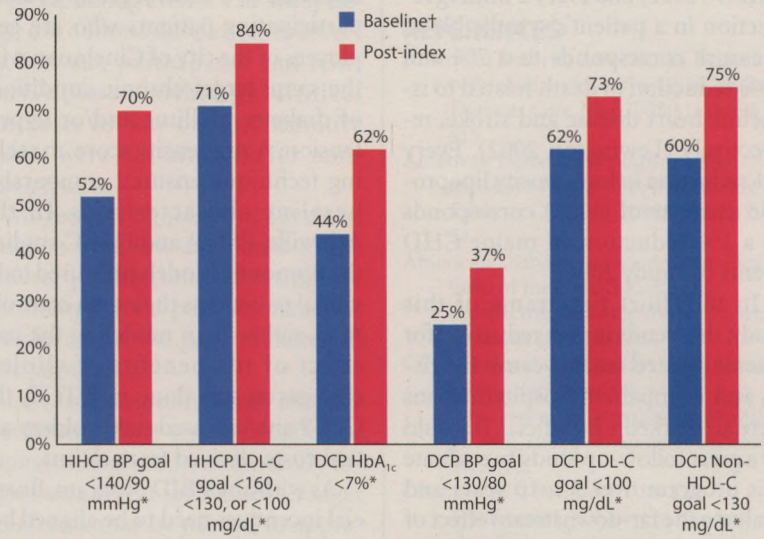
Treatment patterns	HHCP intervention cohort (N=210)			Hypertension control cohort (N=193)		
	Pre-index	Post-index	P values	Pre-index	Post-index	P values
Hypertension medications						
All antihypertensives	188 (89.5%)	196 (93.3%)	0.021	163 (84.5%)	170 (88.1%)	0.483
Beta blocker	75 (35.7%)	82 (39.1%)	0.108	54 (28.0%)	58 (30.1%)	0.755
Calcium channel blocker	55 (26.2%)	60 (28.6%)	0.197	48 (24.9%)	49 (25.4%)	0.478
Angiotensin converting enzyme	51 (24.3%)	51 (24.3%)	1.000	51 (26.4%)	46 (23.8%)	0.392
Angiotensin receptor blocker	29 (13.8%)	31 (14.8%)	0.527	23 (11.9%)	21 (10.9%)	0.259
AHY combination	63 (30.0%)	78 (37.1%)	0.001	40 (20.7%)	48 (24.9%)	0.522
Diuretics	70 (33.3%)	74 (35.3%)	0.450	67 (34.7%)	63 (32.6%)	0.255
Thiazide diuretic	32 (15.2%	38 (18.1%)	0.157	32 (16,7%)	29 (15.0%)	0.097
Loop diuretics	12 (5.7%	12 (5.7%0	1.000	11 (5.7%)	12 (6.2%)	0.757
Dyslipidemia medications						
Statins	87 (41.4%	98 (46.7%)	0.008	86 (44.6%)	91 (47.2%)	0.351
Fenofibrates	11 (5.2%	12 (5.7%)	0.655	4 (2.1%)	7 (3.6%)	0.218
Zetia	16 (7.6%)	15 (7.1%)	0.317	9 (4.7%)	6 (3.1%)	0.164
Diabetes medications						
All antidiabetic medications	4 (1.9%)	8 (3.8%)	0.046	4 (2.1%)	4 (2.1%)	0.048
Sulfonylureas	0	0	—	2 (1.0%)	2 (1.0%)	—
Metformin	4 (1.9%)	6 (2.9%)	0.317	1 (0.52%)	2 (1.0%)	0.731
Thiazolidinediones	0	1 (0.5%)	—	0	0	—
Insulin	0	0	—	1 (0.52%)	1 (0.5%)	—
Proportion of days covered (PDC)						
AHY	0.82±0.26	0.91±0.17	<0.0001	0.86±0.24	0.86±0.21	0.0004
Antidiabetic (excluding insulin)	0.68±0.43	0.88±0.21	0.523	0.64±0.37	0.70±0.42	0.657
Statin	0.76±0.27	0.87±0.22	0.015	0.73±0.29	0.83±0.20	0.660
Antihyperlipidemic	0.77±0.27	0.86±0.22	0.001	0.77±0.28	0.83±0.21	0.415
Total medication classes						
Antidiabetic medication classes	0.02±0.18	0.04±0.19	0.180	0.04±0.30	0.04±0.30	0.277
AHY medication classes	2.21±1.48	2.41±1.47	0.014	1.91±1.29	1.93±1.23	0.081
Antihyperlipidemic classes	0.63±0.79	0.68±0.80	0.034	0.59±0.69	0.62±0.70	0.582

*Pre-index defined as 365 days before index date; post-index defined as 365 days after index date; Chi-Square test for categorical variables and t-test for continuous variables.

104.1 to 97.2 mg/dL and 91.6 to 84.0 mg/dL in HHCP and DCP, respectively ($p<0.05$ for both). Non-HDL cholesterol improved from 131.3 to 122.2 mg/dL and 120.7 to 111.2 mg/dL in HHCP and DCP, respectively ($p<0.05$ for both) as shown in Figure 1a and Figure 1b. The percentage of patients achieving target LDL cholesterol, based on CHD risk factors, increased from 71% to 84% in HHCP, and from 62% to 73% in DCP ($p<0.05$ for both), as shown in Figure 2. Also, the percentage of patients achieving non-HDL cholesterol goal increased from 60% to 75% in DCP ($p<0.05$).

Within DCP, mean HbA_{1c} levels improved from 7.9% baseline to 7.1% in the follow-up period ($p<0.05$) as shown in Figure 1b. More important, the percentage of patients who achieved anHbA_{1c} goal of <7% increased from 44% to 62% in the follow-up ($p<0.05$), as shown in Figure 2.

FIGURE 2
HHCP and DCP clinical goal attainment



*P<0.05 for all comparisons shown
†Baseline was defined as clinical value obtained on index date or up to 183 days before index date. The latest value of the clinical measure within each time interval, if available, was captured for the analysis.

Disease-related health care costs

A review of economic data revealed some positive cost trends for the program groups, compared to controls (Table 3: bit.ly/yAM7iF). For HHCP participants, total hypertension-related costs, as well as hypertension-related inpatient and emergency room costs, were lower relative to patients who were not in the program. Total hypertension-related and all-cause costs, from pre- to post-index in the intervention cohort, showed a greater, but not significant, decrease compared to the control cohort (15.2% vs. 2.6% and 7.9% vs. 4.3%, respectively).

A statistically significant change in hypertension-related ER costs (39.2% decrease vs. 16% decrease) was seen. For DCP participants, cardiovascular-related cost trends were favorable relative to the control group. In particular, pre- to post-index total medical costs increased 11% in the intervention cohort compared to nearly 300% ($p<0.05$) in the control cohort, and ER costs decreased by 89% in the intervention group while increasing 96% in the control group.

Regarding diabetes-related total health care costs, cost trends were higher for the intervention cohort compared to the control cohort (33.2% vs. 20.8%, respectively). All-cause total health care costs increased at about the same rate (approximately 20%) for the intervention and control cohorts; however, increased costs in the intervention cohort were largely due to increased costs for medications and office visits, whereas greater costs in the control cohort were related to inpatient status.

DISCUSSION

The CPCP is an important advancement in the effort to foster collaboration of multiple stakeholders in the health care delivery system through a progressive VBID program that offers both educational and financial incentives. Within this program were 2 care management programs, the DCP and the HHCP, whose criteria are described above.

The program was expected to demonstrate that, in the CPCP patients, improvements would be recognized in major disease-related clinical endpoints through improved health care utilization and increased patient adherence to medication therapies targeting their disorders and better adherence to nationally recognized care management programs.

Prescription costs were expected to increase in the CPCP participants because of improvements in adherence and utilization. Also, in the short term, we expected to see an increase in outpatient costs related to an increase in office visits, as these patients were seen by clinical pharmacists and, potentially, by primary care providers. An offset in costs was expected and realized through the prevention of cardiovascular-related events, as has been established in the published literature.

Specifically, it has been found that every 1% drop in HbA_{1c} corresponds to a 33% reduction in microvascular complications, an 18% reduction in myocardial infarctions, and a 25% reduction in diabetes-related deaths

(DCCT 1996, ADA 2002, UKPDS 1998, UKPDS 1998, UKPDS 1998, UKPDS 2002) and every 2 mmHg reduction in a patient's systolic blood pressure corresponds to a 7% and 10% reduction in death related to ischemic heart disease and stroke, respectively (Lewington 2002). Every 1% reduction in low-density lipoprotein cholesterol (LDL) corresponds to a 1% reduction in major CHD events (Grundy 2004).

In the short timeframe of this study, the trends in cost reduction for disease-related and all-cause ER visits and in inpatient hospitalizations were all markedly beneficial. It would be a great follow-up study to evaluate this program over 5 to10 years and evaluate the far-downstream effect of these coaching programs on relevant outcomes, which we project to provide continued clinical and economic benefits.

The CPCP design applied key aspects identified from previously developed care management programs, with primary design inputs coming from the Asheville Project, PSMP, and the DTCC (Cranor 2003, Garrett 2005, Fera 2009). Like the previous studies, the CPCP's primary purpose was to assess the effect of a pharmacist-based medication therapy management initiative on clinical and economic outcomes when designed within a broader VBID.

Key differences exist between CPCP and Asheville, PSMP, and DTCC in that the CPCP had a larger population enrolled in the care program, a focus on cardiovascular risk management in patients with and without diabetes, and a financial incentive for program participants.

In the analysis of program outcomes, we were able to integrate site-level clinical data capture with claim-level administrative data from the health plan. A more robust clinical and economic analysis could be applied because we had these multiple views of the care continuum through various levels of data elements.

In addition to a pre/post design, the CPCP assessment also incorporated use of a control group of non-participating patients who are employees of the city of Cincinnati with the same target chronic conditions of diabetes mellitus and/or hypertension. A propensity score matching technique ensured comparable baseline characteristics. In the Asheville, PSMP, and DTCC studies, the economic models only used individual patients as their own controls. Also, rather than modeling the cost effect of the benefits of clinical changes as was done in DTCC, the CPCP analysis used stakeholders' actual costs, derived from claims.

As with any VBID program, financial incentives need to be aligned between all stakeholders, including patients, providers, and payers (employers and health plans). In the CPCP, patient and provider incentives included a $100 contribution to the patient's health savings account (only the city of Cincinnati), waived charges for program-related visits with pharmacy coaches, waived/reduced copayments for diabetes, hypertension, and cholesterol medications, and laboratory assessments.

Payers could expect related cost-of-care reductions as increased prescription costs were offset by savings associated with reduced risk of cardiovascular events and diabetes complications. The wait for savings is relatively short. A lower rate of cardiovascular events has been demonstrated in as little as 2–3 years for patients with optimal lipid control (Stanek 2007). Also, using predictive modeling, the Pitney Bowes Co. was able to determine that patients with asthma, diabetes, and hypertension and with poor medication compliance were likely to migrate from a low medical cost category to a high medical cost category in 1 year. By using VBID, they were able to improve compliance and decrease overall spending on diabetes patients by 6% annually over3 years (Mahoney 2008).

Value-based insurance designs are being developed by health insurance companies and utilized by employer customers. Generally with VBID, copayment rate structures are set to encourage use of programs and services that have demonstrated to be of higher value than other programs and services (Chernew 2010, Chernew 2007). Definitions of value within the health care system relate the dollars spent to the outcomes achieved, frequently described as quality divided by cost. In our cohort of patients enrolled in DCP, significant improvements in HbA_{1c}, total cholesterol (TC), LDL, non-HDL, SBP, and DBP were seen at the 1-year follow-up (bit.ly/yAM7iF). Sixty-two percent of patients achieved their ADA HbA_{1c} goal of <7 mg/dL and 73% attained their NCEP goal LDL level of <100 mg/dL. Since patients with diabetes are at an increased risk of having cardiovascular disease-related events, the effects of DCP on reductions in both HbA_{1c} and LDL-C are clinically important in this population. These results are consistent with the PSMP and DTCC findings.

Patients in the HHCP also demonstrated significant improvements from baseline on key clinical measures, including SBP and DBP, TC, LDL-C, and non-HDL cholesterol (Table 3: bit.ly/yAM7iF). Seventy percent of patients in this group met their JNC-7 blood pressure goals, a 35% increase in achieving goal blood pressures from baseline in this population. HbA_{1c} and BP results in the HHCP were comparable to PSMP and DTCC results. LDL changes were smaller, compared to PSMP; however, the final values were lower. This reflects the fact that many participants were already at their LDL goals at baseline.

As expected, adherence improved in patients seen within the CPCP, which is in line with the positive changes seen on their clinical markers. Interestingly, CPCP participants demonstrated significantly more

add-on or changes in their therapy than did patients in the control group, most likely because of more active and aggressive management of their disease states. Also, increased usage of clinically appropriate classes of medications occurred in these patients. This was an important finding because it showed a program benefit beyond medication adherence — it showed that the patients were being actively/aggressively managed.

The analysis of administrative claims data in the HHCP revealed a reduction of 15.2% in total hypertension-related costs. There was a significantly greater increase in pharmacy and office visit costs. For DCP patients, it is interesting to note that the overall all-cause costs pre- to post-index for the intervention patients stayed about the same relative to the control cohort, but the type of resources used differed greatly. In the year after the program, the program participants had higher levels of spending on medications and outpatient services, such as screening tests, while the control group had higher levels of spending on ER visits and inpatient stays. This was particularly evident when comparing cardiovascular-related costs among the cohorts.

LIMITATIONS

Limitations of the study design must be considered when interpreting these results. The retrospective nature of claims analyses allows for the establishment of associations but not causality, and not all factors could be considered or were available for assessment. As with all claims analyses, the study population comprises patients who have sought care or treatment by a provider within the health plan. Administrative claims do not capture disease events and episodes in which treatment is not sought or in which treatment is delivered by a provider not within the health plan.

In addition, there could be self-selection into the program, where participants are likely to be more motivated than nonparticipants to make health-related improvements because of precipitating events. The study design did address differences in severity between participants and nonparticipants, although clinical outcomes by way of administrative claims were not available for nonparticipants.

Moreover, cholesterol levels at baseline were low compared to the general population, reflecting the possibility that the population may be healthier than the general managed care population.

Last, the prospective study analyses constitute a short-term evaluation of a longitudinal study, as the study focused on a 1-year follow-up. A longer timeframe may be needed to appreciate the full economic outcomes related to CV event reduction.

CONCLUSION

The results from the CPCP showed statistically significant and clinically meaningful improvements in hemoglobin A_{1c}, lipid levels and blood pressure readings, as well as greater goal attainment for each of these clinical measures. Program participants were actively and appropriately managed, which resulted in improved adherence. Cardiovascular-related cost trends were favorable for patients participating in the program, although longer follow-up may be needed to evaluate the long-term economic effect. The clinical results correlate well with results found in the Asheville Study, PSMP, and the DTCC, which found improvements in outcomes after enrollment in a similar pharmacy coaching program. Overall results from this study emphasize the importance of VBID in overall quality and cost of care for chronic diseases.

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