

## A Pharmacy-Based Approach to Cholesterol Management

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**Objective:** To determine the clinical and economic impact of a pharmacy-based cholesterol management program in patients with cardiovascular disease.

**Study Design:** Demonstration project.

**Patients and Methods:** From January 1, 1999, through June 30, 1999, 300 patients with a documented history of cardiovascular disease were enrolled in a pharmacy-based cholesterol program. A similar group of 150 randomly selected patients receiving usual care during the same period served as the comparator group. The following were collected for both groups: patient demographics, comorbidities, fasting lipid profiles, cholesterol medication, cost of medication, and cardiovascular events. The McNemar symmetry  $\chi^2$  test was used to compare appropriate laboratory monitoring, receipt of cholesterol medication, and achievement of target low-density lipoprotein cholesterol levels at baseline and 1 year for both groups. Kruskal-Wallis analysis of variance was used to compare the cost of therapy for both groups at baseline and follow-up.

**Results:** Mean  $\pm$ SD age of program and usual care patients was 67 $\pm$ 10 and 69 $\pm$ 11 years, respectively. At 1 year, >95% of program patients were receiving appropriate laboratory monitoring. In 1 year, the percentage of patients reaching target low-density lipoprotein cholesterol levels increased from 45% to 72% ( $P < .01$ ) and from 33% to 43% ( $P = .26$ ) in program and usual care patients, respectively. Despite increased medication use among program patients, their cost per patient per month was lower at 1-year follow-up vs baseline.

**Conclusion:** Regular patient interaction and close patient monitoring allowed the pharmacy-based lipid management program to improve cholesterol management in patients with cardiovascular disease.

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resources each year.<sup>1</sup> Hypercholesterolemia is recognized as an important modifiable risk factor for the development and progression of CVD, with clinical trials<sup>2-6</sup> clearly demonstrating the morbidity, mortality, and economic benefits of cholesterol reduction in this patient population. The National Cholesterol Education Program (NCEP) Adult Treatment Panel II consensus guidelines<sup>7</sup> were developed to guide clinicians in the detection and treatment of hypercholesterolemia.

Despite growing awareness of the importance of cholesterol reduction in patients with documented CVD, adherence to NCEP guidelines remains poor. Survey results indicate that as many as 50% of patients do not have their cholesterol assessed and that only 15% to 45% of patients receive lipid-lowering therapy.<sup>8-16</sup> Also, relative to NCEP guidelines, only 10% to 25% of patients are treated to their target low-density lipoprotein (LDL) cholesterol level. In an attempt to improve cholesterol management, many institutions have developed multidisciplinary lipid clinics with physicians, nurses, pharmacists, and dietitians. Most clinics have been relatively successful at increasing the number of patients achieving NCEP target cholesterol levels.<sup>17-20</sup> However, lipid

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Cardiovascular disease (CVD) is a major cause of morbidity and mortality and a significant public health problem in the United States. It affects more than 2600 Americans each day and consumes approximately \$300 billion in healthcare

clinics generally use a large number of resources and manage only a small portion of the population.

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... PATIENTS AND METHODS ...

**Rationale**

Our medical facility (Univera Healthcare), 1 of 7 satellites within a large managed care organization in western New York, is complete with primary care clinics, an on-site pharmacy, a laboratory, and specialty care clinics. To improve the management of cholesterol for secondary prevention patients at our site, we developed a pharmacy-based monitoring program, designed as a demonstration project, that would capitalize on the regular interaction between pharmacists and patients. The close proximity of medical and laboratory staff as well as access to patient medical and pharmacy records were crucial in facilitating development of the program.

**Program Development**

*Treatment Guidelines.* Based on the recommendations of the NCEP, treatment guidelines were developed to guide the pharmacist in making treatment and monitoring recommendations. Recommendations for cholesterol medication were based on the lipid-lowering capabilities of the various agents and combinations of agents as well as on the organization's preferred drug list.

*Pharmacist Training.* Pharmacists were introduced to the cholesterol program during a formal orientation session that provided a review of the value of cholesterol reduction, an overview of NCEP treatment guidelines, a review of diet and pharmacologic management strategies, and discussion of patient cases. Individual training was conducted with each pharmacist for orientation to patient assessment and intervention procedures as well as standard filing and documentation procedures.

*Information Systems.* All patient clinical data were available through comprehensive electronic medical records. Several changes to the existing database were required to facilitate cholesterol management. A lipid profile screen was developed to display the most relevant information regarding cholesterol management, including patient demographics, a summary of lipid profiles, a lipid medication and refill summary, medication costs, and billing codes for CVD. In addition, a cholesterol assessment screen was developed to document recommendations and monitoring activities. For other healthcare providers to easily note which patients were enrolled in the program, the patient demo-

graphic screen was modified to identify these patients and display the date of the most recent cholesterol assessment.

**Program Operation**

*Patient Identification and Enrollment.* To facilitate recognition of candidates for the program, patients with CVD were identified in the clinical database through a query of diagnosis and procedure billing codes. All patients with documented CVD, including a history of myocardial infarction, cerebral vascular disease, peripheral artery disease, angina, or surgical revascularization, were considered candidates. The initial population included patients cared for by primary care physicians willing to participate in the project. Eligible patients were enrolled in the program as they presented to the pharmacy for routine prescription refills, including medication other than for cholesterol management. Once a patient was enrolled in the program, the prescription entry screen was modified to facilitate subsequent visits to the pharmacy.

Through computer query, we identified all patients with CVD receiving care from providers not involved in the program. A random sample of these patients served as a comparator group to illustrate usual care at our facility during the same period.

*Case Management Scenario.* On routine visits to the pharmacy, patients were introduced to the program with an informational letter explaining the services to be provided. During the initial interview, the pharmacist collected all demographic and medication information. The pharmacist was then responsible for reviewing the patient's medical chart, pharmacy record, and laboratory data to assess clinical status and cholesterol profile when available. A physician report was generated detailing the pharmacist's assessment of the lipid profile and recommendations for laboratory monitoring or changes to therapy. The costs of current and recommended medications were provided for physician review. Also, the pharmacist reported on medication adherence and adverse events, both patient reported and those revealed by abnormal laboratory findings. To ensure consistency among the different pharmacists involved and to simplify documentation of clinical activities, assessments and recommendations were chosen from a standardized list. All reports were sent to the physicians' offices for review and approval. On approval, the pharmacist implemented all recommendations and ensured appropriate follow-up. All reports were then filed in patients' medical charts.

To obtain follow-up fasting lipid profiles (FLPs) and liver function tests, the pharmacist directed the patient to schedule an appointment with laboratory personnel.

During medication counseling sessions, the pharmacist provided education about the role of cholesterol in CVD, emphasized the importance of medication adherence, reinforced the importance of diet and lifestyle changes, and ensured appropriate laboratory monitoring. Regular consultation also allowed the pharmacist to assess cholesterol medication adherence and tolerance and to review the entire medication profile to identify other drug-related problems. The pharmacist consulted with the primary care physician regarding any abnormal findings and was responsible for referring patients to nutritional classes, individual consults with a dietitian, and diabetic teaching when necessary.

#### Data Collection

We documented cholesterol management for patients enrolled in the program from January 1, 1999, to June 30, 1999. Through retrospective medical chart review, we documented cholesterol management for patients receiving usual care in the comparator group. We collected baseline demographics and comorbidities for program and usual care patients. We documented FLPs, cholesterol medication, and cost of medication at enrollment and after 1 year of follow-up. All cardiac events, including myocardial infarction, unstable angina, coronary artery bypass graft, percutaneous coronary interventions, and cardiac-related deaths, were documented for outcome analysis.

#### Assessment of Cholesterol Management

Cholesterol management was assessed at initial enrollment (baseline) and during 1-year follow-up. Assessments were based on appropriateness of laboratory monitoring, receipt of cholesterol medication, and achievement of the target LDL cholesterol level. Patients were considered to have appropriate laboratory monitoring if they (1) were *not* taking cholesterol medication and were at the target LDL cholesterol level and had an FLP within the past year; (2) were taking cholesterol medication for more than 1 year and were at the target LDL cholesterol level and had an FLP and liver function tests within the past year; or (3) were taking cholesterol medication and were *not* at the target LDL cholesterol level and had an FLP with recent medication initiation or dose change and liver function tests as follows: statins, every 3, 6, and 12 months for the

first year and then annually; gemfibrozil, 8-12 weeks after initiation and then annually; and niacin, 8-12 weeks during titration and then annually.

Patients with LDL cholesterol levels <2.59 mmol/L (<100 mg/dL) were considered to be at the target cholesterol level based on NCEP guidelines for patients with a history of CVD.<sup>7</sup> The cost of cholesterol medication per patient per month was determined for patients receiving cholesterol medication.

#### Data Analysis

All data analysis was performed using Systat (Version 7.01; Systat Inc, Evanston, IL). Dichotomous and categorical baseline data were compared using Pearson  $\chi^2$  or Fisher exact tests when the expected value of any cell size was less than 5. Continuous variables were analyzed by Kruskal-Wallis analysis of variance. Appropriate laboratory monitoring, receipt of cholesterol medication, and achievement of the target LDL cholesterol level were compared at baseline and follow-up for program and usual care patients using the McNemar symmetry  $\chi^2$  test. All cardiac events, including myocardial infarction, unstable angina, coronary artery bypass graft, percutaneous coronary interventions, and cardiac-related deaths, were compared in program and usual care patients using the Pearson  $\chi^2$  test.

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### ... RESULTS ...

From January 1, 1999, through June 30, 1999, we enrolled 300 patients in the pharmacy program (mean age, 67 years; age range, 42-90 years; 70% men). The comparator group consisted of 150 patients (mean age, 69 years; age range, 40-91 years; 67% men). **Table 1** shows the demographic information for all patients by treatment group. Patients receiving usual care had a higher incidence of myocardial infarction and angina compared with those enrolled in the program.

Overall, recommendations were well received by physicians, with less than 1% of all recommendations being refused. We documented a total of 496 interventions in 249 patients during 1-year follow-up (**Table 2**).

At baseline, 39% of program patients were treated with lifestyle modification only. After 1 year, 75% of program patients and 50% of usual care patients were receiving cholesterol medication (**Table 3**). In both groups, most treated patients were receiving statin therapy at baseline and follow-up. At follow-up, 4% of program patients vs none of the usual care patients were receiving combination therapy.

**Table 1.** Baseline Demographics\*

	Program Group (n = 300)	Usual Care Group (n = 150)
Age, mean ±SD, y	67±10	69±11
Age ≥75 y	79 (26)	52 (35)
Men	211 (70)	100 (67)
Smokers	32 (11)	16 (11)
Hypertension	164 (55)	88 (59)
SBP, mean ±SD, mm Hg	145±19	143±16
DBP, mean ±SD, mm Hg	82±10	82±10
Diabetes	96 (32)	47 (31)
Glycosylated hemoglobin, mean ±SD	7.3±1.4	7.6±1.8
Myocardial infarction	108 (36)	70 (47) <sup>†</sup>
Angina	74 (25)	69 (46) <sup>§</sup>
Revascularization <sup>†</sup>	166 (55)	80 (53)
Cerebral vascular disease	20 (7)	17 (11)
Peripheral vascular disease	20 (7)	18 (12)
Heart failure	36 (12)	26 (17)
Arrhythmia	44 (15)	27 (18)
Hypothyroidism	26 (9)	17 (11)

SBP = systolic blood pressure; DBP = diastolic blood pressure.

\*Data are given as number (percentage) of patients except where indicated otherwise.

<sup>†</sup>Includes coronary artery bypass graft and percutaneous coronary transluminal revascularization.

<sup>‡</sup>*P* = .029, Pearson  $\chi^2$ .

<sup>§</sup>*P* < .001, Pearson  $\chi^2$ .

For patients receiving cholesterol medication, costs per patient per month are shown in **Figure 1**. Although a greater proportion of patients in the program group received medication, their cost per patient per month was lower at 1-year follow-up vs baseline. In fact, the monthly cost of medication decreased for patients enrolled in the program and significantly increased for the usual care group.

As shown in **Figures 2 and 3**, patients enrolled in the program demonstrated a significant improvement in appropriate laboratory monitoring and a significant increase in the percentage of patients reaching the target LDL cholesterol level during 1-year follow-up. During the same 1-year period, no significant improvements were observed in these parameters for usual care patients. In fact, we observed a significant decrease in the percentage of usual care patients with appropriate laboratory monitoring at 1-year follow-up.

Further analysis of only patients with elevated cholesterol levels at baseline in the program and usual care groups revealed that 64% and 42%, respectively, achieved the target LDL cholesterol level after 1 year (*P* < .01). There were no significant changes in triglyceride or high-density lipoprotein levels from baseline to follow-up for program or usual care patients.

**Figure 4** illustrates the improvement in overall management for both groups. The percentage of program patients receiving appropriate laboratory monitoring and achieving the target LDL cholesterol level significantly increased, whereas no change was observed for usual care patients. There was no difference in the percentage of clinical events during 1-year follow-up for program (6.3%) and usual care (8.7%) patients (*P* = .36).

**Table 2.** Interventions

	Interventions, No. (%) (N = 496)
Laboratory monitoring	
Initial assessment	322 (65)
Safety and/or efficacy follow-up	50 (10)
Subtotal	<b>372 (75)</b>
Medication	
Initiation of drug therapy	36 (7)
Switch to a more cost-effective agent	35 (7)
Adjustment of dose	24 (5)
Addition of a second agent	5 (1)
Subtotal	<b>100 (20)</b>
Dietary*	<b>24 (5)</b>

\*Referral to a dietary class or an individual appointment with a dietitian.

... DISCUSSION ...

Our pharmacy-based cholesterol program improved cholesterol management in high-risk

patients at our healthcare facility. Compared with usual care, patients enrolled in the program showed improvements in appropriate laboratory monitoring and in the percentage of patients reaching the target LDL cholesterol level. Also, despite an increase in cholesterol medication use among program patients, their medication cost per patient per month decreased.

Improved management of hypercholesterolemia with pharmacist intervention is well documented.<sup>17,20-22</sup> Few clinics, however, report the number of high-risk patients achieving target LDL cholesterol levels, and none indicate which patients receive appropriate safety and efficacy laboratory monitoring.<sup>19,23</sup> Our pharmacy-based program ensured appropriate monitoring of nearly all patients enrolled and successfully treated more than 70% of all patients and 64% of patients with elevated cholesterol levels to target LDL cholesterol level.

Our rates are somewhat higher than those of other secondary prevention programs. Bogdon et al<sup>19</sup> reported the results of a pharmacist-physician team in which 38% of high-risk patients reached a target LDL cholesterol level of <2.59 mmol/L (<100 mg/dL). A community pharmacy-based intervention program<sup>23</sup> similar to ours showed that 48% of secondary prevention patients achieved target LDL cholesterol levels.

We observed a significant increase in the percentage of patients enrolled in our pharmacy program receiving cholesterol medication compared with the

usual care group. At the end of 1-year follow-up, 75% of our patients were receiving cholesterol medication. Several other studies also report an increase in medication use in clinic patients. Utilization rates of 87% to 93% have been reported for primary and secondary prevention patients enrolled in specialized cholesterol clinics.<sup>21,23</sup> Also, in a population of only secondary prevention patients, Shaffer and Wexler<sup>24</sup> reported that medication utilization rates increased by 43% and 13% for lipid clinic and general medicine patients, respectively. It is unlikely that a program with focused efforts to reduce LDL cholesterol to a target level of <2.59 mmol/L (<100 mg/dL) would do so effectively without an increase in medication utilization. All patients enrolled in our program were considered high risk because of their history of CVD and would therefore necessitate aggressive treatment, including drug therapy in many cases.

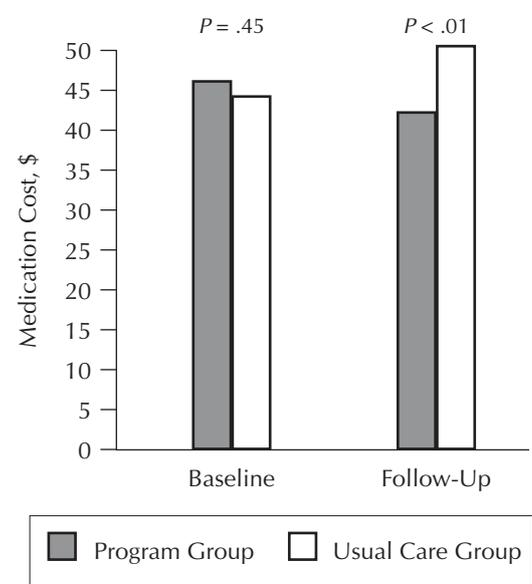
Overall medication costs per patient per month for those receiving cholesterol medication decreased for those enrolled in the program. As shown in previous studies,<sup>25,26</sup> the cost effectiveness of cholesterol medication, measured by cost of treatment per LDL-lowering effect, is different among cholesterol agents. Through promotion of preferred agents and combination therapy, our program was able to minimize drug costs despite increased medication utilization.

**Table 3.** Treatment Summary

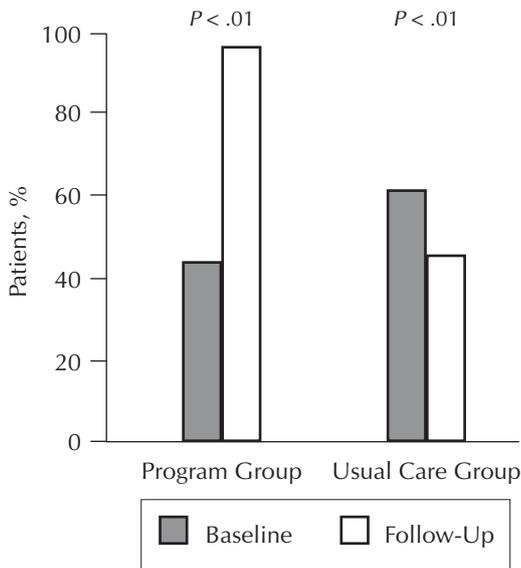
Treatment	Program Group, No. (%)		Usual Care Group, No. (%)	
	Baseline	Follow-up	Baseline	Follow-up
Lifestyle modification only				
Patients	117 (39)	75 (25)	84 (56)	75 (50)
Cholesterol medication				
Patients	183 (61)	225 (75)*	66 (44)	75 (50)
Statins	170 (93)	214 (96)	59 (89)	67 (89)
Gemfibrozil	8 (4)	11 (5)	0	0
Niacin	5 (3)	3 (1)	6 (9)	6 (8)
Bile acid resins	6 (3)	7 (3)	1 (2)	2 (3)

\**P* < .01, McNemar symmetry  $\chi^2$  (baseline vs follow-up).

**Figure 1.** Medication Costs per Patient per Month for Those Receiving Medication



**Figure 2.** Percentage of Patients Receiving Appropriate Laboratory Monitoring and Follow-up

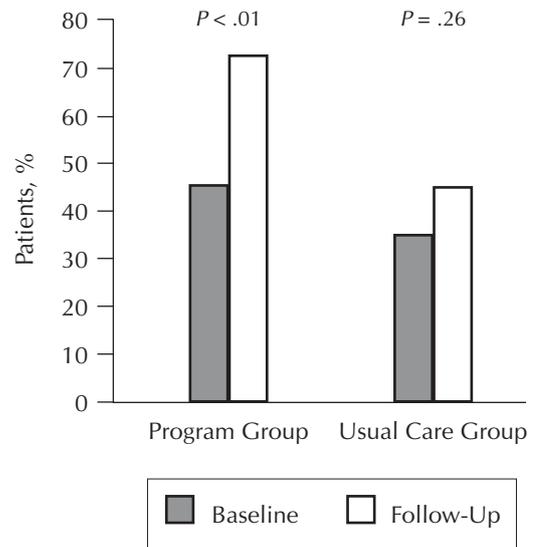


The number of patients with documented cardiovascular events after 1-year follow-up was not different between program and usual care patients. We speculate, however, that longer follow-up would better illustrate the impact of continuous monitoring and management by the pharmacy-based program.

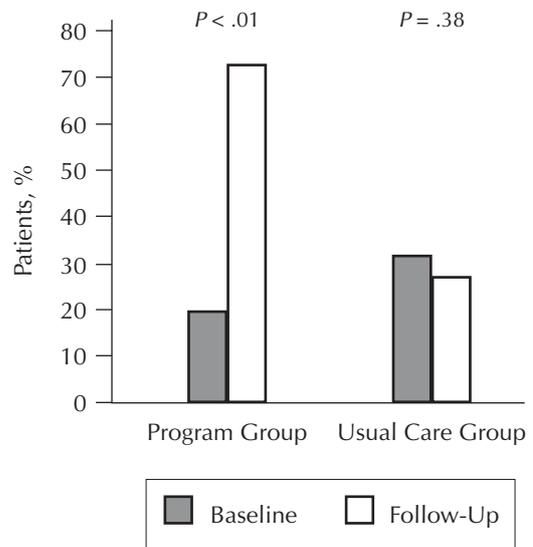
One of the most significant advantages of our pharmacy-based program was the volume of patients (n = 300) managed by the equivalent of one full-time pharmacist. Several other ambulatory pharmacy programs reported managing a much smaller population of patients at individual sites.<sup>22,23</sup> It is important to note that although our entire population was secondary prevention and would therefore require a cholesterol assessment, not all patients required a treatment intervention. However, our program ensured that all patients received a cholesterol assessment and proper follow-up. Also, those requiring other services, such as nutrition classes, nutrition consults, or diabetic teaching, could be identified and referred to other providers as appropriate.

Although certain operational aspects of our program might be difficult to replicate in the community setting, there is potential for this program to serve as a model for other pharmacy programs. The largest obstacles facing most community pharmacy-based programs include access to medical information, communication with physicians, and data management. Although our site has the advantage of

**Figure 3.** Percentage of Patients Achieving Target Low-Density Lipoprotein Cholesterol Levels



**Figure 4.** Percentage of Patients Achieving Target Low-Density Lipoprotein Cholesterol Levels and Receiving Appropriate Laboratory Monitoring



on-site medical records, some information, including cardiovascular history, could be obtained in the community setting through patient interview. Alternate means of communication, including facsimile and electronic messages, between pharma-

cies and physician offices, as well as establishing collaborative prescribing agreements and protocols, are potential ways to allow pharmacists to operate specialized clinics in the community setting. Working with the institution's information systems to accommodate the specific needs of the program within the electronic patient record is a tremendous asset for data management. Alternatively, data management software for specific disease management programs is widely available from pharmaceutical companies.

The unique setting of our program allowed the pharmacist to capitalize on access to medical and pharmacy records. Through regular pharmacist-patient interaction during routine visits to the pharmacy, the pharmacist was able to provide disease, dietary, and medication education as well as continuous follow-up of cholesterol profiles to improve cholesterol management in patients with CVD.

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