

Delivering Effective Lipid Management in the Managed Care Setting

An Interview with Leslee J. Shaw, PhD

Leslee J. Shaw, PhD, is Director of Outcomes Research for the Atlanta Cardiovascular Research Institute in Georgia, and holds a faculty appointment at Duke University in Durham, NC. She has published extensively in the areas of cardiovascular health, screening, and imaging in peer-reviewed journals and medical textbooks. Dr Shaw holds numerous professional committee and task force appointments. She serves on the Outcomes Assessment Committee for the American College of Cardiology, and is a member of the Board of Directors for the Society of Atherosclerotic Imaging.

AJMC: *The medical literature clearly demonstrates that aggressive cholesterol-lowering therapy reduces long-term risk of coronary heart disease (CHD). However, managed care organizations (MCOs) typically experience significant member turnover, and are therefore frequently delivering short-term care. In view of this reality, what are some of the shorter-term benefits of aggressive lipid management?*

Dr Shaw: Aggressive lipid management doesn't just reduce risk of CHD, but it also markedly reduces major adverse cardiac events including nonfatal myocardial infarction (MI) and cardiac death. These events obviously cause a decrease in work productivity and an increase in lost lives, both of which are extremely important to employers and are major reasons why statins are regarded as clinically effective, and also cost-effective. Additionally, there are a

number of clinical trials that have reported near-term benefits with statin therapy. In particular, the Atorvastatin versus Revascularization Treatment trial revealed a significant reduction in the 18-month occurrence of ischemic events.¹ Furthermore, the Veterans Affairs Administration is conducting the COURAGE [Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation] trial, a large-scale clinical trial. The study's objective is to compare percutaneous coronary intervention (PCI) with aggressive medical therapy alone for patients with mild to moderately severe coronary artery disease. The Atorvastatin versus Revascularization Treatment trial demonstrated a 50% reduction in strokes with the use of a high dose of a statin over an 18-month period. As the trial was conducted in patients with established disease, these results represent the benefits for secondary prevention. Primary prevention trials, on the other hand, generally take a substantially longer time to elicit a benefit; therefore, the up-front benefit of treatment and visit costs may not be realized by the MCO. However, when MCOs provide preventive services, patient preferences and satisfaction with treatment tend to be positively affected, thereby leading to greater member retention.

AJMC: *A significant issue in lipid management is that lipid test results often are not available until after the patient has left the MCO. Someone from the doctor's office then needs to inform the patient about the implications of the*

findings and of the next therapeutic steps, possibly warranting a return visit. There's a vast potential for some serious coverage lapses during this process. What can MCOs do to minimize such lapses?

Dr Shaw: A number of MCOs are optimizing care by utilizing non-MD caregivers (ie, RNs, PAs) for just this reason. There also are quick screen tests that provide HDL cholesterol [high-density lipoprotein], LDL cholesterol [low-density lipoprotein], and total cholesterol levels in only a few minutes. Furthermore, patients with the available means may purchase home cholesterol-testing equipment that is relatively inexpensive, but only allows for the assessment of total cholesterol. This may be a positive feedback mechanism for some patients if given the appropriate education from the clinician. Also, it is key that patients fully understand their goals for care and where they need to make changes. The best mechanism for changing patient behavior is through communication: having someone review test results with patients, explain the long-term adverse consequences of hyperlipidemia, and discuss the array of effective therapies that help reduce their cholesterol levels and also reduce their risk of CHD, all of which can be optimized with both written and verbal reports and through feedback from the patients. This, however, is difficult in the MCO setting where patients have minimal contact with the physician. Ideally, the physician should communicate with the patient about what their goals are for treatment and follow that up with some written documentation. Then, when the RN or PA calls to discuss the results, the patient knows and understands what is expected.

Of course, the perfect management program includes more than drug prescriptions; it is a well-rounded program of a low-cholesterol/low-fat diet. Also, a regular program of aerobic exercise will elicit positive changes, especially in HDL cholesterol and weight loss. In the well-rounded cardiovascular risk reduction

program, the hyperlipidemic patient may also participate in nutrition counseling programs or other educational offerings within the institution that may provide another venue for reinforcement of and guidance on preventive behaviors.

AJMC: *Can ambulatory cholesterol monitoring “bridge the gap” between lab readings and follow-up visits? How extensively is managed care using electronic monitoring and other stop-gap measures?*

Dr Shaw: It certainly can bridge the gap—for some patients. For many, though, this added expense is not an option. However, with the right patient, ambulatory cholesterol monitoring certainly can be a motivator. It is my understanding, and this is probably regionally based, that ambulatory monitoring is not widely recommended by the physician, but more often requested by the patient. That is, the patient may go to his or her pharmacy, see the home monitoring equipment, and ask the physician about it. The equipment gives only total cholesterol values and, as such, would NOT preclude or reduce downstream costs of serial monitoring—it would only add to the indirect costs of care. This cost would have to be offset by increased patient compliance, and I have never seen data to support the idea that increased self-monitoring enhances compliance.

AJMC: *Most primary care providers order cholesterol screenings for their patients; few order more comprehensive profiles, including screenings of additional CHD risk markers. In your view, what types of screening test should primary care physicians routinely perform to assess the extent of dyslipidemia, and why?*

Dr Shaw: This area is very controversial right now. However, for the patient who is at intermediate risk for CHD, as based upon the new National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) risk calculator, medical evidence suggests that cardiovas-

cular risk assessment is appropriate. Currently, the largest body of evidence is probably with C-reactive protein (CRP), which is a marker of inflammation. There is a strong association between CRP levels and risk of MI in asymptomatic women and men. In 1997, Ridker and colleagues² reported in the *New England Journal of Medicine* on the correlation of hs-CRP and risk of future MI in apparently healthy men, and then published similar reports of CRP and future risk of MI or stroke in apparently healthy women.^{3,4} The most recent report noted a synergistic relationship between CRP and the ratio of total and HDL-C, such that the highest risk of events was in patients with the highest CRP levels and the worst ratios. Recently, the Centers for Disease Control and Prevention (CDC) has undertaken an evaluation and is probably going to publish standards (as they did for cholesterol testing) for CRP to standardize the measurement. This would help to provide uniformity and data quality, and thus improve patient care. Although they have received some attention, other measures (such as homocysteine) are not commonly used. Some clinicians have recently shown interest in performing advanced lipid analyses, including measures of apolipoprotein A1, B, and LDL fractionation. Although there are some data to support the value of such analyses, this type of testing is NOT supported by large, randomized, controlled clinical trials. It is also quite expensive; the charge for an advanced lipid profile runs from \$395 to \$695. At this time, this type of analysis is not routinely used, and its expense will limit its routine application for the foreseeable future.

AJMC: *The Framingham risk scoring model as a predictor of CHD is the foundation for NCEP ATP III. Yet, some experts suggest that many physicians are not using this tool in their daily practice. Are you aware of any MCO innovations to encourage more widespread use of Framingham risk scoring?*

Dr Shaw: I'm not sure about MCOs, but certainly medical societies and the National Institutes of Health (NIH) are providing options. There are downloadable programs available to calculate the expected 10-year risk of cardiac death or MI on the NIH-National Heart, Lung, and Blood Institute (NHLBI) Web site. Medical societies, as well as the NIH, also have created a downloadable version for personal desk assistants (PDAs). As many physicians use PDAs to manage patient information, this can certainly foster more effective estimation of risk and improve the precision of care for each patient.

AJMC: *Compliance with previous ATP guideline goals has been a continuing issue, not just among patients, but among healthcare providers as well. Do MCOs need to do more to educate providers and to foster more extensive adherence to ATP III guidelines?*

Dr Shaw: Yes, but MCOs also have to provide more in-depth information system improvements. Healthcare information systems with automated medical records integrated with available medical evidence, such as NCEP ATP III risk calculators, would foster improved compliance with medical guidelines, and thus, improve patient care.

AJMC: *The NCEP ATP III guidelines set ambitious goals for LDL cholesterol management among patients at risk for CHD, but also emphasize the importance of treating low HDL cholesterol and hypertriglyceridemia. By setting LDL cholesterol as the primary therapeutic goal, however, do the guidelines at the same time undercut the significance of regulating HDL cholesterol and triglyceride levels, given the realities of clinical practice?*

Dr Shaw: I think that in the near future we will see new drugs in this market that provide tremendous improvements in HDL cholesterol. A number of companies are currently developing drugs whose main benefit is to increase HDL

cholesterol. For years, lowering LDL cholesterol has been a major target. The new NCEP ATP III guidelines provide a thorough synthesis of evidence and tools for management of low HDL cholesterol levels.

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