The Asheville Project: Clinical and economic outcomes of a community-based long-term medication therapy management program for hypertension and dyslipidemia

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Abstract

Objective: Assess clinical and economic outcomes of a community-based, long-term medication therapy management (MTM) program for hypertension (HTN)/dyslipidemia.

Design: Quasi-experimental, longitudinal, pre–post study.

Setting: 12 community and hospital pharmacy clinics in Asheville, N.C., over a 6-year period from 2000 through 2005.

Participants: Patients covered by two self-insured health plans; educators at Mission Hospitals; 18 certificate-trained pharmacists.

Interventions: Cardiovascular or cerebrovascular (collectively abbreviated as CV) risk reduction education; regular, long-term follow-up by pharmacists (reimbursed by health plans) using scheduled consultations, monitoring, and recommendations to physicians.

Main outcome measures: Clinical and economic parameters.

Results: Sufficient data were available for 620 patients in the financial cohort and 565 patients in clinical cohort. Several indicators of cardiovascular health improved over the course of the study: mean systolic blood pressure, from 137.3 to 126.3 mm Hg; mean diastolic blood pressure, from 82.6 to 77.8 mm Hg; percentage of patients at blood pressure goal, from 40.2% to 67.4%; mean low-density lipoprotein (LDL) cholesterol, from 127.2 to 108.3 mg/dL; percentage of patients at LDL cholesterol goal, from 49.9% to 74.6%; mean total cholesterol, from 211.4 to 184.3 mg/dL; and mean serum triglycerides, from 192.8 to 154.4 mg/dL. Mean high-density lipoprotein (HDL) cholesterol decreased from 48 to 46.6 mg/dL. The CV event rate during the historical period, 77 per 1,000 person–years, declined by almost one-half (38 per 1,000 person–years) during the study period. Mean cost per CV event in the study period was $9,931, compared with $14,343 during the historical period. During the study period, CV medication use increased nearly threefold, but CV-related medical costs decreased by 46.5%. CV-related medical costs decreased from 30.6% of total health care costs to 19%. A 53% decrease in risk of a CV event and greater than 50% decrease in risk of a CV-related emergency department (ED)/hospital visit were also observed.

Conclusion: Patients with HTN and/or dyslipidemia receiving education and long-term MTM services achieved significant clinical improvements that were sustained for as long as 6 years, a significant increase in the use of CV medications, and a decrease in CV events and related medical costs.

Keywords: Asheville Project, medication therapy management, disease management, hypertension, dyslipidemia, cardiovascular risk, health care costs, health outcomes, pharmacoeconomics.

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The Asheville Project is a community-based, pharmacist-directed, medication therapy management (MTM) program provided for several employers in the Asheville, N.C. area. In previously published reports, this model demonstrated significant improvements in diabetes and asthma outcomes while reducing the total health care costs paid by participating employers. In each study, medication utilization increased nearly threefold and total health care costs decreased, primarily as a result of decreases in emergency department visits and hospitalizations.[1,2]

Based on the successes of the prior Asheville Project programs and the need for improved care of cardiovascular disorders, a hypertension (HTN) and dyslipidemia program was implemented for employees of the City of Asheville, North Carolina, in 2000. The program was expanded to employees of Mission Hospitals, located in Asheville, in 2001. In this study, as in the diabetes and asthma studies, the employers agreed to compensate educators and pharmacists for education and regularly scheduled face-to-face patient consultations and to waive or significantly reduce disease-related medication copayments as a means of promoting participation in the program.

At a Glance

Synopsis: Clinical and economic benefits resulting from hypertension and dyslipidemia risk reduction education and long-term medication therapy management (MTM) by pharmacists were demonstrated in 12 community and hospital pharmacy clinics in Asheville, N.C., over a 6-year period, as part of the American Pharmacists Association Foundation's Asheville Project. Significant clinical improvements were seen for blood pressure (patients at goal: baseline 40.2%, study end 67.4%), various measures of cholesterol (patients at low-density lipoprotein goal: baseline 49.9%, study end 74.6%), and cardiovascular and cerebrovascular (CV, collectively) event rate (baseline 77 per 1,000 person–years, study end 38 per 1,000 person–years). An approximate threefold increase in CV medication use was observed, but CV-related medical expenses decreased by 46.5%, primarily as a result of the substantial decreases in emergency department visits and hospitalizations.

Analysis: *In the current work, a cost–benefit advantage was demonstrated in a population with generally good baseline CV status. This indicates that aggressively pursuing improvements in CV outcomes through pharmacist intervention in a broad population that includes at-risk patients, as well as patients who have yet to experience a CV event, can be cost effective. The long-term clinical and financial benefits demonstrated here provide convincing evidence to employers and other purchasers of health services that return on investment is likely from programs that include MTM services and other disease management approaches. Future research demonstrating clinical and financial improvements from such interventions in other disease management models is highly recommended.*

Objective

The objective of this study was to assess the clinical and financial outcomes of a long-term, pharmacist-driven MTM program for patients with HTN and/or dyslipidemia who were employees, spouses, or covered dependents of two large employers with approximately 12,000 covered lives in their self-insured health plans.

Methods

Two employers who were already providing long-term MTM programs for patients with diabetes or asthma began offering a similar program for covered health plan members with HTN and/or dyslipidemia. The unique components of the program were self-care education provided by professional educators at Mission Hospital's Health Education Center, face-to-face patient consultation services by community and hospital pharmacists, and financial incentives consisting of significantly reduced medication copayments on blood pressure and cholesterol-lowering medications.

Participating pharmacists received cardiovascular certificate training recognized by the North Carolina Center for Pharmaceutical Care, a service of the North Carolina Association of Pharmacists. All services and incentives were paid by the employers' health plans. The only outside funding used for the program was grant funding by Novartis, through the American Pharmacists Association (APhA) Foundation, to cover the costs of independent data extraction from medical and prescription claims.

This study was approved by the Institutional Review Board of Mission Hospitals. Informed Consent and Authorization for the Use and Disclosure of Protected Health Information was obtained per the board's approved processes.

Interventions

All patients in the study agreed to complete education classes related to cardiovascular risk reduction and to be matched with a participating care manager/coach with whom they would meet on a regular, long-term basis. Patients chose or were assigned to their care manager from the group of participating pharmacist providers. Patients agreed to meet with their care manager as frequently as once a month. However, the frequency of counseling sessions was ultimately determined by the care manager. During the study period, these counseling sessions averaged 30 minutes in length and most often occurred every 3 months. These one-on-one, appointment-based encounters were conducted in a semiprivate or private counseling area. Patients could withdraw at any time, but in doing so would forfeit future reduced medication copayments.

Guidelines based on the Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III) of the National Cholesterol Education Program (NCEP), the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VII), and the American Heart Association (AHA) were used to determine goals for patients unless their physician had established a more specific goal.[3–5] Physicians were asked to share their goals for each patient with the care manager. Medication assessments were provided by care managers, including a comparison of the patient's treatment regimen with those recommended in national guidelines. Blood pressure was checked at baseline as well as during care manager visits. Lipid panels were measured at baseline and at least annually. Recommendations were made to patients' physicians, most commonly via faxes, when potential improvements in therapy were identified.

Design and participants

This was a quasi-experimental, longitudinal, pre–post study. Participants were City of Asheville or Mission Hospitals employees or covered spouses or dependants with HTN and/or dyslipidemia who agreed to participate in a CV risk reduction program sponsored by their health plan.

The providers were community and hospital pharmacists and professional educators. A total of 18 pharmacists at 12 community pharmacy and hospital clinic locations participated. Pharmacists received certificate training to assure that they were up-to-date in national HTN and dyslipidemia guidelines.

Inclusion and eligibility criteria

All patients covered by the participating employer's health plans with a diagnosis of HTN and/or dyslipidemia, regardless of their baseline control, were eligible for enrollment. Admission to this CV risk reduction program occurred continuously from January 1, 2000, to December 31, 2005.

Intention-to-treat methodology was used. Patients were included in the clinical data analysis if they received any program intervention and if data were available on blood pressure and/or lipid values. Patients were included in the economic analysis if they received any program intervention and if health care cost data were available from insurance and prescription claims for at least 6 months preceding their enrollment in the study, and for as long as data were available postintervention, even if they withdrew from the program. When financial data were available for a period of less than 1 year, but more than 6 months, the data were annualized.

Outcomes definitions

The clinical outcomes assessed in this study were changes in blood pressure, low-density lipoprotein (LDL) cholesterol, total cholesterol (TC), serum triglycerides (TGs), high-density lipoprotein (HDL) cholesterol, and the percentage of patients at their goal for each of these parameters. In addition, the percentage of patients with Stage 1 and Stage 2 HTN, as defined by JNC VII, was assessed. The goal LDL cholesterol was defined for each patient individually based on the ATP III guidelines. Goal TG levels, based on AHA guidelines, were defined as levels less than 150 mg/dL. Goal HDL cholesterol levels, also based on AHA guidelines, were defined as 40 mg/dL or more for men and 50 mg/dL or more for women.[5]

We examined medical claims to determine all cardiovascular, cerebrovascular, and peripherovascular events. These are referred to in this article as CV events; they included myocardial infarctions (MIs), non-MI acute coronary syndromes (ACSs), strokes, transient ischemic attacks (TIAs), acute episodes of heart failure (HF), coronary artery bypass grafts (CABGs), percutaneous transluminal coronary angioplasty (PTCA), and peripheral vascular disease (PVD). We also determined the number of CV-related emergency department (ED) visits and hospitalizations, and the direct medical costs of CV events. The economic outcomes and ED/hospital event records were obtained from medical and prescription claims provided by employers through their contracted claims processing organizations. (Prescription claims were provided by American Health Care and Smith Premier; medical claims were provided by Wells Fargo and Kanawha.)

Mean annual CV-related costs were compared over time. Specifically, direct medical costs were defined as the amount paid by the employer's health plan for CV-coded visits to a health care provider or health care facility for CV-related medications, procedures, or services. These including routine physician office visits, ED visits, hospitalizations, prescription medications, program MTM services, program educator fees, and the cost to the health plan of the program's reduced medication copayment incentives. Direct medical costs included the cost of this program itself (MTM services, educator fees, study-related laboratory testing, reduced medication copayments).

Data sources

Demographic data were obtained from enrollment questionnaires and medical records. Clinical data were gathered from baseline and follow-up blood pressure measurements by program trained staff and providers. The majority of baseline and follow-up lipid measurements were conducted by the same laboratory using the same equipment. Data regarding direct CV medical costs were obtained from insurance and prescription claims.

Data measurement

In this intention-to-treat study, all patients enrolled in the program who received any intervention were included in the analyses whenever data were available. Since this was an open-enrollment study of usual patient care rather than a protocol-driven evaluation, the timing of follow-up blood pressure and lipid measurements was not strictly defined. When patients had

multiple measurements throughout the year, we used follow-up values that were closest to each patient's anniversary enrollment date in the analysis. Lipid measurements, which were covered by the employers' health plans, were performed at baseline and every 6 to 12 months thereafter.

Direct medical costs were determined from all available claims data, including postwithdrawal data, for as long as data were available. A minimum of 6 months of preintervention insurance claims were required. When a patient's 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 enrolled but had not been employed for a full year and those who lost health plan coverage (usually due to leaving employment) and had less than a year's worth of subsequent claims data available.

We determined CV-related costs per patient per year and adjusted to 2005 U.S. dollars using the U.S. Consumer Price Index for Medical Care.[6]

Data analysis

Standard statistical analyses were used, including parametric and nonparametric measures where appropriate. Descriptive statistics were used to characterize the findings at each time point and changes over time were evaluated with Wilcoxon sign–rank tests for continuous variables and McNemar's test for categorical variables. Logistic regression was used to calculate odds ratios (ORs) and 95% confidence intervals to estimate the risk of events in the intervention period compared with the historical period. All statistical analyses were performed with SAS (2004 version; SAS Institute, Inc., Cary, N.C.). Probability values are reported without regard to multiple comparisons and represent two-tailed tests. The major endpoints for comparison were annual follow-up from baseline, although the 6-month follow-up is displayed if these were the only data available. The last recorded data point for each individual is reported as "end-of-follow-up."

Because of the open-enrollment format with patients entering the program at different times, we needed to determine each patient's individual baseline year in a consistent and systematic way. For the clinical data this was easily established by using their enrollment date and subsequent annual evaluation dates thereafter. However, since the financial data were based on medical and prescription claims that were available by calendar year, a convention was needed for assigning a calendar year enrollment date to each individual. We assumed that if patients enrolled during the latter half of a year (July 1 or later) they would have minimal opportunity for program interventions to affect their financial outcomes that year, so that year was considered their baseline financial year. If they enrolled earlier in the year (before July 1) our assumption was that the program interventions would have been in place long enough to have an opportunity to influence their financial outcomes during that calendar year, and their baseline year was then defined as the prior calendar year. We were thus able to group all data into preintervention baselines and to group patients by time in the program, regardless of when they enrolled. For the clinical data we used at-enrollment clinical data as their baseline, since this was before any program intervention. For the financial analysis we were able to examine 3 years of historical financial data and designated the immediate year before enrollment as baseline year 1 (B1), data from 2 years prior as B2, and data from 3 years prior as B3. Postintervention years were simply designated as program years 1, 2, 3, 4, 5, and 6.

Results

Inclusion criteria were met by 620 patients for the financial analysis and 565 for the clinical analysis. Of the 565 patients in the clinical cohort (Table 1), 46 withdrew during the study period: 38 withdrew due to employment change, 4 were terminated by the program for noncompliance, and 4 dropped out because they no longer wanted to participate.

Of 906 program enrollees, 25 were excluded from analysis because they enrolled but never received any program interventions (no education or care manager visits). Another 52 were excluded because of a lack of clinical follow-up data due to late enrollment in the study, 129 because they were enrolled in the diabetes study before enrolling in the HTN/dyslipidemia program and were therefore not program naive, and 135 due to missing follow-up data.

Overall, 423 patients with a diagnosis of HTN met the inclusion criteria for the HTN clinical cohort. Significant improvements in both systolic and diastolic blood pressure were noted during the study period (Table 2). As shown in Figure 1, significant improvements were recorded for percentages of patients meeting their blood pressure goals and percentages of patients with blood pressure readings in the hypertensive Stages 1 and 2.

Table 3 provides clinical outcomes for the 424 patients with a diagnosis of dyslipidemia who met inclusion criteria for the dyslipidemia clinical cohort. The change in annual lipid measures was statistically significant at each annual follow-up compared to the baseline level with the exception of years 1, 2, 3, 4, and 6 HDL cholesterol levels. The statistically significant HDL cholesterol decline at year 5 and end of follow-up were the only statistically significant changes of the study that were not clinically favorable. Figure 2 shows the percentage of patients who were at their individualized lipid goals at baseline and at the end of follow-up (using ATP III and AHA guidelines).[3,5] The improvements in individual assessment for LDL cholesterol, TC, and TG goals were all statistically significant ($P < 0.01$).

CV events

As shown in Table 4, a nearly equal number of annual medical claims records from before the program participation (1,189) were available for comparison with those obtained during the program (1,286). The risk of CV events was significantly decreased during the study period, compared with the historical

Table 1. Demographics of patients with hypertension and/or dyslipidemia included in the clinical analysis (n = 565)

Characteristic	HTN only	Dyslipidemia only	HTN and dyslipidemia	All patients
n	141	142	282	565
No. men (%)	70 (49.7)	63 (44.4)	129 (45.7)	262 (46.4)
No. women (%)	71 (50.3)	79 (55.6)	153 (54.3)	303 (53.6)
Age (years), mean ± SD (range)	48.4 ± 9.17 (14–68)	49.7 ± 8.40 (23–64)	51.7 ± 8.10 (22–72)	50.4 ± 8.55 (14–72)
Race, no. (%)				
Black	34 (24.1)	8 (5.7)	33 (11.7)	75 (13.3)
Asian	0 (0)	0 (0)	5 (1.8)	5 (0.9)
White	104 (73.8)	129 (90.9)	240 (85.1)	473 (83.7)
Hispanic	1 (0.7)	3 (2.1)	1 (0.4)	5 (0.9)
Other	2 (1.4)	2 (1.4)	3 (1.1)	7 (1.2)
Education, no. (%)[a]				
Less than 7th grade	0 (0)	0 (0)	1 (0.4)	1 (0.2)
7th–11th grade	12 (10.0)	4 (3.6)	19 (7.8)	35 (7.4)
High school graduate/GED	32 (26.7)	25 (22.5)	50 (20.5)	107 (22.5)
Some college/vocational	45 (37.5)	30 (27.0)	84 (34.4)	159 (33.5)
College	24 (20.0)	34 (30.6)	65 (26.6)	123 (25.9)
Postgraduate	7 (5.8)	18 (16.2)	25 (10.3)	50 (10.5)
Employer, no. (%)				
City of Asheville	39 (27.7)	47 (33.1)	74 (26.2)	160 (28.3)
Mission Hospitals	102 (72.3)	95 (66.9)	208 (73.8)	405 (71.7)
Medical conditions, no. (%)[b]				
Diabetes	35 (24.8)	20 (14.1)	88 (31.2)	143 (25.3)
Heart failure	2 (1.4)	2 (1.4)	13 (4.6)	17 (3.0)
Asthma	23 (16.3)	13 (9.2)	31 (11.0)	67 (11.9)
COPD	1 (0.7)	0 (0)	6 (2.1)	7 (1.2)
Kidney disease	2 (1.4)	2 (1.4)	8 (2.8)	12 (2.1)
CV event history, no. (%)[b]				
Myocardial infarction	4 (2.8)	4 (2.8)	19 (6.7)	27 (4.8)
Stroke	0	1 (0.7)	3 (1.1)	4 (0.7)
Angina	7 (5.0)	8 (5.6)	31 (11.0)	46 (8.1)
Peripheral arterial disease	1 (0.7)	2 (1.4)	8 (2.8)	11 (2.0)
CABG/PTCA	5 (3.6)	5 (3.5)	15 (5.3)	25 (4.4)
Weight (pounds), mean ± SD (range)	215.0 ±59.95 (108–450)	181.61 ± 41.18 (119–364)	207.3 ± 46.60 (122–398)	204.2 ± 50.94 (108–450)
Current smoker, no. (%)[c]	17 (14.9)	7 (6.5)	39 (16.8)	63 (13.9)

Abbreviations used: CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; CV, cardiovascular; GED, general equivalency diploma; HTN, hypertension; PTCA, percutaneous transluminal coronary angioplasty.

[a]Missing values for 90 patients.

[b]Missing values considered as negative for medical conditions and CV event history.

[c]Missing values for 111 patients.

period. Overall, 13 patients had two or more CV events within a year during the historical period, compared with 2 patients in the study period. The overall number of CV events per year in the historical period ranged from 0 to 5; this decreased to 0 to 2 CV events per year in the study period.

Rates of CV events per 1,000 patients are depicted in Figure 3. Based on incidence rates in the historical period and study period, one would have expected 98 CV events in the study period. With the actual number of events of 48, the risk of having a CV event in the study was decreased by 53%, compared with the historical time point (OR 0.4691 [0.328–0.671]).

Patient use of EDs and need for hospitalization significantly decreased during the study, by 54% overall (Figure 4; OR 0.461 [0.349–0.611]. $P<0.0001$). The trends shown are based on 81 CV-related ED visits and 74 CV-related hospitalizations during the historical period, compared with 45 CV-related ED visits and 37 CV-related hospitalizations during the program study period.

Financial outcomes

Average health plan expenditures for CV-related medical costs decreased by 46.5% when comparing averages for the historical 1,189 patient–years to the study period's 1,268 patient–years. Per person per year (PPPY) CV-related medical health plan expenditures before the start of the program averaged $1,362; this decreased to an average of $734 over the course of the study period (Figure 5). The per person per month (PPPM) cost for CV-related medical costs decreased by $52.42.

Table 2. Outcomes in patients with diagnosis of hypertension

Time period	No. patients at start of period/no. patients with available data[a]	SBP (mm Hg) Mean ± SD	DBP (mm Hg) Mean ± SD
Baseline	301	137.3 ± 16.85	82.6 ± 11.62
1 year	306/229	129.3 ± 14.80[b]	79.1 ± 9.20[c]
2 years	264/204	127.8 ± 15.05[b]	78.9 ± 10.01[b]
3 years	181/157	127.5 ± 12.57[b]	78.3 ± 8.33[b]
4 years	114/107	127.0 ± 13.93[b]	76.0 ± 8.98[b]
5 years	77/75	125.0 ± 13.00[b]	75.9 ± 8.11[b]
6 years	26/25	127.5 ± 11.60[b]	77.0 ± 8.37[b]
End of follow-up	375/278	126.3 ± 14.20[b]	77.8 ± 9.67[b]

Abbreviations used: DBP, diastolic blood pressure; HTN, hypertension; SBP, systolic blood pressure.
[a]Declining number of participants over time is a result of fewer patients being in the program for the full 6 years of the study, compared with those who were in the program for at least 1 year.
[b]Significantly different from baseline at P <0.0001, Wilcoxon sign-rank test.
[c]Significantly different from baseline at P <0.0005, Wilcoxon sign-rank test.

Average health plan expenditures for CV-related drug costs increased by 290% over these same comparison time periods. The CV-related health plan expenditures for blood pressure and lipid drugs before the start of the program averaged $287 PPPY; this increased to an average of $846 PPPY over the course of the study period. The PPPM cost for blood pressure and lipid drugs increased by $45.83 PPPM. Savings due to lower CV-related medical costs exceeded increased blood pressure/lipid medication and program costs by 12.6%.

The percentage of total health plan costs that were CV-related in the historical period was 30.6%, which decreased to 19% of total health plan costs during the study period. For 92 CV-related events reported in the previous section, the mean cost during the historical period was $14,343 per event. This decreased during the program period to $9,931 per event, and the number of events declined to 48. A comparison of expected costs in the program period ($1,405,614) compared with actual costs ($476,688) equates to a reduction of $928,926 in averted CV-related medical event costs.

Discussion

Included in the March/April 2003 issue of the *Journal of the American Pharmacists Association (JAPhA)*[1] were results of a 5-year study of the long-term outcomes of the Asheville Project's disease management program that provided patient education and MTM services for 194 patients with diabetes. In the March/April 2006 issue of this same journal the results of a 5-year study of the long-term outcomes of the Asheville program for 207 patients with asthma were published.[2] Significant clinical, humanistic, and economic improvements were demonstrated in both of these studies. The current study was implemented to assess the effectiveness of this model for two other chronic conditions, HTN and dyslipidemia.

This 6-year study found significant improvements in a financial cohort of 620 patients and a clinical cohort of 565 patients. With the advent of MTM as a reimbursable service under Medicare in 2006, it is important to compare the value of MTM approaches for chronic illnesses such as diabetes, asthma, HTN, and dyslipidemia, to outcomes achieved with routine care. This is the only study of which we are aware that has examined the effects of providing cardiovascular risk reduction education and MTM services on the control of blood pressure, lipids, and direct medical costs over a time period as long as 6 years. In addition, our study group was derived from a general population of patients and did not

Table 3. Outcomes in patients with diagnosis of dyslipidemia

	Mean ± SD (no. patients at start of period/no patients with available data)[a]			
Time period	LDL (mg/dL) Mean ± SD (n)	TC (mg/dL) Mean ± SD (n)	TG (mg/dL) Mean ± SD (n)	HDL (mg/dL) Mean ± SD (n)
Baseline	127.2 ± 36.60 (369)	211.4 ± 45.70 (341)	192.8 ± 171.41 (340)	48.0 ± 13.35 (374)
1 year	111.4 ± 32.99 (326/293)[b]	189.6 ± 38.72 (323/272)[b]	153.7 ± 79.85 (323/272)[b]	48.6 ± 13.03 (327/296)
2 years	107.0 ± 29.20 (273/236)[b]	186.2 ± 37.35 (267/214)[b]	161.8 ± 91.39 (266/213)[c]	48.1 ± 12.35 (278/242)
3 years	104.6 ± 27.74 (187/166)[b]	183.2 ± 35.52 (175/136)[b]	164.2 ± 114.23 (174/135)[d]	48.4 ± 13.67 (191)
4 years	105.1 ± 26.91 (112/99)[b]	181.6 ± 33.73 (110/83)[b]	162.6 ± 100.52 (110/83)[e]	48.3 ±14.75 (114/102)
5 years	111.0 ± 34.54 (68/63)[b]	187.3 ± 41.91 (68/55)[b]	144.4 ± 71.50 (68/55)[b]	47.4 ±12.34 (68/63)[f]
6 years	110.4 ± 32.15 (32/30)[g]	183.9 ± 38.88 (32/27)[b]	142.2 ± 65.43 (32/27)[h]	45.3 ± 11.26 (32/30)
End of follow-up	108.3 ± 32.06 (404/353)[b]	184.3 ± 38.55 (404/326)[b]	154.4 ± 88.35 (402/323)[b]	46.6 ± 12.24 (412/362)

Abbreviations used: HDL, high-density lipoprotein cholesterol; LDL, low-density lipoprotein cholesterol; TC, total cholesterol; TG, triglycerides.
[a]Declining number of participants over time is a result of fewer patients being in the program for the full 6 years of the study, compared with those who were in the program for at least 1 year.
[b]Significantly different from baseline at P <0.0001, Wilcoxon sign-rank test.
[c]Significantly different from baseline at P = 0.0002, Wilcoxon sign-rank test.
[d]Significantly different from baseline at P = 0.0077, Wilcoxon sign-rank test.
[e]Significantly different from baseline at P = 0.0005, Wilcoxon sign-rank test.
[f]Significantly different from baseline at P = 0.0388, Wilcoxon sign-rank test.
[g]Significantly different from baseline at P = 0.0029, Wilcoxon sign-rank test.
[h]Significantly different from baseline at P = 0.01, Wilcoxon sign-rank test.
[i]Significantly different from baseline at P = 0.0015, Wilcoxon sign-rank test.

Table 4. Changes in numbers of cardiovascular, cerebrovascular, and peripherovascular events during historical (n = 1,189 patient–years) and study (n = 1,286 patient–years) periods

CV event	Historical period No. events	Study period No. events	% Change (expected versus actual)[a]	Odds ratio (95% CI)
MIs	23	6	−86	0.24 (0.098–0.594)[b]
Non-MI ACS events	58	37	−40	0.60 (0.392–0.910)[b]
Other[c]	11	5	−59	0.41 (0.155–0.856)[b]
Total	92	48	−53	0.47 (0.328–0.671)

Abbreviations: ACS, acute coronary syndromes; CV, cardiovascular, cerebrovascular, and peripherovascular events; MI, myocardial infarction.
[a]Expected values were calculated by adjusting the actual number during the historical period for the increased number of records available during the study period.
[b]Significantly decreased at $P < 0.05$.
[c]Hypertensive crisis, acute heart failure, coronary artery bypass grafts, percutaneous transluminal coronary angioplasty, transient ischemic attack, and peripherovascular disease.

focus solely on patients with poorly controlled conditions, making the differences we found all the more impressive.

Despite being gainfully employed, under the care of a physician, and having a health plan that included good prescription and medical benefits, less than one-half of the participants in our study—40.2%—were achieving their blood pressure goal, and only 49.9% were at their LDL cholesterol goal at the time they enrolled. Although goal achievement was obviously low, usual care in our community appears to be better than the national average. For example, only 35.1% of Americans with HTN have their blood pressure controlled ,according to the AHA.[7]

In the APhA Foundation's Project ImPACT: Hyperlipidemia, pharmacists working with patients with significantly elevated LDL cholesterol values (baseline average 153.7 mg/dL) were successful in accomplishing significant decreases in this key clinical indicator.[8] In this current study of a general population of people with the diagnosis of dyslipidemia with a much lower baseline LDL (127.2 mg/dL), the benefit of pharmacist MTM services was still demonstrated through a reduction in CV events. Even more surprising, a cost-benefit advantage was demonstrated. To see a cost benefit in this general population with relatively good baseline control is remarkable. This offers evidence that effective population management is possible and that it can be cost-effective. Considering our findings from a cost-benefit perspective, limiting disease management programs to only patients who have recently experienced cardiovascular events is not wise—it can be cost-effective to aggressively address broader populations that are at risk, including patients who have not yet experienced CV events.

Of the 20 CV outcome and indicator measures we evaluated, only 1—HDL cholesterol at year 5 and the end of follow-up—failed to improve significantly over time. This could have resulted from a lack of attention on this cholesterol component or an unintended consequence of focusing primarily on LDL cholesterol. Regardless, this finding emphasizes the importance of attempting to lower LDL and raise HDL cholesterol fractions simultaneously in patients with dyslipidemia who are participating in an MTM program.

The litmus test for the effectiveness of a program aimed at improving CV outcomes is to observe decreased ED visits and hospitalizations. After participation in this program patients were 50% less likely to have a CV-related ED visit and 55% less likely to have a CV-related hospitalization. Another key outcome measure was the impact on the actual number of CV events, which decreased by more than half, despite the aging of these at-risk participants over the 6 years of this study. Perhaps the most dramatic outcome of this study was the observed decrease in number of MIs, from 23 in the 3-year historical period to only 6 in the 6-year program period. This and the rest of our findings suggest a significant impact not only on primary but secondary prevention as well.

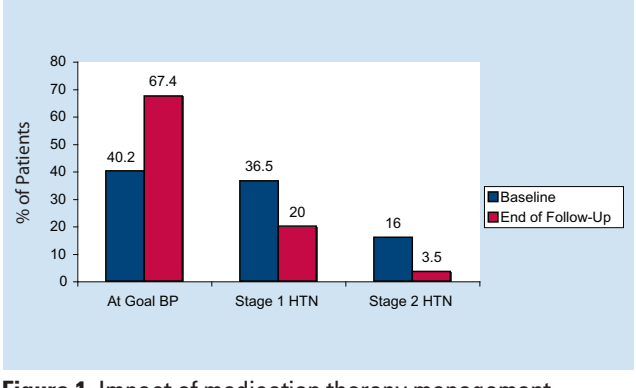

Figure 1. Impact of medication therapy management program on attainment of blood pressure goal
Abbreviations: HTN, hypertension; BP, blood pressure; JNC VII, Seventh Report of the Joint National Committee.
Goals individualized for each patient based on the national goals presented in reference 4; definitions of stages 1 and 2 HTN are also from that reference. Numbers of patients are presented in Table 2.

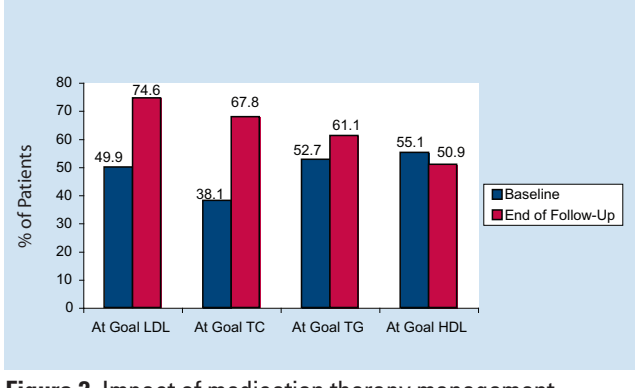

Figure 2. Impact of medication therapy management program on attainment of cholesterol goals
Abbreviations used: LDL, low-density lipoprotein cholesterol; TC, total cholesterol; TG, triglycerides; HDL, high-density lipoprotein cholesterol.
Goals individualized for each patient based on the national goals presented in references 3 and 5. Numbers of patients are presented in Table 3.

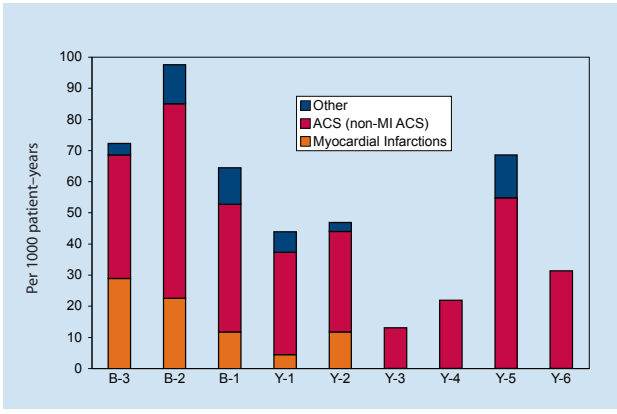

Figure 3. Frequency of cardiovascular, cerebrovascular, and peripherovascular events during historical and study periods

Abbreviations: ACS, acute coronary syndromes; MI, myocardial infarction.
See Table 4 for odds ratios for the events summarized in this figure.

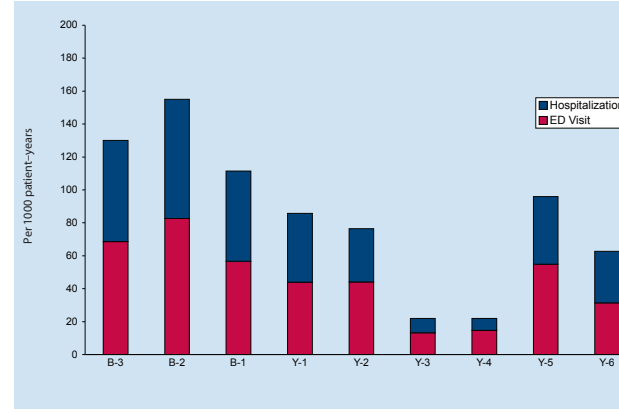

Figure 4. Use of emergency departments and hospitalizations during historical and study periods

Abbreviation: ED, emergency department.
See Table 5 for odds ratios for emergency department visits and hospitalizations.

From the health plan's perspective, the critical litmus test is the impact on net costs produced by a disease management program. In this study we saw a 46.5% decrease in mean health plan costs for CV-related medical care. This saving was partially offset by an increase in medication costs. However, one can assume that the 50 avoided CV events and associated $928,926 savings would not have occurred without this increased use of medications. Not only were there fewer events in the program period, but when these events occurred, costs were lower, indicating less severe events and/or sequelae. Compared with the previous two Asheville studies that showed a return on investment of approximately 4 to1, the return on investment in this model was modest. A positive return of 12.6% seems modest until one considers that this was a group of patients whose previous CV-related health care costs were relatively low ($1,362 PPPY). By contrast, according to the American Diabetes Association, the average health care costs of a person with diabetes exceeds $14,000 PPPY. Also, only 5.6% of our study group experienced a CV event in the 3 years before the start of the program. Considering these factors, the potential savings in a general population of patients with HTN and/or dyslipidemia is relatively small and therefore more difficult to demonstrate.

Also, in this study we only measured direct costs. We made no attempt to determine the value of these avoided events in terms of indirect cost reductions (disability and lost productivity). National data indicate that $148.6 billion of the total $431.8 billion cost burden of cardiovascular disease is attributable to indirect costs.[7] If nondirect medical and nonmedical costs were included in this calculation, the cost–benefit ratio would further improve. Therefore, the real value of this approach in terms of total cost benefit may be grossly underestimated.

Disease management programs, whether the more traditional telephonic nurse-driven model or a community-based pharmacist-driven model, need to demonstrate not only clinical and financial improvements, but that these improvements are sustainable over long periods of time, as was demonstrated in all three of the Asheville Project studies. Although clinical improvements are important to employers and purchasers of health care, evidence that these programs save more than they cost is crucial for financial support. Understandably, many purchasers of health care services will be skeptical of approaches such as MTM or other disease management approaches until they see convincing evidence that a return on investment is likely. At a time when rising health care costs threaten the insurability of many Americans, it is extremely important to determine whether preventive approaches are cost-effective. Studies that demonstrate the net financial impact in addition to particular disease management models are critically needed.

Limitations

The longitudinal analysis of patients in this pre–post study is subject to the limitations that are typical of a nonrandomized, real-world study with no control group. Of particular concern with this type of study is the possibility of regression to the mean (i.e., the chance that patients would have improved without the program interventions because, on average, a bad year would be followed by better years). We addressed this by looking back historically for 3 years before enrollment to ensure that patients had not enrolled in the program simply because they had a bad year. Our CV event data (Figure 3) indicate that the highest CV event rate in the 3-year historical period occurred 2 years before enrollment and that the lowest CV event rate occurred in the year immediately before enrollment. In addition, the 6-year length of the study further lessens the chance of this type of bias.

Another limitation derives from the implementation of two interventions at the onset of the study: waiving of copayments and pharmacists' services. Patients who agreed to participate in the study had medication copayments waived, and the resulting increased access to prescription drugs contributed to better

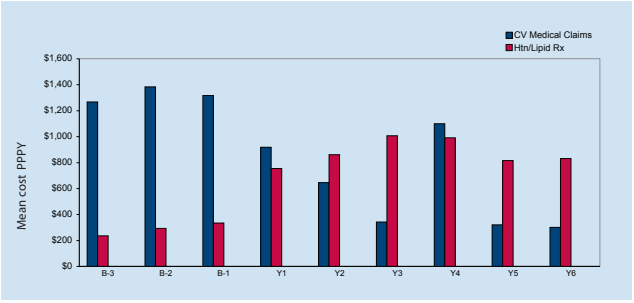

Figure 5. Annual mean direct medical costs for cardiovascular, cerebrovascular, and peripherovascular events during historical and study periods

Abbreviations: CV, cardiovascular, cerebrovascular, and peripherovascular events; HTN, hypertension; Rx, prescriptions; PPPY, per patient per year.

adherence rates that we observed during the study. We were not able to quantify the relative impact of the two interventions on the clinical and economic outcomes we observed.

Specific limitations to this study include missing and/or unreported clinical data, diminished cohort sizes over time, and limitations in the level of detail of claims data used for economic assessments. Cohort size diminished over time because we examined data by length in the program. Of note, the decrease in patients, as indicated in the tables and figures, is not a result of patient withdrawal; instead, the decrease is due to fewer individuals who were in the study for the full 6 years compared with those who were in the program for at least 1 year. However, this did not affect statistical tests because paired comparisons were used. Neither providers nor patients followed a specific study protocol or an electronic documentation system, which led to variability in the frequency of patient follow-up and availability of patient data. This is reflected in the exclusion of 135 patients due to a lack of clinical information. Of these, at least 12 were excluded because whether they had HTN, dyslipidemia, or both at the time of enrollment was unclear in their records. The majority of our demographic data were self-reported by the patients on their program enrollment form. Although we asked patients about their event history, we relied on medical claims data for our actual study of CV events changes over time. Because of the separate data sources for the two cohorts, matching patients in the clinical cohort to their corresponding economic outcomes in the financial cohort was not feasible.

The introduction of new therapeutic modalities could have accounted for improvements in a population followed for a lengthy time period. However, during the study period, no important new classes of medications for blood pressure or cholesterol were introduced. The concurrent clinical improvement, dramatic increase in medication use, and decline in CV events provides strong evidence that the improved outcomes resulted from MTM interventions.

Conclusion

A community-based CV disease management program that provided CV risk reduction education and face-to-face counseling by specially trained community and hospital pharmacists resulted in significant improvements in clinical and financial outcomes. After participation in the program, patients were significantly less likely to have a CV-related ED visit or hospitalization, a CV-related event, or CV-related medical expenses. This simple community-based model uses resources available in many communities and has now demonstrated long-term effectiveness for four chronic medical conditions; diabetes, asthma, HTN, and dyslipidemia. This model should be considered for populations with chronic medical conditions for whom self-care knowledge and appropriate medication use are important for improving outcomes.

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