VIEWPOINT

Lipid Management by Pharmacists: Evidence of Benefits

Robert L. Talbert

In this issue of *JAPhA*, two studies of community pharmacists' interventions with patients with lipid abnormalities shed light on the potential for pharmaceutical care services to improve care.[1,2]

Project ImPACT: Hyperlipidemia is a study of sufficient size and diversity of practice environments to allow generalization of the results to much of contemporary community pharmacy practice.[1] Using point-of-care lipid-profile testing, intensive patient education and follow-up, and frequent communication with each patient's physician, pharmacists demonstrated enhanced compliance (percentage of patients taking their medications) and persistence (fraction of patients staying on medication therapy over time).

Clinical management of hyperlipidemias is fraught with problems. Not only are many patients with elevated cholesterol levels never diagnosed, but clinicians often do not sufficiently motivate patients to follow dietary, exercise, and pharmacotherapy regimens. Compliance and persistence rates with lipid-lowering drug therapy are woefully inadequate. Despite the well-validated risks of hyperlipidemias and/or coronary artery disease (CAD), practitioners are often lackadaisical in conveying to the patient the need for therapy and the gravity of their clinical situation. As a result, the reported fraction of diagnosed patients at or below their National Cholesterol Education Program (NCEP) goals is never more than 30%. In the Project ImPACT study, an impressive 67.4% of patients treated for primary prevention met their NCEP targets, as did 47.5% of secondary intervention patients.

Project ImPACT patients also enjoyed low-density lipoprotein cholesterol (LDL-C) levels that were reduced by 22% and high-density lipoprotein cholesterol (HDL-C) levels that were increased by 14%. Although the reduction in LDL-C is somewhat less than the reduction generally seen with aggressive statin therapy, it is similar to that noted in several large randomized clinical trials (RCTs), including those cited by the authors in their Discussion section. In contrast, the increase in HDL-C is greater than the typical response noted in RCTs. Recent RCTs focusing on mortality and CAD events have demonstrated a 1.0% to 1.5% reduction in CAD events with each 1 percentage point reduction in LDL-C, while each percentage point increase in HDL-C is associated with a 2% to 3% decrease in number of clinical events. Assuming that the lipid changes noted in Project ImPACT could be maintained over the long term, this would translate into a potential 30% to 40% reduction in CAD events.

Several aspects of Project ImPACT deserve comment. First, the number of interventions per patient is relatively small. Among 397 patients, 346 interventions were made, or 0.87 interventions per patient. Because many patients require two or more dose titrations to achieve NCEP targets, it is somewhat surprising that so few interventions were required to reach the target in one-half of the secondary intervention patients and two-thirds of the primary prevention patients. If collaborative drug management agreements had been in place in each pharmacy rather than relying on inter-office communication to initiate dose titration or other changes in therapy, the fraction reaching NCEP targets might have been even greater.

In addition, 60% of the patients in the study were recruited directly by pharmacists based on prescription record review and personal contact. Fewer numbers of patients were referred by physicians (15%), self-referred (13%), or identified through community screening efforts (12%). Patients recruited by the pharmacist could be less likely to continue in the program after its formal conclusion.

Possible selection bias exists, since patients were not randomized into this trial. Because 14 of Project ImPACT's 26 sites were independent community pharmacies—whose patients often have close relationships with their pharmacists—the type of patient included in the study may not be representative of the U.S. population in general.

Lastly, the pharmacist-driven program enrollment may have implications for other types of pharmaceutical care programs. Could a diabetes care program be based solely on patients recruited by pharmacists? Would other health care providers, such as Certified Diabetes Educators, view a pharmacist-run diabetes program as an infringement on their area of expertise and seek to compete for patients? What about physicians who care for patients with chronic diseases such as asthma and hypertension? Would they refer patients to pharmacist-run programs in large enough numbers?

Given the growing body of evidence that pharmaceutical care—as provided by pharmacists in studies such as Project ImPACT—can make a real difference in clinical outcomes and people's lives, pharmacists and professional organizations should now turn their attention to quantifying this impact and the associated costs. In the current project, the fees sought and presumably paid by patients and third party payers were in the range of $30 to $35 per visit. Assuming an average pharmacist salary and benefits of $35 per hour and lengths of the initial visit of 45 minutes and follow-up visits of 22 minutes, personnel costs of $26.25

and $12.83 per visit are generated. Does that leave enough margin to cover overhead expenses, technician salaries, and renovation of facilities to provide the service and equipment, including equipment such as the Cholestech instrument? While a break-even situation might be acceptable now, more financial analysis and a higher margin will be needed in the future.

Further, how will health care policy makers, payers, and regulators view pharmaceutical care? Health care economists will seek to know how pharmacists compare with the usual care provided by a physician, or how pharmacists compare with other nonphysician providers, such as nurse practitioners and physician assistants. While I believe that pharmacists would fare quite well in such a comparison, the profession needs to tackle this issue directly and quickly, for such answers may be vital to our long-term survival and our ultimate role in health care.

The second study[2] was conducted at a single site. Although 437 patients were screened for elevated lipid levels, pharmacists enrolled only 51 patients. In the 25 intervention patients, pharmacists' efforts significantly increased the number of patients receiving needed therapy (an increase from 2 to 12 on statin therapy). Among 26 control patients, the number receiving therapy remained about the same (an increase from 4 to 7 patients on statin therapy). The number of intervention patients achieving their NCEP goals was 8 (32%), compared with 4 (15%) control patients, a difference that approached significance.

However, the reduction in lipid levels among intervention patients was disappointing and disconcerting in the Nola et al. study.[2] Total cholesterol and LDL-C values remained about the same in intervention patients, while HDL-C rose in both intervention and control patients. One possible explanation for the lack of effect of statin therapy is that the intervention group was seen only every 1 to 2 months, and no intervention or referral to a physician was attempted until the third visit. This may have been too late to implement therapy and document benefit from it.

Several other aspects of this study may have precluded success of pharmacists' interventions. First, lipid levels were obtained via venipuncture and samples were analyzed off site. The lag time between sample collection and the availability of lipid levels may have served as a disincentive for patient participation, causing them to lose interest. The intervention and control groups had an unequal number of visits. Because any contact with health care providers has the potential to increase patients' adherence to therapies, the unequal number of contacts in this study makes it difficult to attribute differences to the specific interventions made by the pharmacist. Any benefit due to the intervention is less likely, since the groups were handled differently. Patients with coronary artery events were excluded from the trial; this is unfortunate, since such patients are highly motivated and are more likely to receive benefit at that point from education and interventions.

Considering the efforts of intervention pharmacists, the Pharmaceutical Care Satisfaction Questionnaire showed few meaningful differences between control and intervention patients in terms of their opinions of the care provided to them by pharmacists. As with some other recent studies,[3–5] people do not seem to (1) notice when they have received what pharmacists call pharmaceutical care services and (2) patients not exposed to pharmaceutical care seem quite satisfied with whatever pharmacy services they receive. Low expectations are easily surpassed, it seems.

Lastly, this report does not include assessment of pharmacists' effects on compliance, persistence, and the number of interventions attempted per patient.

Lowering cholesterol, improving compliance and persistence, and improving the numbers of patients reaching their NCEP goals are laudable goals. They are also surrogate markers for the more important clinical outcomes related to improved lipoprotein profiles. Is the 22% reduction in LDL-C reported in Project ImPACT clinically meaningful, and will it lead to a reduction in myocardial infarction, stroke, and cardiovascular death? The clinical literature says "yes" to both these questions.

But extrapolation and generalization will not suffice in today's cost-conscious and competitive health care world. Pharmacy must now turn its attention to randomized, controlled analyses of pharmaceutical care and sound studies of clinical outcomes produced by regular medical care and nonphysician providers. The dreams and aspirations of pharmacists, as reflected in the ideals and goals of pharmaceutical care, may well depend on the results.

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See related articles on pages 157 and 166.

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