

MCO Decisions and Solutions

... OVERVIEW ...

With the wealth of knowledge now available about cholesterol effects and treatment, making decisions regarding cholesterol management for member populations can be challenging and sometimes confusing for clinical decision makers within managed care organizations (MCOs). In this section, medical and pharmacy directors from four MCOs describe how they wrestled with and resolved the questions of statin selection, formulary management, physician and patient support, and care coordination.

... MCO PRESENTATION #1 ...

Pharmacy Management: Considering Efficacy, Effectiveness, and Efficiency

Selection of simvastatin as the preferred lipid-lowering agent on the formulary at the Henry Ford Medical Group in Detroit has resulted in clinical benefits as well as cost effectiveness. This experience was described by Alan Johnson, RPh, the Group's Director of Pharmacy Programs, and Antonio Pettitta, RPh, MBA, Clinical Pharmacist at Henry Ford Hospital, also in Detroit.

Selecting a Statin

At the time a new preferred agent was being considered at Henry Ford, studies were beginning to demonstrate that HMG-CoA reductase inhibitors, or statins, were the therapy of choice. Patients taking older lipid-lowering agents complained of side effects, and very few were compliant. For example, only 1 in

10 patients was able to continue taking niacin at Henry Ford. The newer statins were more potent and better tolerated.

A review was undertaken at the Henry Ford Medical Group to determine which of the four available statins (fluvastatin, lovastatin, pravastatin, simvastatin) would be the best one to put on the formulary. To facilitate the decision-making process, a clinical evaluation and economic/contracting evaluation were performed simultaneously.

The clinical evaluation rested on a review of the literature, drug monographs, 67 references, a compilation of the adverse events, and expert opinion. The economic/contracting review involved contacting drug manufacturers, evaluating the contracts, estimating the probability of success, and considering net costs relative to the clinical evaluation.

The clinical evaluation showed that simvastatin achieved the greatest reduction in LDL cholesterol compared to the other three agents (Table 1). The stud-

Table 1. Effectiveness Table

Drug	LDL	HDL	TriGly	LDL/HDL
Lovastatin 20 mg	-24-28%		-6-12%	4.0
Lovastatin 40 mg	-27-35%	+4-12%		4.1
Lovastatin 80 mg	-38-40%		-10-19%	
Simvastatin 10 mg	-27-32%			3.9
Simvastatin 20 mg	-30-38%	+4-14%	-4-16%	4.0
Simvastatin 40 mg	-37-46%			
Pravastatin 20 mg	-24-27%	+7-14%		
Pravastatin 40 mg	-27-33%		-6-19%	
Fluvastatin 20 mg	-18-22%			
Fluvastatin 40 mg	-23-26%	+2-8%	-8-10%	

ies in simvastatin's favor were well designed. The drug was effective in a wide range of doses and appeared to be viable monotherapy for the vast majority of patients. Further, the price was competitive. Four months later, the 4S study was released, and results confirmed the Pharmacy and Therapeutics (P&T) Committee's choice of simvastatin.

To gain a driving share of prescriptions, a communications plan was set in motion. Newsletters were sent to physicians, presentations in favor of simvastatin were given at staff meetings, and performance indicator reports were sent to medical directors to show how simvastatin was doing.

"The performance indicator reports were a report card on progress in getting prescriptions for simvastatin. This was a macro approach. Panel level reports were a micro approach; the pharmacist would take these reports and talk to patients who were not on the preferred agent," explained Mr. Johnson.

Using this strategy, simvastatin's market share rose within the MCO from 30% to 71% in 1995. Lovastatin lost the most market share. Savings were estimated at \$600,000 per year.

The next steps include improving follow-up on patients taking statins, which would enhance compliance. Also, an attempt will be made to identify patients at high risk of CHD and recommend statin therapy and increase the dose for those taking an HMG-CoA reductase inhibitor but not achieving goal level. The Henry Ford pharmacists also plan to collect long-term outcomes data to compare effectiveness of the various statins.

Simvastatin: Cost Effective?

A cost-effectiveness study undertaken to support the formulary decision found that simvastatin resulted in large cost savings, even though only about 60% of patients had converted to the preferred drug at the time of the study. The objective of the study was to determine the impact of formulary policies on the cost effectiveness of HMG-CoA re-

ductase inhibitors. The database included 3,500 patients who took a statin at any one time.

Mr. Petitta and his coauthors included 150 of these patients and their actual costs using a Markov Model, which looks at patients in one of three conditions at a given time: alive with no CHD (primary prevention); alive with CHD (secondary prevention); and deceased. Health outcomes were determined according to increased life years gained by being treated with an HMG-CoA reductase inhibitor.

"One patient living for 1 year equalled one life saved per year. Ten patients living for 1 year equalled 10 lives saved per year," explained Mr. Petitta.

The 4S study was used to model CHD risk factors, which included age, race, sex, diabetes, smoking, left ventricular hypertrophy, HDL and LDL cholesterol, and the presence of pre-existing CHD. Data from the Henry Ford files were used on the four available statins—fluvastatin, lovastatin, pravastatin, and simvastatin. Cost assumptions were also taken from Henry Ford data.

The study compared the costs of treatment in June 1994 (when simvastatin was deemed the preferred drug), with costs in November 1995. In June of 1994, the average cost of drug treatment was \$1.69/day/patient. After receiving discounts from manufacturers, costs began to decline; by November 1995, costs were \$1.42 per patient per day. This decline resulted in \$300,000 saved in 1 year. "If 100% conversion to simvastatin had been achieved, we would have saved \$600,000 in 1 year," observed Mr. Petitta (Figure 1).

In June of 1994, only 5% of the patients were being treated with simvastatin. At that time, the total cost of drug treatment with an HMG-CoA reductase inhibitor was \$23,800 per year of life saved (including drugs and monitoring but minus \$4 million in hospitalization avoided by drug treatment). By November of 1995, 59% of patients had con-

verted to simvastatin. The total cost of treatment was reduced to \$16 million, and the cost per year of life saved was \$15,400.

"This was a difference of \$8,400. If we had achieved 100% conversion to simvastatin, we would have saved even more. The cost per year of life saved would have been \$12,200," Mr. Petitta said.

When asked whether physicians were taking the opportunity to increase the dose when target LDL-C level is not achieved, Mr. Johnson said there is a "dosage creep," but even with that, a 22% reduction in cost was observed. "And we are buying a better outcome for our patients," he added.

In conclusion, the cost per year of life saved decreased at the Henry Ford Medical Group as a result of selecting simvastatin as the preferred cholesterol-lowering agent. An even greater savings would have accrued had 100% conversion been achieved.

Using cost-effectiveness articles for formulary decisions avoids using intermediate outcomes as a final outcome. Data from published cost-effectiveness articles must be adjusted to the individual organization. Using a balance-sheet approach will save money, said Mr. Petitta.

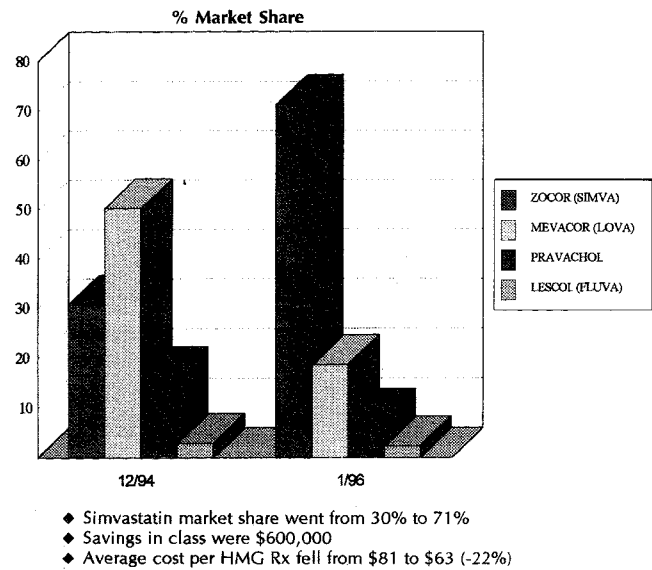
... MCO PRESENTATION #2 ...

**Formulary Management:
Switching for Quality and Cost**

The process by which CIGNA Healthcare selected one statin to be on the formulary was outlined by John Poniatowski, RPh, MS, Regional Director, CIGNA Healthcare, Hartford, Connecticut. CIGNA is a leading healthcare provider, with 4.7 million lives in medical indemnity and 3.9 million lives in medical HMOs. CIGNA offers an HMO or PPO in 43 states and is a mixed model of Individual Practice Association (IPA) and staff.

CIGNA has its own pharmacy network, and the formulary is about 95%

Figure 1.



standardized across the United States. "A nonformulary drug is not covered for a CIGNA member," stated Mr. Poniatowski. "If a physician is unwilling to change to a formulary drug, we allow a one-time authorization; then we communicate with the physician about alternatives. If the doctor thinks he still requires an exception, the pharmacy director will make the decision whether to grant approval," he explained.

Converting to Simvastatin

CIGNA had had good previous results with an H₂-antagonist conversion program, and the organization was encouraged to undertake a similar conversion program for statins. In the middle of 1994, costs and utilization of lipid-lowering treatments were rising. At that time, both lovastatin and simvastatin were on the CIGNA formulary, but fluvastatin and pravastatin were not.

In 1994, the P&T Committee met and took the first steps toward the conversion program. A drug review of the available statins was prepared by an outside, university-based drug information consultant. The consultant reported

that fluvastatin had the least efficacy, while lovastatin, pravastatin, and simvastatin had comparable efficacy and side effects (this was before 4S results were published). The report concluded that it was clinically appropriate to base a formulary decision on cost. "The goal was to have one agent on formulary, if clinically appropriate," said Mr. Poniatowski.

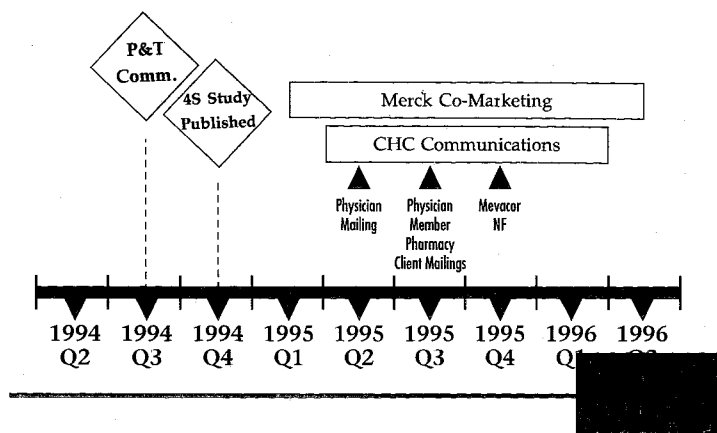
Negotiations with the manufacturers of the respective statins were initiated. Based on these discussions, simvastatin was selected as the sole statin on the formulary. Then the conversion process was begun (Figure 2).

"We learned from our previous process with the H₂-antagonists that there can never be too much communication," he said.

Six months before lovastatin was taken off formulary, physicians were targeted with a mailing that included a letter explaining the benefits of simvastatin, the 4S results, and a copy of the 4S study. A list of the physician's patients currently on lipid-lowering therapy was also included, as was a recommendation to switch these patients to simvastatin. A nonformulary request was enclosed.

Three months later, a repeat mailing was sent to physicians, and a separate mailing targeted members. In addition, CIGNA Pharmacy staff members met with the health plan sales force to educate further and communicate more about the conversion process. Newsletters about lipid lowering with simvastatin were sent to providers and members.

Figure 2. Timeline of Simvastatin Conversion Process



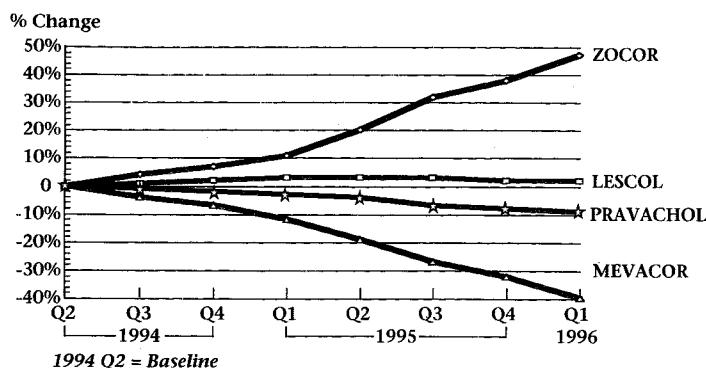
Results of Converting to Simvastatin

National data from CIGNA showed that simvastatin increased its market share by 47% and lovastatin declined by 47% (Figure 3). "There were still some users of pravastatin and lovastatin at CIGNA through nonformulary requests. A few of the health plans within CIGNA still had open formulary, which may account for some of the use of these two agents," Mr. Poniatowski said.

Cost savings were considerable after the conversion to simvastatin, when numbers for the second quarter of 1994 were compared to the first quarter of 1996. The average cost per treatment for lipid-lowering therapy declined by 11%.

"In July, 1994, when the P&T Committee made its decision, we did not anticipate the huge increase in utilization that we saw, which was spurred by the 4S study. Also, we didn't expect higher dosing; about 50% of patients are taking 20 or more mg/day, which is related to target LDL-C goals," he explained.

Figure 3. HMG Market Share Movement



"The conversion process raised concerns that increased awareness might result in increased utilization," Mr. Poniatowski added.

In fact, he said, it appeared that some degree of inappropriate dosage conversion did occur. "Some patients were switched from lovastatin 20 mg/day to simvastatin 20 mg/day. Many of these patients might be well controlled on 10 mg/day," he explained.

Overall, the conversion process went smoothly. Physicians generally did not debate the clinical wisdom of switching to simvastatin. Since several agents were deemed therapeutically equivalent in 1994, the decision was primarily based on price. Since then, the powerful results of 4S suggest that simvastatin reduces overall mortality as well as CHD mortality, and the drug may turn out to have effects that go beyond lipid lowering.

... MCO PRESENTATION #3 ...

Providing Physician and Patient Support

Community Health Plan (CHP) of Greater New York, a mixed staff model and network HMO, has developed a simplified system for the management of hypercholesterolemia that provides support for both the patient and physician.

"Our system is based on a simple idea: We provide a structure to make the primary care physician's job easier, which is the best way to improve outcomes. We've structured all aspects of our HMO to support the goal of improved outcomes," explained Paul E. Lemanski, MD, Director, Lifestyle Modification Program, Community Health Plan in Latham, New York.

Achievable outcomes have been defined by several recent large, randomized trials including 4S and the CARE trial. The 4S study showed that aggressive lipid lowering with a statin (in this case, simvastatin) can decrease cardiovascular death by 42%, decrease cardiovascular events by 34%, and reduce the

need for revascularization (PTCA and CABG) by 37%.

Gap Between Trials and Practice

"There is a gap between results of clinical trials and what happens to patients' cholesterol levels in the community. Our strategy is to focus on the primary care physician to close this gap. We don't target cardiologists, because

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— Paul E. Lemanski, MD

they usually aren't responsible for treating lipids. They don't have the time, they don't see their patients monthly, they are not set up to titrate drugs, and they are procedure oriented," explained Dr. Lemanski. "We also focus on patients who are partners with physicians for their care," he added.

The "hub" of the CHP system is the Lipid Clinic, which coordinates activities of four departments: Guidelines, Pharmaceutical and Nutrition Services, Laboratory, and Medical Information Services.

CHP Guideline

The CHP guideline is a simplified version of the NCEP ATP II guidelines and is structured to be user friendly for primary care physicians. A study by Grover et al, demonstrated that the cholesterol/HDL-C ratio is as good a predictor of cardiovascular deaths and events as LDL-C less than 100 mg/dL.¹ Because of that, CHP uses the total cholesterol/HDL-C ratio as a screening tool to stratify patients according to risk. Patients at increased risk have their LDL cholesterol measured.

"It is too complicated to have all of the various nonlipid risk factors assessed

for every single person, so we use the total cholesterol/HDL-C as our initial screening tool. We do assess all the other factors when that ratio points to an increased risk," Dr. Lemanski said.

The Lipid Clinic has an integrated system that incorporates nutrition referral for patients with elevated cholesterol and known coronary artery disease. A dietitian consults with hypercholesterolemic patients, puts them on a low-cholesterol diet, and then assesses compliance at three consecutive monthly intervals. The dietitian checks each patient's LDL-C level and lets the doctor know whether the patient is compliant and if target LDL-C has been achieved by diet.

"The dietitian relieves the primary care doctor of responsibility for dietary intervention, and at the end of 3 months, after the patient is assessed, the ball is in the physician's court regarding whether drug therapy is necessary," he elaborated.

Patient support is also provided by the dietitian. Patients are put on a 7-gram-saturated-fat diet, which simplifies dietary recommendations and takes advantage of new labelling laws for foods. The diet allows 1 gram of saturated fat for breakfast, 1 gram for lunch, and 5 grams for dinner. Saturated fat content is used because it is the type of fat known to elevate LDL-C. Patients are given a small, hand-held counter to count the grams of saturated fats in their food choices.

"A 7-gram-saturated-fat diet provides 20% of calories from fat and can achieve a 20% decrease in LDL-C, if followed. It is a more stringent diet than the AHA Step II diet, and it is easier to follow," said Dr. Lemanski.

Doctors are brought into the loop by inviting them to a 5-gram-saturated-fat dinner, but they are not told that it is a low-saturated-fat dinner. After eating and enjoying the meal, they are made aware of the saturated fat content. This gives them first-hand experience that the meal is satisfying and that they are not asking their patients to do anything extreme.

Patients themselves are able to see a change in their LDL levels with this diet, and this gives them meaningful feedback that encourages them to continue. In this way, physicians and patients cooperate as partners in risk factor management.

The CHP guideline also includes a section dealing with drug therapy to simplify management of hypercholesterolemia, continued Dr. Lemanski. A specially designed grid allows the physician to plot the patient's blood lipid values and place the grid over a table to determine appropriate therapy. "It's another strategy to make the physician's job easier," said Dr. Lemanski.

The other side of the paper with the treatment algorithm for a specific drug has complete prescription information on that drug; everything the physician needs is on one piece of paper.

Patient monitoring is the responsibility of the lipid nurse at CHP's staff model HMOs. The patient goes to the pharmacy with the prescription; the pharmacist calls the lipid nurse, and the nurse calls the patient and educates him or her about the drug(s) that have been prescribed. When the patient has questions, he or she calls the nurse. The physician is free from the tasks of patient education and answering patient queries; the job is simplified to making changes in management on the basis of the lab values and patient response.

CHP offers lipid-lowering treatment with bile acid sequestrants, niacin, and statins. "We expected most prescription protocols for niacin, because these protocols simplify the titration of initial drug therapy. Interestingly, the most protocols have been written for statins," he commented. Physicians appreciate the convenience of not having to make sure that appropriate laboratory follow-up is ordered. The lipid nurse orders all the monitoring tests during the first several months. With statins, liver function tests are performed once a year after the dosage is titrated.

CHP is currently developing a program to identify which patients need

aggressive lipid lowering as primary prevention. The Medical Information Service is incorporating the CHP Guideline into computer laboratory software. When the physician orders cholesterol tests, he or she needs only to check appropriate boxes on a form designed to identify nonlipid risk factors. The computer will take these responses, along with the patient's lipid levels, age, and sex, and find the target LDL-C and may even suggest possible appropriate medications for physician consideration.

"This will also give us the ability to follow patients with specific risk factors and tailor a package for groups stratified according to risk. We expect this program to be up and running within the next 6 months," said Dr. Lemanski.

... MCO PRESENTATION #4 ...

Coordinating Care and Interventions

Experience in developing a Care Process Model for management of hyperlipidemia at Intermountain Health Care (IHC), a mixed model HMO/PPO in Salt Lake City, Utah, was detailed at a workshop led by Larry Staker, MD, Director of Clinical Quality Improvement, and David Clark, RPh, MBA, Director of Pharmacy Services. Intermountain Health Care is an integrated system that encompasses 23 hospitals, 56 practice clinics, and an insurance plan with more than 500,000 covered lives, serving communities in Utah, Idaho and Wyoming.

IHC decided to focus on management of hyperlipidemia as a result of several recent milestones. Results of well designed, randomized clinical trials, including 4S, WOSCOPS, and CARE, documented the importance of aggressive lipid lowering and the ability of simvastatin to reduce mortality. The NCEP guidelines recommended aggressive lipid lowering for patients with CHD and risk factors. Eminent organizations such as the American Heart Association and the American College of Cardiology endorsed aggressive lipid lowering as a

central component of coronary prevention programs.

Choosing a Drug Therapy

At the time IHC was developing a Care Process Model for management of hyperlipidemia, there were four available HMG-CoA reductase inhibitors: simvastatin, lovastatin, pravastatin, and fluvastatin. Fluvastatin was the one on the IHC formulary, but the formulary selection was changed to simvastatin following protests by physicians affiliated with IHC.

"Fluvastatin was the least effective of these drugs. With the publication of 4S results showing a 30% risk reduction in survival with simvastatin, there was a strong movement from our MDs to change to simvastatin," explained Dr. Staker.

Prior to switching from fluvastatin to simvastatin, usage patterns at IHC showed the following:

- Fluvastatin: 11.81%
- Lovastatin: 27.6%
- Pravastatin: 22.1%
- Simvastatin: 38.5%.

"About 75% of patients were on a strength of drug that could be switched to another agent. We wanted to work with clinicians to achieve the best outcome. Not all of our patients were being treated to goal, and we wanted to treat aggressively," explained Mr. Clark.

After reviewing the percentage decrease in LDL-C for the four agents and the cost for each of these agents, the cost/benefit of simvastatin compared to other interventions was apparent. For \$600 per year, a 30% reduction in LDL-C could be achieved with 20 mg simvastatin (Table 2).

The selection of simvastatin as the sole statin on the formulary simplified the treatment pathway of the Care Process Model. Therapy was initiated at a starting dose of 20 mg per day and titrated up to achieve goal LDL-C of <100 mg/day. Four months after simvastatin was selected, usage patterns changed as follows:

Table 2. Cost Comparison of Lipid-Lowering Strategies

	% Decrease in LDL-C	% Increase in HDL-C	Cost/Year (\$)
Step 1 Diet	2		100
Step 2 Diet	5		200
Step 3 Diet	10		500
Niacin	15	10	200
Binders	10		1,128
Fibrinates	10		792
Premarin	15	30	216
Folate			25
Anti-Ox			150
Simvastatin 20 mg	30		600
Simvastatin 40 mg	38		720
Pravastatin 20 mg	25		636
Pravastatin 40 mg	26		1,044
Lovastatin 20 mg	30		600
Lovastatin 40 mg	38		1,056
Fluvastatin 20 mg	20		396
Fluvastatin 40 mg	29		444

- Fluvastatin: 10%
- Lovastatin: 21%
- Pravastatin: 18%
- Simvastatin: 50%

“We found that there were 68% who were switchable and that more patients were being treated to goal. The cost of statin therapy decreased; the net cost per member per month decreased from \$.27 to \$.25 for statin treatment,” Mr. Clark told workshop attendees. “Our clinicians were uncomfortable with fluvastatin and ordered many lab tests, whereas they were very comfortable with simvastatin.”

Care Process Model

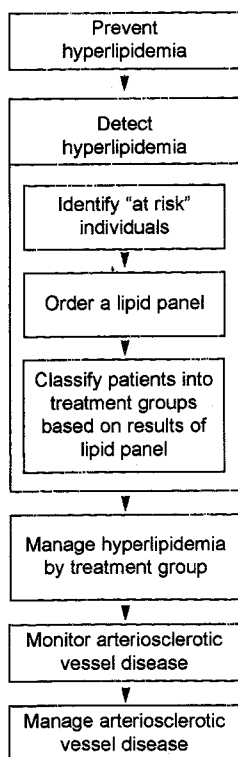
“The Care Process Model has three main components: detect, classify, and manage,” explained Dr. Staker (Figure 4).

The Care Process Model was developed according to a flowchart that depended on identifying at-risk individuals, ordering a lipid panel, and classifying patients according to risk on the basis of risk factors, LDL-C level, and HDL-C level: extreme risk, high risk, moderate risk, or mild risk. The model stipulates that all patients receive education about hyperlipidemia and atherosclerosis, as well as printed materials about diet and exercise. Statin therapy was to be initiated in patients at extreme- and high-risk. Moderate-risk patients were to be screened again in 1 year, whereas low-risk patients would be rescreened in 5 years.

The flowchart was presented to thought leaders in IHC and then to the full medical staff anywhere from six to eight times. “Implementing the model is the hard part. It is our belief that change cannot be accomplished until the physicians make the decisions,” commented Dr. Staker.

The goal is to motivate physicians to institute aggressive secondary prevention in patients with known coronary artery disease, that is, those with myocardial infarction and positive angiograms. Also, the IHC lipid management

Figure 4. The Care Process Model



model focuses on the need to treat patients with diabetes and those with familial hyperlipidemia.

"We want to drive home the message that physicians should treat patients with CHD and those at high risk to a goal LDL-C level of 100 mg/dL or less," emphasized Dr. Staker. "A 35% reduction in LDL-C is acceptable. We educate our physicians about the NCEP guidelines and ask them to follow the flowcharts. The goal for at-risk patients with no CHD is LDL-C less than 130 mg/dL."

Although the NCEP guidelines stipulate starting with diet before progressing to treatment with drugs, the IHC model recommends starting drug treatment and diet simultaneously. Data are not yet available on how effective the model has been in getting patients treated to goal LDL-C levels. Preliminary 6-month data are encouraging, according to Dr. Staker and Mr. Clark.

Efforts are being targeted to motivate physicians. Several approaches are being used, including Continuing Medical Education (CME) programs, newsletters, incentives, and cooperating with detailing programs that aim to change physician behaviors.

"Physicians are comfortable with CME, but studies show that only 15% will change behavior as a result of CME. We are using multiple approaches, including teaming up with detail people to change physician behavior," said Dr. Staker.

... REFERENCE ...

1. Grover SA, Coupal L, Hu XP. Identifying adults at increased risk of coronary disease: How well do the current cholesterol guidelines work? *JAMA* 1995;274:801-806.