FEATURE

Interim Report from Project ImPACT: Hyperlipidemia

Collaborative practice model shows promise for improving patient care.

Benjamin M. Bluml, James M. McKenney, Mark J. Cziraky, and R. K. Elswick Jr.

What would happen if pharmacists worked with patients and their physicians to identify and manage chronic disease? What could happen if pharmacists used point-of-care testing technologies to obtain objective patient data in the pharmacy? What are the possibilities for improving patient outcomes if pharmacists take the initiative to re-engineer their practice to provide patient-centered services? What role can pharmacy play in the health care delivery system when pharmacists demonstrate that they add value to the process and outcomes of care? These are the key questions being addressed in this demonstration project.

Project ImPACT (*Im*prove *P*ersistence *A*nd *C*ompliance with *T*herapy): Hyperlidemia, initiated in 1996, is an ongoing, two-year, community pharmacy–based demonstration project being conducted by the American Pharmaceutical Association Foundation. The project is documenting the contributions pharmacists can make to health and quality of life in patients with lipid disorders. As of spring 1998, pharmacists at 29 of the original 32 sites were continuing to conduct cholesterol testing and provide this patient-focused disease state management service in their practices.

This article is based on data collected through December 1997 and reports the experience of 469 patients who have continued in the project for an average of 14 months. Observed rates for persistence and compliance with medication therapy are 84.0% and 84.3% respectively, and 44.3% of these patients have reached their National Cholesterol Education Program (NCEP) lipid goals. The final report will be issued after the project concludes on December 31, 1998.

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Rationale

Hyperlipidemia was considered an ideal area in which to demonstrate the benefits of collaborative practice between and among patients, pharmacists, and physicians for the following reasons:

- Coronary heart disease (CHD) is the leading cause of death in the United States and accounts for an annual expenditure of $100 billion for health care.[1]
- Hyperlipidemia has been associated with increased risk of CHD in large-scale epidemiologic studies.[2]
- Reduction in low-density lipoprotein cholesterol (LDL-c) levels has been shown to produce reductions in CHD events and total mortality.[3-9]
- Other modifiable CHD risk factors are present in the hyperlipidemic patient, including hypertension, diabetes, obesity, and sedentary lifestyle.
- Pharmacist services are widely accessible to patients, physicians, and other health care providers.
- Evidence suggests that pharmacists who provide disease management services can increase patient compliance and improve treatment outcomes.[10-12]
- A point-of-care testing device for measuring lipid levels, the Cholestech LDX Analyzer, is available to pharmacists and other health care providers. The device also calculates individualized patient cardiac risk from additional patient data that are compared with Framingham Heart Study data programmed into the analyzer.
- The availability of patient lipid profile results and risk factor information within five minutes of obtaining a blood sample by finger-stick allows the pharmacist to be directly involved in the management of lipid-lowering therapies and patient outcomes.
- The management of cholesterol disorders represents a major benchmark by which quality health care services can be evaluated by accrediting agencies and purchasers of health care.[13]

Data obtained thus far from Project ImPACT: Hyperlipidemia are demonstrating that pharmacist interventions using point-of-care testing technology in the management of patients with lipid

Table 1. NCEP Guidelines for Selected Measures

Total Cholesterol	Triglycerides	High-Density Lipoproteins	Low-Density Lipoproteins
< 200 mg/dL desirable	< 200 mg/dL desirable	≥ 35 mg/dL desirable	< 160 mg/dL goal if < 2 RFs
200–239 mg/dL borderline	200–400 mg/dL borderline	< 35 mg/dL low	< 130 mg/dL goal if ≥ 2 RFs
≥ 240 mg/dL high	400–1,000 mg/dL high		≤ 100 mg/dL goal if CHD history
	> 1,000 mg/dL very high		

CHD = Coronary heart disease.
NCEP = National Cholesterol Education Program.
RF = Risk factor.

disorders have a positive influence on medication compliance and persistence. Ultimately, it is expected that such improvements in the medication use process will result in a greater number of patients reaching their target lipid goals. If patients reach and maintain these target lipid goals, it is assumed that cardiovascular-related risk will be reduced. Table 1 provides an overview of desirable ranges for selected lipid measures as recommended by the NCEP.

Collaborative Practice Model

This demonstration project is based on a practice model that uses health care resources that are available today in an increasing number of ambulatory-care pharmacy practice settings:

- Private or semiprivate areas for patient consultation.
- Technician support to free pharmacists for patient care activities.
- Documentation systems for recording and tracking patient care interventions.
- Experience with patient-focused disease state management programs.
- Demonstrated communication skills.
- Ability to implement point-of-care testing technologies.

The practice model was designed to bring about a high level of collaboration in care by increasing communication between and among patients, pharmacists, and physicians. Enhanced communication promotes sharing of pertinent clinical data, including the objective lipid measures obtained in the pharmacy, and the facilitation of evaluation of patient progress toward lipid goals and adjustments in the patient's treatment plans.

The model was also designed to allow sufficient flexibility to accommodate the different practice settings represented in the study (see Table 2), the specific demographics of the patient cohort served, and those practice arrangements already existing within local and/or regional health care marketplaces.

Figure 1 illustrates the collaborative care process that defines the practice model.

Table 2. Project ImPACT: Hyperlipidemia Participating Pharmacies by Setting

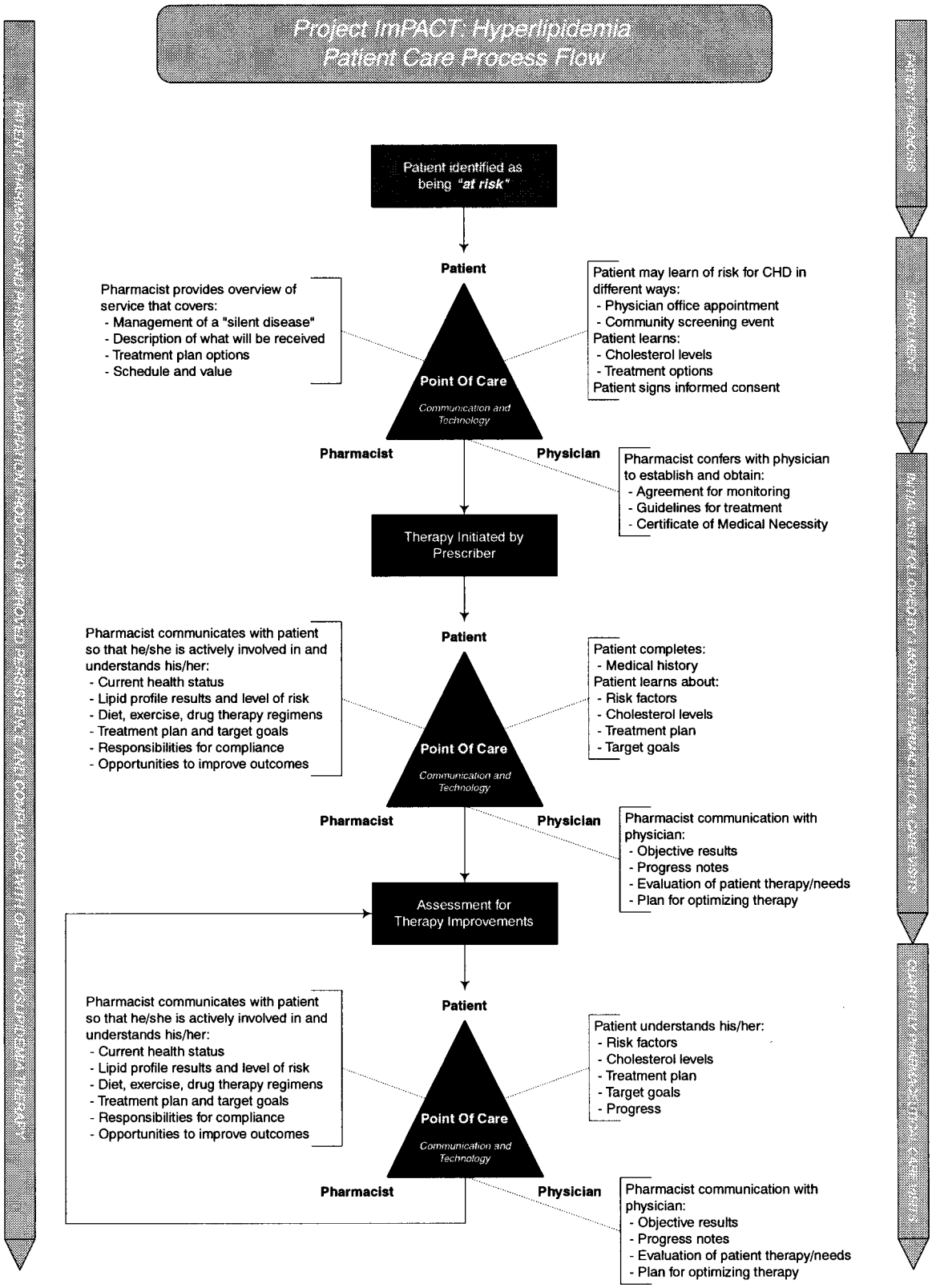
Community Pharmacy Practice Setting	No.
Independent	17
Clinic pharmacy	4
Chain—professional	3
HMO/managed care	2
Home health/home infusion	2
Chain—grocery store	1

The Project ImPACT Process

Each participating pharmacy site was asked to enroll 30 patients who were either newly diagnosed with dyslipidemia (e.g., hypercholesterolemia, mixed hyperlipidemia) or already receiving lipid-lowering medications but poorly controlled (i.e., not yet at target lipid goal). The enrollment period and project duration were established in the project planning stage to allow sufficient time for pharmacists to monitor each patient for a minimum of 12 months and a maximum of 24 months. Patients were identified either through referrals from local physicians or by patient self-referral. In the latter case, the patient's physician was contacted by the pharmacist and involved from that point forward in the patient's care. All patients were required to give written consent once they had been informed of the pertinent background information on the project, what their participation would involve (including potential benefits, risks, inconveniences, discomforts), their right to confidentiality, and their right to withdraw at any time.

After signing the informed consent to participate and an authorization for medical information to be sent to the pharmacist by other health care providers, the patient was assigned a project patient code (known only to the patient and the pharmacist). At that time the patient completed a one-page personal information form, which remains on file in the pharmacy's patient record. Each participating patient also completed a four-page patient history form that provides general health information, which the pharmacist used to fully assess the patient's CHD risk. A fingerstick was then performed to obtain a blood sample for a fasting lipid profile analysis. Lipid profile results and subsequent

Figure 1. Project ImPACT Collaborative Care Process



intervention activities were logged on a project clinical activity form. (*Note: patient history and clinical activity forms used to collect data for the project identify patients only by their project patient code, thus maintaining patient confidentiality.*)

After the initial visit and consultation with the pharmacist, patients were asked to schedule follow-up visits every month for the first three months and quarterly thereafter. Over the course of the project, participating pharmacists have maintained communications with patients and their physicians. In addition to being actively involved in their own therapy, treatment plans and goal setting, patients are regularly informed about their progress: their cholesterol test results, condition, and CHD risk. While project pharmacists were encouraged to prospectively establish fees and request compensation as a means to inform patients and payers of the value of their services, an inability or unwillingness to pay did not preclude an otherwise qualified patient from enrollment in the demonstration project.

Results for Patients Enrolled 6 to 19 Months

During the first 19 months of the project, a total of 546 patients were enrolled. Seventy-seven patients (14.1%) chose not to continue for various reasons: 17 did not return after the initial visit, 15 withdrew in the first 90 days, 14 moved or transportation became unavailable, 13 lacked the motivation to continue, 7 were lost to follow up, 5 did not want to continue with medication therapy, and 6 withdrew for personal or other reasons.

The interim results presented here relate to reported data on 469 patients who have been enrolled in the project for 6 to 19 months (average = 14 months). The population consists of 53.9% women and 46.1% men, with an average age of 56 years. Of these patients, 24.1% had previously experienced a coronary event and therefore fell into a secondary prevention category; the other 75.9% had no history of CHD and were categorized as primary prevention patients. Of the 469 patients evaluated, 357 (76.1%) are being treated with lifestyle modifications and lipid-lowering medications, while the remainder continue with lifestyle modifications focused on diet and exercise in an effort to reach target cholesterol goals. The distribution of lipid-lowering medication use is as follows: 79% HMG-CoA reductase inhibitors, 8% niacin, 8% fibrates, and 5% bile acid resins.

Persistence with Medication Therapy

The persistence measure used for the project was defined as: a patient who started on medication, has remained on medication subsequent to drug therapy initiation, and continues to be on medication as of his or her last visit. Of the 357 patients started on medication, 300 continue with drug therapy, for a resultant medication persistence rate of 84.0% (average medication therapy duration = 10 months).

Compliance with Medication Therapy

Compliance was determined through an evaluation based on the number of missed doses for each lipid-lowering medication and refill timing. Any patient who missed doses for five days or missed a scheduled refill visit by more than five days was considered noncompliant at that visit. Of 1,719 documented visits for patients on medications, there were 1,449 occurrences of compliance reported, for a resultant per-visit medication compliance rate of 84.3%.

Lipid Levels

The fasting mean lipid levels presented in Table 3 demonstrate statistically significant improvements using a paired two-tailed *t*-test analysis, from initial visit to end-of-period measurements, for the 469 patients who have continued in the project for an average of 14 months. Mean reductions of 7.7% ± 0.9% and 6.8% ± 2.2% were observed for total cholesterol and triglycerides, respectively, while a mean increase of 7.6%

Table 3. Fasting Mean Lipid Levels

	mg/dL (± SD)			
Measure (No. Patients)	Initial Visit	End of Period*	Mean Change	*p* value†
Total cholesterol (n = 454)	240.7 (48.0)	222.2 (42.3)	– 18.5 (2.2)	< 0.0001
Triglycerides (n = 450)	232.6 (130.6)	216.8 (111.4)	– 15.8 (5.0)	< 0.0016
High-density lipoproteins (n = 436)	43.4 (14.5)	46.7 (15.9)	+ 3.3 (0.48)	< 0.0001
Low-density lipoproteins (n = 380)	155.2 (41.0)	134.8 (37.3)	– 20.4 (2.0)	< 0.0001

*Average = 14 months.
†Using two-tailed paired *t*-test comparing all initial visit and end-of-period values.
SD = Standard deviation.

Figure 2. Percentage of Patients to NCEP Goal

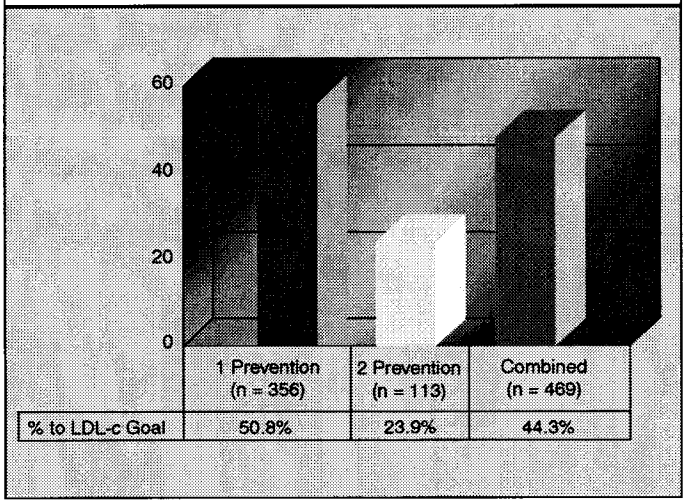
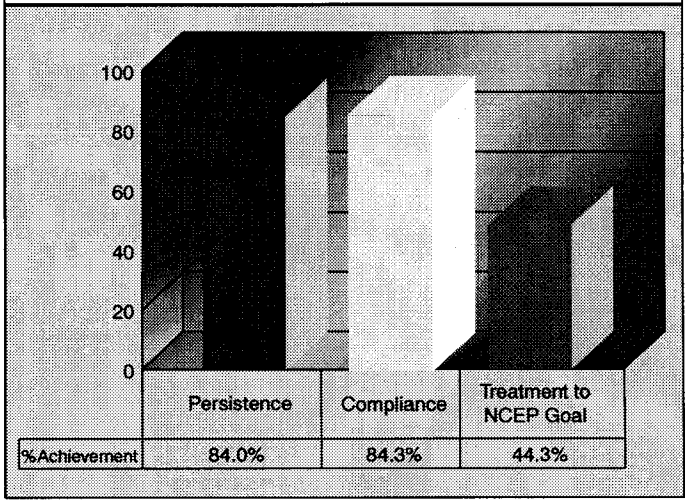


Figure 3. Medication Persistence, Compliance, and Treatment to NCEP Goal



± 1.1% was observed in high-density lipoprotein levels. Overall, a mean reduction of 13.1% ± 1.3% was observed for LDL-c values. A detailed analysis of lipid levels will be included in the article on final project results.

The NCEP Adult Treatment Panel II guidelines recommend LDL-c goals of < 160 mg/dL for patients with less than two CHD risk factors, < 130 mg/dL for patients with two or more CHD risk factors, and ≤ 100 mg/dL for patients with a history of CHD. Based on these NCEP guidelines, 331 of the 469 patients (70.6%) have been at or below goal on two or more visits, and 208 (44.3%) were at or below goal on their last documented visit. Figure 2 depicts NCEP goal achievement at the end of this period of evaluation in the primary and secondary prevention groups, and in the combined patient population enrolled for 6 to 19 months (average = 14 months).

Discussion

Many recent studies on the treatment of CHD indicate that a significant number of eligible patients go untreated and that a high percentage of the treated patient population fails to achieve LDL-c goals.[14-18] One relevant study of dispensing data in 138 community pharmacies revealed that, in a comparable population of 610 adults (49% men) with a mean age of 58 years, 60% of patients discontinued their lipid-lowering medication over a 12-month period.[14] Other data indicate that treatment to goal generally ranges from 8% to 33%.[18-20] At this interim point, with medication persistence of 84.0%, medication compliance of 84.3%, and overall treatment to goal of 44.3% (see Figure 3), the Project ImPACT: Hyperlipidemia model of collaborative practice shows promise for improving care and effectively reducing the risk for cardiovascular events. Table 4 lists sites participating in Project ImPACT: Hyperlipidemia.

Table 4. Participating Sites—Project ImPACT: Hyperlipidemia

Baggett Pharmacy	Levelland, Tex.
Bel-Aire Pharmacy	White Bear Lake, Minn.
Bohlman Drug Store, Inc.	Boscobel, Wis.
Elgin Discount Pharmacy	Elgin, Okla.
Family PharmaCare, Center, Inc.	West Lafayette, Ind.
Fifth Avenue Prescription Pharmacy	Seattle, Wash.
Goodrich Pharmacy	Anoka, Minn.
Goodrich Pharmacy	Elk River, Minn.
Gull Road Pharmacy	Kalamazoo, Mich.
Hadfield's Pharmacy	Edmonds, Wash.
Health Core, Inc.	Newark, Del.
Jones Pharmacy & Home Health Care	Spokane, Wash.
Kaiser Foundation Health Plan Pharmacy	Cleveland, Ohio
Lutz Pharmacy	Altoona, Iowa
Mar-Main Pharmacy	South Bend, Ind.
Medicap Pharmacy	Urbandale, Iowa
Medicap Pharmacy	Wilmington, N.C.
Mullins Drugs	Birmingham, Ala.
Northaven Pharmacy	Seattle, Wash.
Osterhaus Pharmacy	Maquoketa, Iowa
Pharmaceutical Care Clinic, College of Pharmacy, Ohio State University	Columbus, Ohio
Red Wing Corner Drug	Red Wing, Minn.
Ritzman Pharmacy	Akron, Ohio
The Medicine Shoppe Pharmacy	Youngstown, Ohio
Travis Pharmacy, Inc.	Shenandoah, Ia.
Ukrop's Pharmacy	Richmond, Va.
Uptown Pharmacy	Westerville, Ohio
View Ridge Pharmacy	Seattle, Wash.
West End Drug	Bar Harbor, Maine

Significance for Practicing Pharmacists

The management of patients with hyperlipidemias is an important component of any strategy aimed at improving the health of the American people. Even though death rates from heart attacks have dropped over the past 10 years, CHD still remains the leading cause of death in the United States, killing more than 500,000 people each year.[1] The NCEP Expert Panel on the Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults guidelines provide a meaningful, consensus-based direction for effective cardiovascular risk reduction in collaborative practice. In addition, the National Committee for Quality Assurance—in identifying cholesterol management as an important issue—has included in its Health Employer Data Information Set (HEDIS) for 1999 a test measure titled "Cholesterol Management after Acute Cardiovascular Event" that lends further support to the need for controlling lipid levels.[13]

Effective management of this "silent disease" requires a team of dedicated providers who work together to ensure that patients understand their condition, their level of risk, their cholesterol results, their treatment and goals, as well as the fact that they can be in control of their disease. Point-of-care testing and communication technologies present opportunities to reinforce persistence and compliance with diet, exercise, and drug therapy. Pharmacists are in a prime position to assure the success of collaborative practice efforts because of their patient and physician accessibility, resources to provide an advanced level of care, information management capabilities, motivation to expand care, and education and training to provide patient-focused disease state management services.

Pharmacists who develop the resources and skills necessary to collaborate in identifying, managing, and empowering patients with chronic diseases will be well positioned to participate in the growing number of managed care plans that are dominating the Nation's health care marketplace today. Already, two managed care plans have contracted with two project sites to use this collaborative practice model to ***Im***prove ***P***ersistence ***A***nd ***C***ompliance with ***T***herapy for the health plan's beneficiaries. Project ImPACT: Hyperlipidemia is teaching pharmacists that, in the words of renowned computer science visionary Alan Kay, the best way to predict the future is to invent it.

Benjamin M. Bluml is senior director for research, APhA Foundation, Washington, D.C. James M. McKenney, PharmD, is professor, School of Pharmacy, Virginia Commonwealth University, Richmond. Mark J. Cziraky, PharmD, is vice president and chief operating officer, Health Care, Inc., Newark, Del. R. K. Elswick Jr., PhD, is assistant professor, Department of Biostatistics, Virginia Commonwealth University, Richmond.

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