APhA

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The National Professional Society of Pharmacists

5135 '00 APR 28 P2:56

April 27, 2000

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. 00N-0352

Dear Sir/Madam:

Thank you for the opportunity to comment on the interim study of the status of useful written prescription drug information for patients. The American Pharmaceutical Association (APhA), the national professional society of pharmacists, represents more than 53,000 practicing pharmacists, pharmaceutical scientists, and pharmacy students. Pharmacists wholeheartedly support efforts to improve the quality of consumer health education through private sector efforts.

The interim study provides the first "progress-check" on work to achieve the goals of Public Law 104-180. Importantly, the study proposes a structure to apply the Criteria detailed in the Action Plan for the Provision of Useful Prescription Information to written information distributed by pharmacists. Establishing the structure and communicating that structure to health care professionals and information vendors (the producers of these products) is essential if the goals of Public Law 104-180 and the Action Plan are to be met. Without a clear idea of the assessment to be conducted—a clear idea of the measured components—success will be impossible. As the Agency reviews comments and considers revision to the interim study, we recommend strongly that such revisions be communicated to the relevant audiences. Such communication will help information vendors and health care professionals ensure the information they distribute meets the proposed criteria.

APhA also offers comments on a few of the specific questions posed in the Federal Register notice:

What should be the minimum standard or threshold that must be met for written information to be considered useful?
Usefulness of information is not an all-or-nothing proposition, and should not be measured as such. Usefulness, rather, should be assessed in a range—evaluating the information against the Action Plan criteria and determining relative compliance. One option for such a range is use of the Level 4 and Level 5 indicators from the 1-point method in the study, i.e., information meeting the standards of Level 4 or Level 5 could be deemed "useful".

Should certain criteria derived from the Action Plan recommendations be given more weight than others? If so, which criteria should be weighted more strongly, and why?

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The importance of individual criteria is likely to vary with the specific medications evaluated. For example, proper storage instructions (Criterion 6) are more important for labile products, products subject to degradation or lack of effectiveness such as antibiotic suspensions reconstituted at the pharmacy. For other products, storage conditions may be less important. We recommend weighting be applied only in review of those products and categories where special considerations deem it important.

Are the evaluation forms an accurate translation of the Action Plan's criteria?
The evaluation forms appear to translate the Action Plan criteria well. Most importantly, however, the forms *do* translate the information and provide a tool for health care professionals to use to evaluate the information they disseminate. Should substantial changes be proposed to the evaluation forms, such changes should be communicated to the communities of interest.

Should the evaluation panel include consumers with varying educational backgrounds? If so, how should they be involved in the evaluation process?
Addition of consumers with varying experiences to the evaluation panel would be helpful, particularly in evaluating the criteria on legibility and comprehensibility and ensuring lack of bias in content and tone. The panel should continue to include practicing pharmacists and any other health care professionals actively involved in the distribution of written information about prescription medications.

Are there ways to expand sampling to include mail-order or other nonretail pharmacies?
Sampling limited to community pharmacies creates the impression that only this sector of the health care community is responsible for ensuring the provision of useful information to patients. Medications are dispensed in other environments, however, including not only other pharmacy settings but also physician offices and other sites. Expansion could follow a scenario similar to that used by the patient-observers, with modifications specific to the practice site surveyed.

Finally, we would be remiss if we did not take this opportunity to comment again on the fundamental flaw present throughout the discussion of MedGuide: the inappropriate emphasis on written information as the primary tool to improve the use of medications. The Steering Committee process yielding the Action Plan diminished the prominence of an important piece of the statutory requirements of Public law 104-180--the provision of oral counseling. The resulting plan, while it addresses the need for oral counseling, does not place the proper emphasis on this professional practice that it deserves. Obviously, the path of least resistance for this plan would be to recommend that physicians talk to patients about their medications while pharmacists would be relegated to handing out paper. This scenario is unacceptable, as it fails to recognize the valuable role of the pharmacist in one-on-one communication with the patient. As an illustration of the effect of pharmacist interaction, attached please find a re-print of the findings of Project ImPACT:Hyperlipidemia. While the project involved interaction beyond the oral counseling referenced in MedGuide discussions, the substantial increase in patient compliance and achievement of treatment goals is

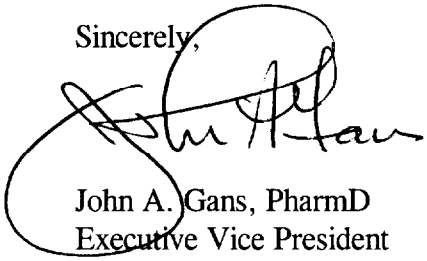
important. APhA continues to urge consumers and health care professionals to place oral counseling in a position of equal, if not greater, prominence with written information.

APhA fully supports the provisions of the Action Plan which speak to the role of oral counseling by pharmacists, including the removal of financial and other barriers that discourage the provision of this service today by pharmacists as well as other health professionals.

Again, as the Agency reviews comments and revision to the interim study, we recommend strongly that such revisions be communicated to the relevant audiences, and that dialogue on this important issue continues.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan C. Winckler, APhA's Group Director of Policy and Advocacy, with any questions at 202-429-7533or scw@mail.aphanet.org.

Sincerely,



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Pharmaceutical Care Services and Results in Project ImPACT: Hyperlipidemia

Benjamin M. Bluml, James M. McKenney, and Mark J. Cziraky

Objective: To demonstrate that pharmacists, working collaboratively with patients and physicians and having immediate access to objective point-of-care patient data, promote patient persistence and compliance with prescribed dyslipidemic therapy that enables patients to achieve their National Cholesterol Education Program (NCEP) goals. ***Design:*** Observational study. ***Participants:*** 26 community-based ambulatory care pharmacies: independent, chain–professional, chain–grocery store, home health/home infusion, clinic, health maintenance organization/managed care. ***Main Outcome Measures:*** Rates of patient persistence and compliance with medication therapy and achievement of target therapeutic goals. ***Results:*** In a population of 397 patients over an average period of 24.6 months, observed rates for persistence and compliance with medication therapy were 93.6% and 90.1%, respectively, and 62.5% of patients had reached and were maintained at their NCEP lipid goal at the end of the project. ***Conclusion:*** Working collaboratively with patients, physicians, and other health care providers, pharmacists who have ready access to objective clinical data, and who have the necessary knowledge, skills, and resources, can provide an advanced level of care that results in successful management of dyslipidemia.

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Project ImPACT: Hyperlipidemia, a community pharmacy–based demonstration project, was initiated in March 1996 and completed in October 1999. *ImPACT* is an acronym for Improve Persistence And Compliance with Therapy.

Dyslipidemia (hyperlipidemia) was considered an ideal area in which to demonstrate the value that pharmacists can add to the patient care process for several reasons:

- Coronary artery disease (CAD) is the leading cause of death in the United States and accounts for an annual expenditure of $100 billion for health care.[1]
- Dyslipidemia has been shown to be associated with increased risk of CAD in large epidemiologic studies.[2]
- Reduction in low-density lipoprotein cholesterol (LDL-C) levels has been shown to produce reductions in CAD events and total mortality.[3–9]
- Other modifiable CAD risk factors are invariably present in patients with hyperlipidemias, including hypertension, diabetes, obesity, and sedentary lifestyle.
- Pharmacist services are widely accessible to patients, physicians, and other health care providers and add a unique pharmacotherapy management resource to the health care delivery team.
- 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 availability of reliable patient lipid profile results within 5 minutes of obtaining a blood sample by fingerstick allows the pharmacist to be directly involved in 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]

Lifestyle modifications combined with improvements in persistence and compliance in the use of lipid-lowering medications will result in a greater number of patients reaching their target lipid goals. If patients reach and maintain their National Cholesterol Education Program (NCEP) goals, cardiovascular-related risk will be reduced,[6,7] resulting in positive health care outcomes. Table 1 provides an overview of desirable ranges for selected lipid measures as recommended by the NCEP.[3]

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See related Viewpoint on page 143.

Table 1. Desirable Ranges for Selected Lipid Measures

Total Cholesterol	Triglycerides	HDL-C	LDL-C[a]
< 200 mg/dL desirable	< 200 mg/dL desirable	≥ 35 mg/dL desirable	< 160 mg/dL goal if < 2 risk factors
200–239 mg/dL borderline	200–400 mg/dL borderline	< 35 mg/dL low	< 130 mg/dL goal if ≥ 2 risk factors
≥ 240 mg/dL high	400–1,000 mg/dL high		≤ 100 mg/dL goal if CAD history
	> 1,000 mg/dL very high		

CAD = coronary artery disease; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol.
[a]National Cholesterol Education Program Guidelines.

Objectives

The core objectives of Project ImPACT: Hyperlipidemia were to:

1. Improve patient persistence and compliance with lipid-lowering therapy.

2. Increase communication and the flow of clinical information among patients, pharmacists, and physicians.

3. Improve the cholesterol levels of individual patients over time.

4. Increase the population of patients who reach and maintain their NCEP lipid goals.

Methods

Site Selection

As the result of a competitive application process, 32 community pharmacy practice sites distributed across 15 states were selected to participate in Project ImPACT: Hyperlipidemia. Selection was based on criteria that addressed the readiness of the pharmacy to provide basic pharmaceutical care services as evidenced by the availability of certain health care resources and the requisite knowledge and skills to facilitate the delivery of such services:

- Private or semiprivate area for patient consultation.
- Technician support.
- Documentation system for recording, tracking, and reporting patient care interventions.
- Experience with patient-focused disease state management programs.
- Demonstrated communication skills.
- Ability to implement point-of-care testing technologies.

In addition, participating pharmacists from all sites attended a 2½-day orientation and training program at the project's inception. That training program was the basis for the APhA certificate program "Pharmaceutical Care for Patients with Dyslipidemias."

Of the 32 pharmacies, 2 sites were unable to implement the project (one secondary to regulatory issues, and the other secondary to departmental reorganization), 2 experienced unexpected staffing challenges, 1 moved to another location, and 1 pharmacy was sold and closed. Thus, a total of 26 pharmacy practice sites in 12 states completed the study (Table 2).

Patient Enrollment

Patients enrolled in the project were either newly diagnosed with dyslipidemia (e.g., hypercholesterolemia, mixed hyperlipidemia) or were already receiving lipid-lowering medications but were poorly controlled (i.e., not yet at target lipid goal). Patients were identified through referrals from local physicians or other health care providers, by the project pharmacists, or by patient self-referral. In cases of nonphysician referral, patients' physicians were contacted by pharmacists and were involved from that point forward in the patient's care. Patients were informed about the expected effects of their participation in the project (i.e., potential benefits, risks, inconveniences, discomforts), were assured confidentiality (patient privacy was protected by use of an assigned code in all reporting), and told about their right to withdraw at any time. Patients gave written informed consent and authorized that medical information from other health care providers could be sent to the pharmacist.

Process of Care

Patients provided the necessary personal and general health information that the pharmacist used to assess their CAD risk. From a fingerstick blood sample, a fasting lipid profile was obtained using the Cholestech LDX Analyzer (a point-of-care testing device in the "waived" category under the Clinical Laboratory Improvement Amendments[14]), and results were logged into a clinical activity record at each project visit. After the initial visit and consultation with the pharmacist, patients were asked to make follow-up visits every month for the first 3 months and quarterly thereafter. In addition to being actively involved in their therapy, treatment plans, and goal setting, patients as well as their physicians were kept informed about clinical progress in these areas:

- Cholesterol test results.
- Condition.
- CAD risk.
- NCEP goal achievement.

Practice Model

The practice model designed for the project was sufficiently flexible to accommodate variations in staffing and types of resources available at the practice sites represented in the study.

Table 2. Project ImPACT: Hyperlipidemia Participating Pharmacies by Practice Setting

Community Pharmacy Practice Setting	No.
Independent	14
Baggett Pharmacy (Levelland, Tex.)	
Bel-Aire Pharmacy (White Bear Lake, Minn.)	
Goodrich Pharmacy (Anoka, Minn.)	
Lutz Pharmacy (Altoona, Iowa)	
Mar-Main Pharmacy (South Bend, Ind.)	
Mullins Drugs (Birmingham, Ala.)	
Northaven Pharmacy (Seattle, Wash.)	
Osterhaus Pharmacy (Maquoketa, Iowa)	
QFC Pharmacy (Seattle, Wash.)	
Red Wing Corner Drug (Red Wing, Minn.)	
Ritzman Pharmacy (Akron, Ohio)	
Travis Pharmacy, Inc. (Shenandoah, Iowa)	
Uptown Pharmacy (Westerville, Ohio)	
West End Drug (Bar Harbor, Maine)	
Chain–professional	3
Medicap Pharmacy (Urbandale, Iowa)	
Medicap Pharmacy (Wilmington, N.C.)	
Medicine Shoppe Pharmacy (Youngstown, Ohio)	
Chain–grocery store	1
Ukrop's Pharmacy (Richmond, Va.)	
Home health/home infusion	2
Bohlman Drug Store, Inc. (Boscobel, Wisc.)	
Jones Pharmacy & Home Health Care (Spokane, Wash.)	
Clinic pharmacy	4
Family PharmaCare Center, Inc. (West Lafayette, Ind.)	
Goodrich Pharmacy (Elk River, Minn.)	
Hadfield's Pharmacy (Edmonds, Wash.)	
PharmaceuticalCare Clinic, Ohio State University (Columbus, Ohio)	
Health maintenance organization/managedcare	2
Health Core, Inc. (Newark, Del.)	
Kaiser Foundation Health Plan Pharmacy (Cleveland, Ohio)	

ImPACT = Improve Persistence And Compliance with Therapy.

The practice model structure:

- Established a process for the seamless flow of patient care data between and among patients, pharmacists, and physicians.
- Used point-of-care testing technology to obtain timely, objective information about the patient's progress in a community practice setting.
- Organized methods for pharmacists to document, interpret, and report their lipid management interventions.

Figure 1 depicts the collaborative care process that provided the framework for the Project ImPACT practice model.

Persistence and Compliance Measures

The persistence measure used for the project was defined as follows: a patient who started on medication, remained on medication subsequent to drug therapy initiation, and continued to be on medication as of his or her last visit. Persistence as a percentage was calculated by dividing the number of persistent patients by the total number of patients who started on medication. 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 5 days or more or who missed a scheduled refill visit by more than 5 days was deemed to be noncompliant at that visit. Compliance as a percentage was calculated by dividing the number of visits at which patients were compliant by the total number of patient visits.

End-of-Project Survey

A final project survey was conducted with all 26 sites to gain an understanding of what factors were likely responsible for creating the environment that produced the persistence, compliance, and treatment-to-goal results. The survey also included queries about the sites' experiences with obtaining payment for the pharmaceutical care services delivered during this project.

Results

A total of 574 patients were enrolled at the 26 sites before July 1, 1997. Of those, 397 patients completed the entire study, and results are presented for those patients in the following section. There were 34 patients who completed only 1 visit and had insufficient data to allow reporting of results. The remaining 143 patients did complete at least 2 visits to the pharmacy, but did not complete the full 2-year observation period: 29 withdrew in the first 90 days, 30 moved from the area, 33 gave personal reasons, 22 had logistical or medical complications, and 29 were lost to follow-up. The results for these 143 patients are reported separately at the end of the Results section.

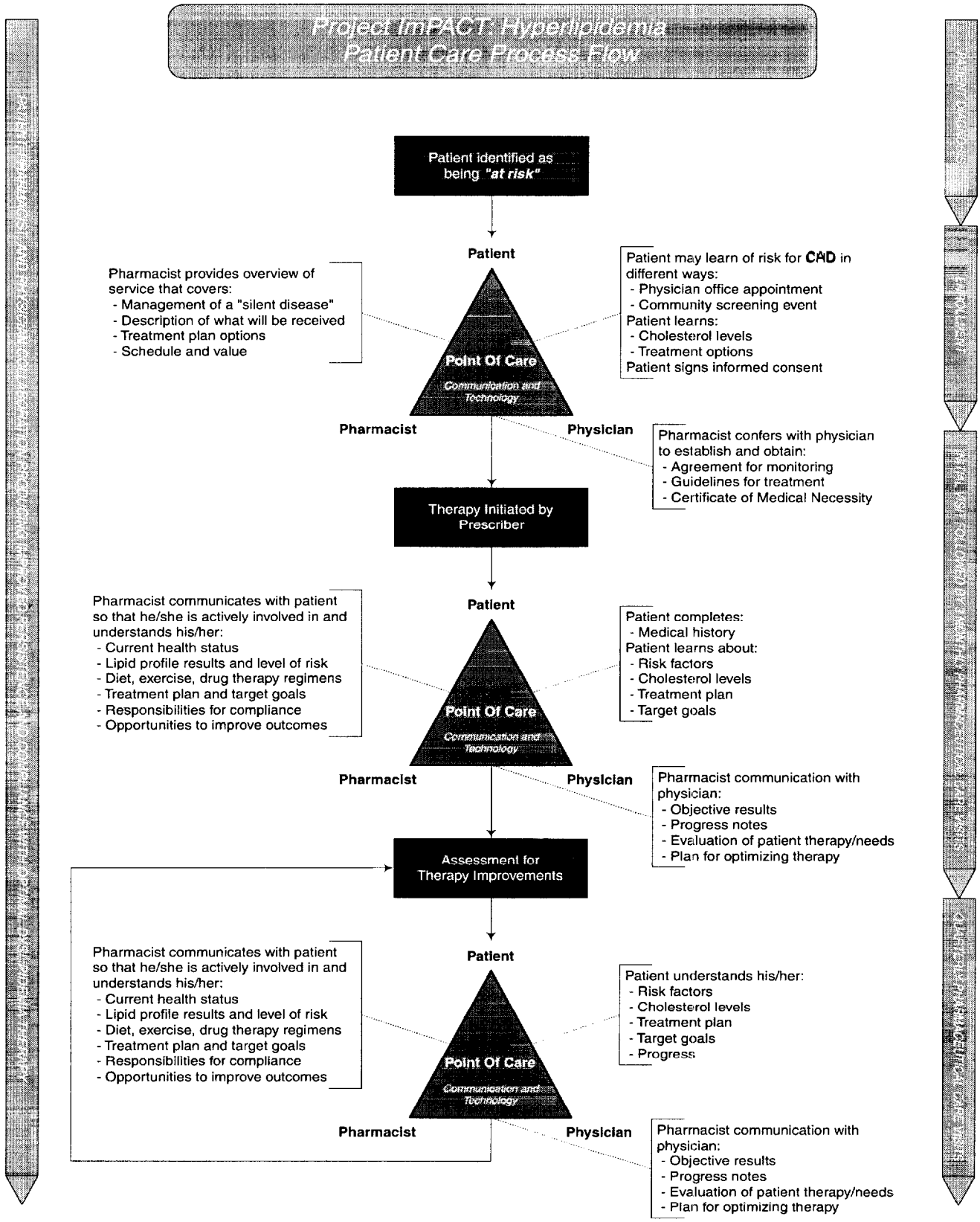
Patient Population Characteristics

At the beginning of the study, 153 (38.5%) of the 397 patients were either newly diagnosed or had been taking lipid-lowering medications for less than 1 month, and 244 (61.5%) had been on lipid-lowering medications for longer periods but remained poorly controlled. This combined population consisted of 51.6% women and 48.4% men, with an average age of 57 years. Of these patients, 298 (75.1%) had no history of CAD and were categorized as primary prevention patients (199 with an LDL-C goal < 130 mg/dL and 99 with an LDL-C goal < 160 mg/dL), while the other 99 (24.9%) had previously experienced a coronary event and therefore fell into a secondary prevention category (LDL-C goal ≤ 100 mg/dL). Patient ethnicity was as follows: 24 (6%) African American, 3 (0.8%) Asian, 337 (84.9%) Caucasian, 1 (0.2%) Hispanic, and 32 (8.1%) not specified.

Persistence and Compliance with Medication Therapy

Of the 397 patients who completed the 2-year study,

Figure 1. Project ImPACT Collaborative Care Process



CAD = coronary artery disease; ImPACT = Improve Persistence And Compliance with Therapy.

345 (86.9%) patients were treated with lipid-lowering medications and lifestyle modifications, while 52 (13.1%) continued with lifestyle modifications focused on diet and exercise in an effort to reach target cholesterol goals. The distribution of lipid-lowering medication use was as follows:

- 89% HMG-CoA reductase inhibitors.
- 5% niacin.
- 4% fibrates.
- 2% bile acid resins.

Of the 345 patients started on medication, 323 continued with drug therapy, for a resultant patient medication persistence rate of 93.6%.

Of 2,817 documented visits for patients on medications, 2,539 occurrences of compliance (i.e., within 5 days of expected refills) were reported, for a resulting per-visit medication compliance rate of 90.1%.

Resultant Lipid Levels

Using the two-tailed Student *t* test for paired data, statistically significant improvements were found for the 397 study patients using beginning and ending LDL-C measures (mean duration = 24.6 months; Table 3). Mean (± standard deviation) reductions of 12.8% ± 1.6% and 10.0% ± 6.5% were observed for total cholesterol and triglycerides, respectively, while a mean increase of 14.2% ± 3.9% was observed in high-density lipoprotein levels. Overall, a mean reduction of 22.1% ± 2.6% was observed for LDL-C values. In addition, the midpoint measures (mean interval from beginning = 12.1 months; Table 3) demonstrate progressive improvements over time.

The NCEP Adult Treatment Panel II (ATPII) guidelines recommend LDL-C goals of < 160 mg/dL for patients with less than two CAD risk factors, < 130 mg/dL for patients with two or more CAD risk factors, and ≤ 100 mg/dL for patients with a history of CAD (see Table 1). Based on these NCEP guidelines, 290 of the 397 patients (73.1%) were at or below goal on two or more visits during the study, and 248 (62.5%) were at or below goal as of their last full lipid profile. Figure 2 depicts NCEP goal achievement at the end of the project in the primary and secondary prevention groups and in the combined patient population.

Pharmacist Interventions

Pharmacists intervened with physicians to request a variety of therapeutic changes during the course of the study. These interventions were focused on improving NCEP goal achievement through drug therapy optimization and addressed issues that included coordination of care, adverse drug reactions, drug interactions, drug dosing, drug selection, and side effects. Physicians accepted the pharmacist recommendations and made changes in 265 (76.6%) of the 346 reported interventions.

Practice Model Observations

While implementation of the Project ImPACT practice model may have varied slightly from site to site to accommodate practice differences, it consistently produced an environment that resulted in a high level of collaboration through the following:

- Regular communications between and among all involved parties.
- Referral of patients by pharmacists to physicians and other providers (family practitioners, internal medicine physicians, cardiologists, dietitians, nurse practitioners, and endocrinologists).
- Referral of patients to pharmacists by physicians and other providers (family practitioners, internal medicine physicians, cardiologists, and nurse practitioners).
- Increased availability and use of objective clinical measures.
- Sharing treatment data and pertinent lifestyle and clinical information, including objective lipid measures obtained in the pharmacy, with patients and physicians.
- Periodic evaluation of the patient's progress toward lipid goals, and, if necessary, consultation and intervention with the patient's physician.
- Timely adjustments in the patient's treatment plans.

Process of Care Observations

Eligible "at risk" patients who were enrolled in the project were identified through community screening events (12%), patient self-referrals (13%), physician referrals (15%), and pharmacist identification and referral (60%).

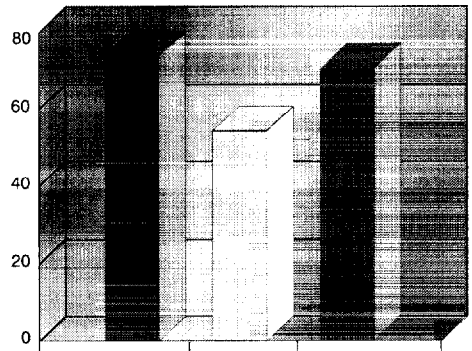
Two critical components of the process of care in the pharmacy were scheduling appointments for patients and arranging for ade-

Table 3. Fasting Mean Lipid Levels of Patients in Study

Measure (No. Patients)	Beginning Measure mg/dL (SD)	Midpoint Measure mg/dL (SD)	Ending Measure mg/dL (SD)	Mean Change	*P* value[a]
Total cholesterol (396)	238.0 (46.7)	216.7 (44.3)	207.5 (41.1)	−30.5 (3.9)	< .0001
Triglycerides (394)	216.6 (111.3)	199.1 (95.7)	195.0 (91.3)	−21.6 (14.1)	< .0001
High-density lipoproteins (394)	43.1 (14.1)	46.6 (15.6)	49.2 (16.5)	+6.1 (1.7)	< .0001
Low-density lipoproteins (387)	153.7 (41.3)	130.4 (37.8)	119.8 (35.7)	−33.9 (4.0)	< .0001

SD = standard deviation.
[a]Change calculated as ending measure less the beginning measure (mean duration = 24.6 months) and compared using a two-tailed Student *t* test for paired data.

Figure 2. Percentage of Patients Who Achieved Their NCEP Goals During Study



	1 Prevention (n = 298)	2 Prevention (n = 99)	Combined (n = 397)
% to LDL-C Goal	67.4	47.5	62.5

ImPACT = Improve Persistence And Compliance with Therapy; LDL-C = low-density lipoprotein cholesterol; NCEP = National Cholesterol Education Program.

Table 4. Scheduling and Staffing Arrangements in Study Pharmacies

Description	% of Sites
Appointment scheduling	100
Before regular hours	80
Morning appointments	100
Afternoon appointments	88
Evening appointments	43
After regular hours	21
Weekend appointments	80
Added pharmacist staff	29
Increased pharmacist overlap	48
Changed pharmacist duties	72
Added technician staff	17
Increased technician overlap	5
Changed technician duties	59

quate personnel to provide the services. The end-of-project survey asked about the mechanisms that pharmacists used to accomplish these tasks. Table 4 lists the scheduling mechanisms and staffing arrangements used to accommodate the increased time commitment needed for the project. The right column indicates the percentage of sites in which those accommodations were made.

Because of the time management challenges that pharmaceutical care services can and often do present, the survey asked about the amount of time spent for the initial visit and for scheduled follow-up visits. On average, pharmacists spent 30 to 60 minutes (mean = 45 minutes) with patients at their initial visit and 10 to 30 minutes (mean = 22 minutes) with patients during follow-up visits.

Table 5 lists the various services that project sites used in managing the care of patients with dyslipidemia and the frequency with which these services or techniques were employed.

Pharmacists were asked to describe their level of satisfaction with their own role, their relationships with patients and physicians, and their perceptions of how satisfied patients and physicians were with pharmacists' services provided as a part of the project. The percentages of pharmacists responding "very satisfied" and "satisfied" were as follows:

- With their professional role, 88.5% and 11.5%, respectively.
- With their relationship with patients, 84.6% and 15.4%, respectively.
- With their relationship with physicians, 19.2% and 46.2%, respectively (with another 30.8% being "neutral" and 3.8% "dissatisfied").

Pharmacists perceived that 53.8% of their patients were "very satisfied" and 46.2% "satisfied" with the services provided. Pharmacists' perceptions of the physicians' feelings about the value of their services were not as strong: "very satisfied," 19.2%; "satisfied," 46.2%; "neutral," 26.9%; and "dissatisfied," 7.7%.

Pharmacists at 25 of the 26 project sites planned to continue to provide this service. Respondents at all sites recommended that other pharmacists implement these same types of services in their practices.

Payment Observations

Although the project was not designed as a payment demonstration, participants were asked about the value of their services and their experiences in obtaining payment. Pharmacists indicated an average assigned value of $55 per visit—$28 for counseling services and $27 for lipid profiles. With respect to patients paying for these services, pharmacists indicated that, of 232 patients who were asked for payment, 174 (75%) paid an average of $35 per visit. Of 121 third party payers billed for services, 64 (53%) paid an average of $30 for each visit billed. Of these 64 payers, 30 paid for counseling services and 53 paid for lipid profiles (some paid for both). Two project sites secured contracts with managed care organizations to deliver services to those health plan beneficiaries, one under a fee-for-service arrangement and the other under capitation.

Patients Not Completing Study

The results presented thus far are for the population of patients who continued for the full duration of the project (Group 1). Data for those patients who did not complete the entire project (Group 2) show the following (Table 6):

- Patient demographics (age, ethnicity, sex, and CAD status) for Group 2 did not vary by more than 3% from Group 1.
- Average length of participation in the project was 7.2 months for Group 2, compared with 24.6 months for Group 1.
- Enrollment category distribution, newly diagnosed and poorly controlled, were 47.6% and 52.4%, respectively, in Group 2, and 38.5% and 61.5%, respectively, in Group 1.
- There were 20% fewer patients on drug therapy treatment in Group 2 as compared with Group 1.

- Persistence for Group 2 was 96.8%, compared with 93.6% for Group 1.
- Compliance for Group 2 was 86.1%, compared with 90.1% for Group 1.
- Clinical outcomes for lipid level and NCEP goal achievement measures for Group 2 were approximately 50% of those achieved by Group 1.

Discussion

When evaluating the current state of dyslipidemia management in the existing health care delivery system, a less-than-optimal picture develops. Recent studies on the treatment of CAD indicate that the majority of eligible patients go untreated.[15] Of those patients who are treated, only 40% remain on their lipid-lowering medication therapy after 12 months.[16–18] Literature from primary care settings indicate that successful treatment-to-goal results range from 8% to 33%.[19–21]

The outcomes from Project ImPACT: Hyperlipidemia present a dramatically different picture. In the project, pharmacists demonstrated that they can, in collaboration with patients and physicians, effectively identify patients with lipid disorders who require treatment and support them in their efforts to improve persistence, compliance, and treatment to goal. The results presented herein (see Figure 3), if compared with the existing health care delivery system, represent a twofold to fourfold improvement.

Project ImPACT: Hyperlipidemia provides a contemporary view of the capabilities of pharmacists, with the appropriate resources, to empower patients to achieve therapeutic outcomes through the effective application of a process of care to manage dyslipidemia. Pharmacists are in a prime position to ensure the success of collaborative practice efforts because of their accessibility to patients and physicians, their ability to use resources in providing an advanced level of care, and their information management capabilities, motivation to expand care, and education and training in the area of patient-focused disease management services. New point-of-care testing and communication technologies provide pharmacists with accurate, objective data to reinforce their counseling and intervention activities relative to persistence and compliance with diet, exercise, and drug therapy.

The project results suggest that patients receiving pharmaceutical care in a collaborative practice environment can make significant short-term improvements in persistence and compliance. However, longer-term participation in such an environment is required to achieve greater improvements in clinical outcomes.

Table 5. Frequency of Use of Various Patient-Education Techniques in Study Pharmacies

Service Provided	All or Most	Some	Rarely or Never
Explanation of the rationale for therapy	×		
Description of the dangers of atherosclerosis	×		
Education about the benefit of therapy in terms of reduced risk and enhanced chance of survival	×		
Explanation of how to interpret the lipid profile	×		
Identification of an LDL-C goal for the patient	×		
Identification of other health-related goals for the patient (e.g., weight, fat consumption)	×		
Showing patients a chart of their LDL-C results to monitor progress toward goal	×		
Praising patients for making progress toward (or achieving) their LDL-C (or other) goal	×		
Reinforcing the importance of compliance in reducing the risk of a heart attack	×		
Reviewing patients' compliance with therapy through such mechanisms as pill counts and refill records	×		
Questioning patients when noncompliance is detected or suspected	×		
Taking compliance histories during follow-up visits	×		
Answering questions patients have about atherosclerosis and its treatment	×		
Discussing the benefits and risks of lipid-lowering medications	×		
Encouraging patients to keep a log of the doses they take		×	
Encouraging patients to keep a log of their cholesterol results		×	
Helping patients solve problems in overcoming barriers to compliance		×	
Teaching a friend or family member about treatment in order to help them help the patient			×
Giving a tangible reward (e.g., coupon) for good compliance or achievement of goal			×
Giving patients ways to remind them of their doses (e.g., setting alarms, putting reminders on the refrigerator, putting the prescription bottle on the kitchen table)			×
Packaging the medication in ways to help patients take their drugs (e.g., organizers)			×
Calling patients at home to remind them of medication refills			×

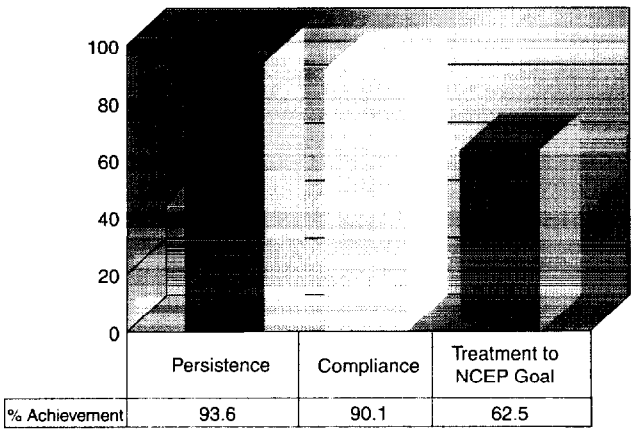
LDL-C = low-density lipoprotein cholesterol

Table 6. Comparative Profile of Patient Data[a]

Characteristic/Measure	Group1[b]	Group 2[c]	All Patients
Total number of patients	397	143	540
Average age (years)	57.0	54.7	56.4
Ethnicity			
African American	24 (6)	8 (5.6)	32 (5.9)
Asian	3 (0.8)	0 (0)	3 (0.5)
Caucasian	337 (84.9)	123 (86)	460 (85.2)
Hispanic	1 (0.2)	1 (0.7)	2 (0.4)
Not specified	32 (8.1)	11 (7.7)	43 (8.0)
Sex			
Women	205 (51.6)	78 (54.5)	283 (52.4)
Men	192 (48.4)	65 (45.5)	257 (47.6)
CAD status			
Primary prevention	298 (75.1)	111 (77.6)	409 (75.7)
Secondary prevention	99 (24.9)	32 (22.4)	131 (24.3)
Project participation			
Average duration (months)	24.6	7.2	20
Enrollment category			
Newly diagnosed	153 (38.5)	68 (47.6)	221 (40.9)
Poorly controlled	244 (61.5)	75 (52.4)	319 (59.1)
Treatment			
Drug therapy and lifestyle modifications	345 (86.9)	95 (66.4)	440 (81.5)
Persistence with drug therapy (% patients)	93.6	96.8	94.3
Compliance with drug therapy (% patients)	90.1	86.1	89.7
Lifestyle modifications only	52 (13.1)	48 (33.6)	100 (18.5)
Clinical outcomes			
Total cholesterol (% change from baseline)	−12.8	−5.4	−10.8
Triglycerides (% change from baseline)	−10.0	−5.7	−8.7
HDL-C (% change from baseline)	+14.2	+6.5	+12.2
LDL-C (% change from baseline)	−22.1	−13.1	−19.8
NCEP goal achievement (% at ending measure)	62.5	38.5	56.1

CAD = coronary artery disease; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol; NCEP = National Cholesterol Education Program.
[a]Data are presented as number of patients (%) unless otherwise indicated. Includes all patients with more than one visit.
[b]Patients who continued for the full duration of the project.
[c]Patients who did not complete the entire project.

Figure 3. Persistence, Compliance, and Treatment to NCEP Goal for 397 Patients in Group 1



ImPACT = Improve Persistence And Compliance with Therapy; NCEP = National Cholesterol Education Program.

Limitations

The results reported are based on data from 26 sites that continued for the duration of the project. Since the project used an observational, single-cohort design, the results should not be interpreted as proving a cause-and-effect relationship.

Conclusion

Working collaboratively with patients, physicians, and other health care providers, pharmacists who have ready access to objective clinical data, and the necessary knowledge, skills, and resources, can provide an advanced level of care that results in successful management of dyslipidemia. In this project, mean reductions in both total cholesterol and LDL-C exceeded 30 points for a diverse, multicenter patient population that included both treatment-naïve and previously treated patients who had not achieved goals. Patients enrolled in this project achieved medica-

tion persistence and compliance rates significantly higher than those previously found in the literature from similar ambulatory care settings.

Project ImPACT offers a sound model for pharmacists to use in empowering patients and improving the quality of consumer health outcomes. This approach to health care delivery warrants further investigation and consideration for widespread adoption.

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