Reimbursement Considerations In the Treatment of Hypercholesterolemia:

Economics and Implications for Medical Groups

A ROUNDTABLE DISCUSSION LED BY ROBERT A. MENDES, M.D.

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CHAIRPERSON/MODERATOR ROBERT A. MENDES, M.D., Medical Director and Chairman, P&T Committee, Scripps Clinic: Our objective for this meeting is to review and discuss the impact of hypercholesterolemia on cardiovascular risk and public health. In addition, we will explore the clinical and pharmacoeconomic profiles of the statins and consider their implications for medical group contracts with HMOs.

THERAPY OVERVIEW

STEPHEN R. CRESPIN, M.D., Associate Professor of Clinical Medicine, Washington University School of Medicine: 1998 was a landmark year for the treatment of patients with dyslipidemia, particularly as the condition relates to CHD. Studies released over the course of the year buttressed the position that greater amounts of LDL-lowering yield proportional increases in CHD health. In addition, data were released that pointed toward more targeted, cost-effective, and efficacious therapeutic approaches.

The great concern about hypercholesterolemia is its connection with CHD and the fact that this disease state is the single largest killer of men and women in our society.[1] In cost to society and frequency of illness, CHD equals virtually the sum total, in both dollars and number of patients affected, of every other health care problem in the United States.[1] An enormous number of patients in this country have dyslipidemic cholesterol levels.

The problem is that therapy for all these other risk factors has been disappointing. How, then, are we going to conquer CHD? Over the past five years, the medical community has accumulated a great deal of data showing that lowering serum cholesterol can be a useful approach to coronary heart disease management.

DIETARY FACTORS

Many patients are responsive to diet. Diet is a major problem for Americans, who tend to consume a lot of fat. Despite the fact that people in this country are highly knowledgeable about the benefits of a cholesterol-lowering diet, their practice of such a diet lags far behind. A tremendous number of patients are not meeting their cholesterol-level

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goals. Medical professionals have been frustrated in their attempts to effect lifestyle changes.

IDEAL CHOLESTEROL LEVELS

According to the National Institutes of Health's National Cholesterol Education Program (NCEP) expert panel on detection, evaluation, and treatment of high blood cholesterol in adults, the optimum cholesterol target in a primary preventive context is 130mg/dL. Patients with established coronary heart disease, or any other atherosclerotic manifestation of CHD (i.e. — stroke, severe peripheral vascular disease), should be treated down to a goal of less than 100 mg/dL. The NCEP defines a number of risk factors, including but not limited to: advancing age (males over 45, females over 55), premature menopause without estrogen replacement therapy, heredity, smoking, hypertension and diabetes mellitus.

The target of 130 mg/dL represents the average cholesterol level of healthy, noncoronary-disease-prone middle-aged Americans. "Average" is a relative term, however: America's average "healthy" cholesterol level is very high by global standards. The American average is associated with quite a bit of atherosclerosis, and the target level may be revised downward in the future (Figure 1).

A number of studies have shown conclusively that first and second coronary events can be prevented by pharmacologic intervention. A growing body of research supports the cost-effectiveness of LDL-lowering therapy.[2]

There is a tendency, as lower LDL levels are achieved, for the rate of risk reduction to decline. Currently, no one knows exactly how low we should go; that's going to be a profound question over the next couple of years.

HITTING THE TARGET

When cholesterol levels are not responsive to nonpharmaceutical lifestyle changes (i.e. — diet, exercise, smoking cessation), lipid-lowering therapy is indicated. According to voluminous data, the statin drug class represents the optimum LDL-lowering approach. What is basically a new twist on therapy for 1998 is the realization that higher dose and more efficacious statins can also lower triglycerides. The drugs, as a class, have become significantly more versatile. While a case can be made for choosing an individual statin due to specific cost and/or quality considerations, the entire class has been shown to be effective in decreasing LDL cholesterol, and, by extension, coronary events.

A recent primary prevention trial, the Air Force and Texas Coronary Artery Prevention Study (AFCAPS/TexCAPS),[3] examined a large group of male and female patients who were not severely dyslipidemic. After one year of drug therapy, their LDL cholesterol was reduced to a much better level. There was little change in HDL and a modest lowering of triglycerides, both of which are typical results. Many clinical investigators believe that the statin therapy not only removes LDL of ordinary composition from the circulation, but also pulls out small dense LDL.

One conclusion of the AFCAPS/TexCAPS study was that roughly 3,000 patients must be treated for five years in order to save about 60 patients from having a primary event.

Figure 1

Coronary Heart Disease Risk Factors

Positive

- Age: Male 45 years+, Female 55 years+ or premature menopause without estrogen replacement therapy
- Family history* of premature CHD
- Current cigarette smoking
- Hypertension ≥140/90 mmHg or taking antihypertensive medication
- HDL-C <35 mg/dL
- Diabetes mellitus

Negative

- HDL-C >60 mg/dL

NCEP Risk Categories and LDL-C Lowering Goals

	Dietary Initiation Level	Drug Therapy Consideration Level	LDL-C Goal
Without CHD and fewer than two risk factors	≥160 mg/dL	≥190 mg/dL	**<160 mg/dL**
Without CHD and two or more risk factors	≥130 mg/dL	≥160 mg/dL	**<130 mg/dL**
Without CHD	>100 mg/dL	≥130 mg/dL	**<100 mg/dL**

***CHD family history**
If parent or sibling suffered from heart disease before age 55 (if male), or before age 65 (if female).

Source: Expert panel on detection, evaluation, and treatment of high blood cholesterol in adults. *Summary of the Second Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults* (Adult Treatment Panel II). NIH Publication No. 93-3095.

The cost of CHD continues to rise as long-term medical care is necessary for the patient who has angina pectoris, needs an angioplasty, or survives a myocardial infarction (MI) (Figure 2).

The AFCAPS/TexCAPS trial was significant because it showed that higher-risk patients without established CHD benefited from aggressive lipid-lowering drug therapy. If the risk factors had been analyzed even further, more benefit in certain patient groups would have been seen. For example, smokers have high rates of coronary disease. Many studies have shown that a large degree of CHD risk can be eliminated in this population if cholesterol-lowering drug therapy is undertaken. Studies suggest that the same benefits exist for the diabetic patient population.

ADDITIONAL CLINICAL EVIDENCE

In the recent Atorvastatin Versus Revascularization Treatments (AVERT) study, emergency-room patients presenting with chest pain underwent coronary catheterization.[4] Those patients not excluded because they had severe triple-vessel disease or an acute MI were randomized into two groups. One group had angioplasty plus usual care (aspirin, beta blockers, antihypertensive therapy, and lipid-lowering therapy) but not atorvastatin. The other group of patients received 80 mg atorvastatin per day but had no surgical intervention; they also had the other aspects of usual care. The two groups were followed for 18 months.

The atorvastatin group suffered 36 percent fewer total ischemic events (Figure 3). In addition, the time before the patient suffered a first ischemic event was delayed in the atorvastatin population. The angioplasty-treated group, which was allowed lipid-lowering drug therapy, showed a modest change in lipids; its LDL cholesterol fell from about 147 mg/dL to about 119 mg/dL. The LDL level of the atorvastatin-treated group fell from 144 mg/dL to 77 mg/dL; HDL cholesterol didn't change much. The major difference, of course, was the lowering of LDL cholesterol (Figure 4). There were no clinically significant differences in adverse event rates.

This trial also gives us important safety data. Although we have known for some time of the lipid effects and the safety profile of atorvastatin, this is the first clinical outcome trial of this medication. The AVERT trial provides crucial data to clinicians concerning what they can expect from atorvastatin.

THE CURVES TRIAL

Data gleaned from the CURVES Trial can provide insights relating to appropriate pharmacologic therapy.[5] The CURVES Trial looked, for the first time, at the comparative efficacy of the five different statins that were available by January 1997. A group of 500 hypercholesterolemic patients was randomized to 1 of 15 possible dosing regimens. Eight weeks later, their blood was sampled. A dose-

FIGURE 2: Air Force/Texas Coronary Atherosclerosis Prevention Study: Risk Reduction by NCEP LDL-C Cutpoints

Baseline LDL-C (mg/dL)	*<130*	*130 to <160*	*≥160*
n	691	4092	1822
Relative Risk	0.65	0.62	0.63
(95% CI)	(0.33, 1.28)	(0.45, 0.85)	(0.42, 0.93)

Source: Abstract Book for the American Heart Association, November, 1998, Dallas.

FIGURE 3: Summary of Primary Efficacy Parameter of Ischemic Events (Percent [n] of Patients)

Ischemic Events	*Atorvastatin n = 164*	*RUC* n = 177*	*% Reduction from RUC*	*P-value***
Patients With Any Ischemic Event	**13% (22)**	**21% (37)**	**36%**	**0.048**
Cardiac Death or Fatal MI	1% (1)	1% (1)		
Resuscitated Cardiac Arrest	0% (0)	0% (0)		
Nonfatal MI	2% (4)	3% (5)		
CVA	0% (0)	0% (0)		
CABG	1% (2)	5% (9)		
Revascularization	11% (18)	12% (21)		
Worsening Angina with Objective Evidence Resulting in Hospitalization	7% (11)	14% (25)		

*34% of the baseline procedures in the RUC group contained at least one stent; 48% of the follow-up procedures in the RUC group included at least one stent compared to 40% of follow-up procedures in the atorvastatin group.
**The significance level for the analysis of incidence of ischemic events was adjusted from a $P < 0.05$ to a $P < 0.045$ after two interim analyses were done using the O'Brien-Fleming stopping rule.

response curve was created that showed that, at every dosing level, atorvastatin therapy was associated with the greatest degree of LDL-lowering (Figure 5).

With each doubling of the dose of atorvastatin, another 6 percent reduction in LDL is achieved. As the doses increase, the curves level off. The 20-mg dose of atorvastatin reduced LDL by 46 percent. You would have to give 80 mg simvastatin (which was not done in the CURVES study) to achieve the same results.

Until atorvastatin became available, an average LDL could be reduced by only 25–35 percent. Despite therapeutic advances, the U.S. medical community faces numerous challenges when treating these patients. According to the data, the ability of diet alone to put the CHD patient at his or her LDL goal is limited.[6] Only 7 percent of patients can get their LDL to less than 100 mg/dL by dietary means alone. In the United States, very few high-risk patients can be brought to goal strictly with dietary therapy. Most patients with CHD, and those without CHD but who have two additional risk factors, probably need pharmacologic therapy.

Statins are being actively studied in terms of their ability to reduce stroke and change carotid artery diameter. This will be one of the major aspects of statin therapy in the next five years. The other big question that studies will attempt to address is how far down on the LDL curve that cost-effective interventions can occur.

A new worldwide study using atorvastatin, the Treat to New Target study,[7] involves patients with established CHD. Patients are randomized to either 10 mg atorvastatin (which is believed will bring their LDL down to about 100 mg/dL) or 80 mg, which, as we saw in the AVERT trial, will probably reduce LDL to 70 mg/dL or less. Patients will be followed for five years to address the question of whether the lower LDL level is better.

CONCLUSION

Clearly, statins are the most appropriate lipid-lowering therapy choice. Of statins, the atorvastatin evidence is the strongest. Atorvastatin has been shown to be very effective both in patients with hypercholesterolemia and modest hypertriglyceridemia and mixed dyslipidemia. In addition, atorvastatin is a drug which simultaneously will reduce triglycerides by almost 30 percent.

The data on statins are encouraging. However, pharmaceutical advances only solve part of the CHD equation. Clinicians still have a long way to go in terms of patient compliance. A major challenge is that dyslipidemia is basically asymptomatic. Untreated LDL leads to costly adverse events. At the research level, scientists must explore many other aspects of atherosclerosis, including thrombosis, infection, and immunology, before coronary disease can be conquered.

FIGURE 4: Analysis of Covariance (ANCOVA) Results for Adjusted Mean Percent Change From Baseline in Lipid Parameters at the Last Visit (Mean [Standard Error])**

Parameter	*Atovastatin n = 159*	*RUC n = 172*
LDL-C (mg/dL)		
Baseline	144.5 (2.5)	1473. (2.3)
End Study	76.7 (2.4)	118.8 (2.4)
% Change	–46* (2.6)	–18 (2.6)
TC (mg/dL)		
Baseline	222.6 (2.9)	222.0 (2.8)
End Study	150.8 (2.9)	197.4 (2.6)
% Change	–31* (1.8)	–10 (1.9)
TG (mg/dL)		
Baseline	167.9 (6.4)	160.6 (5.5)
End Study	139.0 (7.1)	164.7 (8.1)
% Change	–11* (5.4)	10 (5.5)
HDL-C† (mg/dL)		
Baseline	44.6 (0.9)	42.6 (0.8)
End Study	46.7 (1.0)	46.3 (0.9)
% Change	8 (2.2)	11 (2.2)

*Significantly different from RUC ($P < 0.05$).
**These changes represent incremental changes. At the time of randomization, 26% of subjects in the atorvastatin group and 19% of subjects in the RUC group were receiving lipid-lowering therapy, including statins; there was no washout period prior to entering the study.
†HDL-C = High-density lipoprotein cholesterol

RISK FACTOR MANAGEMENT

BRIAN P. GOLDSTEIN, M.D., M.B.A., Medical Director, Cardinal Healthcare: Can you address patient age as a consideration for pharmacologic treatment of hyperlipidemia? Please discuss this in terms of risk factor management in the primary prevention arena.

CRESPIN: Primary prevention yields are much lower than secondary prevention yields. If someone has made it to age 70 or 75 without many, or any, manifestations of severe atherosclerosis (especially considering the kind of food we eat in this country), one can assume that he or she has been blessed with a pretty healthy metabolism and can fend off the deluxe cheeseburgers.

In primary prevention, I tend to be conservative because the yield is low. How many extra years of life can a person gain by lowering lipids, especially since time and nature have already shown what this patient's biology is like? Many patients now live to be 90 or older, and they present interesting challenges. In past generations, the medical system didn't have to worry much about 90-year-old patients. One must take it on a case-by-case basis. On the other hand, once a patient has manifested coronary disease, regardless of age, that patient should be on a statin for life, given the enormous benefits in terms of secondary event reduction.

The Quebec Cardiovascular Study[8] showed that if insulin, APO B, and small dense LDL levels were measured, the sum of those three risk factors would better predict CHD vulnerability. The next couple of years will refine risk assessment. The guesswork involved in some of these issues is tricky. If a patient can get through the fast-food era and make it to age 70 or 75 without a lot of atherosclerosis, I would try a conservative, nonpharmacologic approach. In the patient with existing cerebral or peripheral vascular disease, however, atherosclerosis is already there. That patient needs to be treated aggressively.

PREVENTIVE THERAPY

GOLDSTEIN: The data presented in the AFCAPS/TexCAPS on the frequency of annual ischemic events shows two bars side by side (Figure 6). One appears to represent the control group, and the other the treatment group. It looks almost as though the slope of the two lines is the same.

CRESPIN: Each year of the study, about 33 patients without treatment have an event. Patients receiving drug therapy have 23 events. Was your interpretation that the effect leveled off?

GOLDSTEIN: Do these data suggest that we're merely postponing events rather than preventing them?

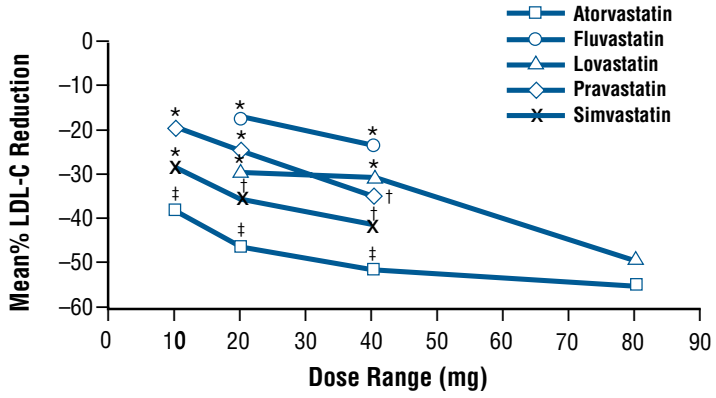
CRESPIN: Yes, to an extent. That is true of virtually all drug therapy. Pharmacologic interventions push premature events into the future. The patient in this study who might otherwise have had an MI in his or her 50s may instead have coronary disease at 70. The same is true of patients whose potential stroke is prevented with antihypertensive therapy. Unfortunately, we all rust internally. Pharmacology may remove some of the rust, but it's certainly not going to enable you to live to be 200. The rationale for therapy and the scheme of the National Cholesterol Education Panel guidelines is to identify those patients at greatest risk who otherwise might succumb prematurely.

COMPLIANCE ISSUES

JORDAN BUSCH, M.D., Co-Chairman, Pharmaceuticals and Therapeutics Committee, CareGroup Provider Services Network: What is the cause of patients' noncompliance or discontinuation of a drug? Is decreased libido involved?

CRESPIN: Decreased libido has not been a complaint. As the Viagra experience demonstrates, however, patients have been reluctant to discuss sexual dysfunction. High cholesterol is like any other asymptomatic illness. If a patient's stomach is not burning, he stops taking stomach medication; if a patient's joints are not hurting, her antiarthritic medication is forgotten. Complying with medication for asymptomatic illness is difficult. A significant segment of society experiences cost and reimbursement problems. Even if the medication was

FIGURE 5



*Significantly less than atorvastatin 10 mg ($P < 0.02$).
†Significantly less than atorvastatin 20 mg ($P < 0.01$).
‡Significantly greater than mg-equivalent dose of comparative agents ($P < 0.01$).
Jones P et al. *Am J Card.* 1998; 81:582–587.

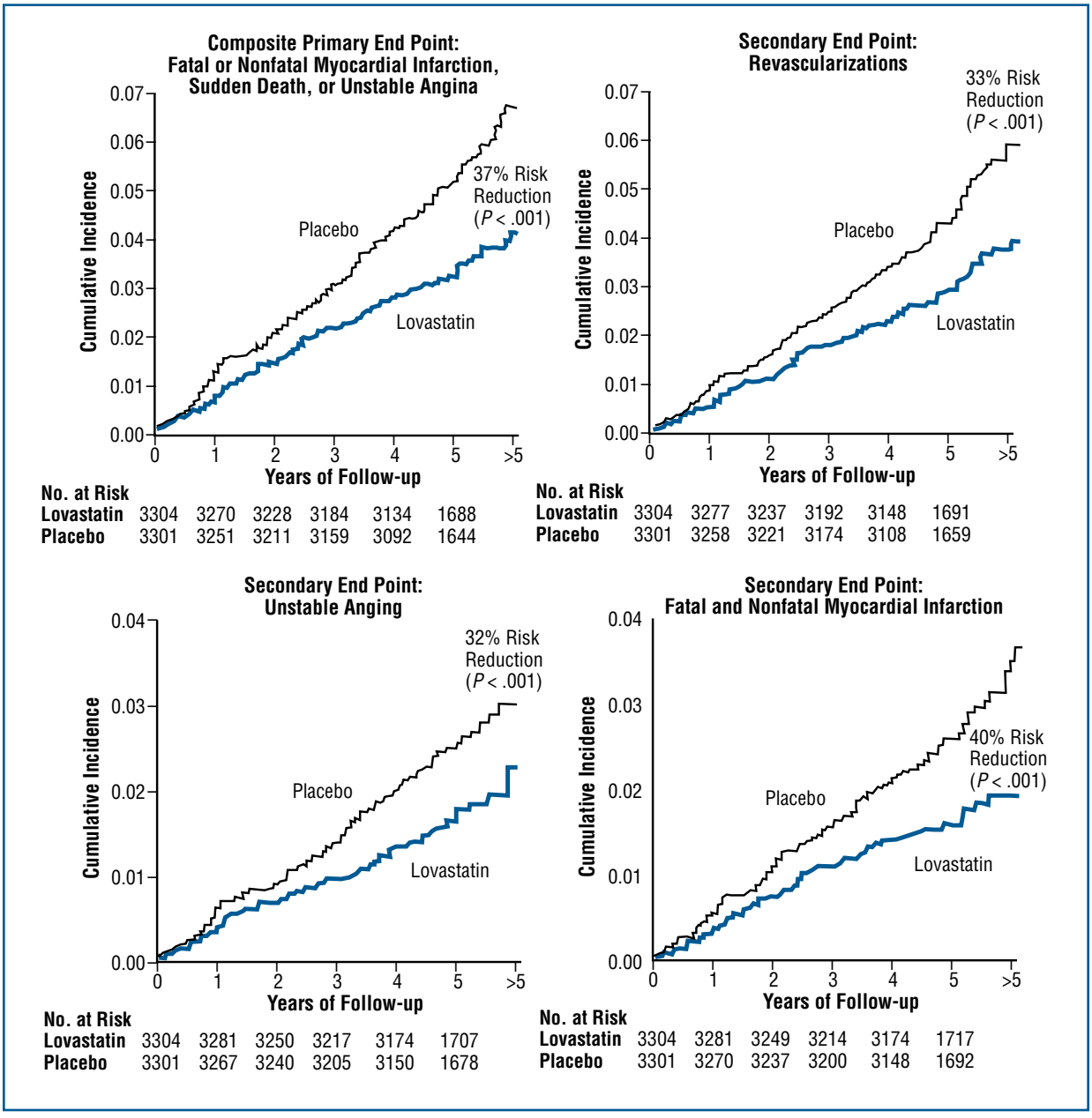


FIGURE 6

dispensed for free, however, a lot of people still would stop taking it. It's human nature to disregard an illness that has no symptoms.

MENDES: Are patients and payers aware of these issues? Are they sensitive to the impact on public health, and are patients being diagnosed and successfully treated?

BUSCH: The general approach in this country has been to educate physicians. Pharmaceutical companies have spent a lot of time detailing physicians as to how successful their drugs can be in affecting a given outcome.

To date, the medical community has not approached patients successfully. Patients, as they become aware of a problem, run to the doctor and demand that it be addressed. Therefore, it is not enough to tell patients that cholesterol is important; patients know that. It is not enough to say that heart disease is significant; patients are aware of that. The medical community has to educate patients on what treatment-to-goal is. This, in turn, will drive physicians to work cooperatively with patients. Patients are not sensitive to the true impact of CHD in their own lives.

For payers, CHD is a cost-effectiveness issue. They are aware of it, but it

costs money up front. Patients tend not to stay with a single health plan, and payers often gamble that by the time a problem presents, reimbursement will be Medicare's problem.

MENDES: Who should design patient education programs? Should individual physicians educate their patients during office visits? Is this education something that other groups should do? Should pharmaceutical companies do direct-to-consumer marketing?

BUSCH: Generally speaking, I am opposed to direct-to-consumer marketing, but the CHD situation may be an exception. The pharmaceutical industry can do us a favor by raising risk-factor awareness. Direct-to-consumer advertisements should say: "Talk to your doctor about optimum therapy to reduce your risk," not "Use pravastatin" or "Use fluvastatin." It's frustrating when the pharmacy and therapeutics (P&T) committee develops guidelines based on the premise that it provides the most cost-effective treatment modalities, and patients come in requesting a specific drug they saw on the Internet or on television.

MENDES: Are payers sensitive to this?

MARY LAWLOR, M.D., Associate Medical Director, Advocate Lutheran General Health Partners: Payers are looking at the bottom line every year. There is system-wide shortsightedness, however. As physicians, we are not educated in public-health impact. Physicians look at individual patients, not necessarily at public health. We treat the "worried well." The people we need to treat are not necessarily coming into the office.

DONALD R. LURYE, M.D., Medical Director for Managed Care, Meridian Medical Group: Consider asthma, another serious chronic illness that also is treated by level of severity. Guidelines exist for intermittent, mild, moderate, and severe persistent asthma, but there is a discrepancy between recommendations and actual practice. Asthma is a symptomatic disease that causes people to miss school or work. If the health care system cannot align asthma theory and practice, how are we going to do it with a disease that usually has no appreciable symptomatology? Education is key, any way it can be done; it doesn't necessarily matter who does it.

BUSCH: Whether or not payers care about patient education probably depends on the type of system they are in. In Massachusetts, where we have heavy managed-care penetration, managed care organizations (MCOs) seem to care more about patient education. MCOs want to come across as caring for patients. Many produce patient education material; they are also involved in preventive care. In Massachusetts, we probably could get support from the payers.

An integrated health care system has the goal of reducing costs and improving outcomes. That's what attracts patients to your system. So, we want to be able to sell ourselves as better than the rest. We want hard data to demonstrate our success.

MENDES: Are you actually tracking the outcomes in your patient population? When you find that you have good outcomes, do you publish or otherwise make the results known?

BUSCH: That is difficult to do until some type of electronic record system is in place. Care Group is moving to an electronic platform that will enable us to conduct electronic chart reviews and make CHD data available.

DEBI REISSMAN, PHARM.D., President, RxPerts: Patient awareness is a tremendous issue. Patients simply do not realize that CHD is still going to be their major killer as they grow older. Awareness is tied to treatment compliance. For example, my friend takes atorvastatin. Her comment to me was, "Now that I'm on this drug that treats my cholesterol, I can go back to eating the way I used to." People taking these drugs typically believe that they can go out and eat their french fries and doughnuts. Patients must learn that the pills are not magic, but merely part of a treatment that includes behavior modification.

DIET MANAGEMENT

MENDES: What role do patients think diet plays in the management of hypercholesterolemia?

LURYE: For patients, part of the problem with diet management is that it just doesn't rise above the noise level. The current health delivery model is focused on the treatment of acute illness. It does that very well. What you are talking about amounts to a privatized public health effort. We have to get away from the exam room being the place where everything must happen. For example, Kaiser, Southern Colorado, has a group-visit program for people with chronic illnesses. In our own group, we employ nutritionists who run classes and schedule individual appointments. The system needs to look beyond physicians and other acute-care providers. Physicians cannot be responsible for everything. Purveyors of lipid-lowering agents, the government, and various disease-oriented foundations can be of help. In general, we need to look outside the acute-care model because it does not do well with chronic illness.

MENDES: A few years ago, it was recommended that everybody be given a three- to six-month trial of diet management before more aggressive therapy is initiated. Is this the current standard of practice in your medical groups or community?

GOLDSTEIN: I typically ask my patients what kind of diet they are currently following. Plenty of studies indicate that people do not tell their doctor the truth about their diet, so I factor that in. If patients are honest enough to tell me, "I eat cheeseburgers three times a week," then I

might give diet management a shot; however, if patients tell me that they eat a healthy diet, many times I don't take the time to recommend a dietary trial. It also depends on how high the cholesterol is, whether the patient has other risk factors, and what the LDL goal is.

Diet management is tremendously important. It is something that we have to keep talking about, although I agree that it cannot be an isolated event in the physician's office. That said, even the most intrusive public health effort would have a tough fight against the constant barrage of advertising and the availability of these foods in this country. Parke-Davis and Pfizer may be reluctant to do direct-to-consumer advertising, but fast-food restaurants are not. Physicians bristle when drug companies put a consumer-directed ad in a magazine, but, unfortunately, we do not think about the damage that junk-food manufacturers and fast-food restaurants can do with direct-to-consumer advertising.

LURYE: A healthy diet prevents a great many things besides high lipids, so diet management is worth pursuing in any event.

NCEP GUIDELINES

MENDES: Do primary care physicians typically follow the National Cholesterol Education Panel (NCEP) guidelines?[9]

LAWLOR: Yes. When the cardiologists in our medical group reviewed their patient population, they found that only about 50 percent had blood lipids within NCEP guidelines. The cardiologists believed that they were treating very aggressively, so now they are trying to figure out what happened and how this percentage can be increased.

JOSEPH L. GEIERMAN, JR., PHARM.D., Director of Pharmacy & Formulary Administration, Beaver Medical Group, LP: Parke-Davis has made slide-dosers based on NCEP guidelines for our physicians. Our organization has distributed these slide-dosers two times to make sure that physicians are aware of the goals and easily can start their patients on correct dosages. This program has been highly beneficial. In the fourth quarter of 1996, our organization had 2,200 people on statins; by the second quarter of 1998, that number had increased to 3,800.

HEDIS GUIDELINES

MENDES: Are HMOs encouraging physicians to follow the NCQA's Healthplan Employer Data Information Set (HEDIS) guidelines, which differ slightly from the NCEP guidelines, when treating patients for hypercholesterolemia?

SAMI E. KHOURY, M.D., Medical Director, Caremore Medical Group: The HEDIS guidelines are usually the measure they grade us on. I have about 14 outcomes-based assessments that my organization will be graded on this year.

REISSMAN: HMOs are looking at HEDIS as *the* measurement tool.

MENDES: How different are the HEDIS guidelines from the NCEP guidelines?

BUSCH: HEDIS says that high-risk patients (those with more than two risk factors who have had an event) must be brought down to 130 mg/dL, as opposed to NCEP's guideline of less than 100.

REISSMAN: Doesn't that change with HEDIS 1999? I think that the 1999 measures bring it down to 100.

BRUCE TAYLOR, Director, HealthCare, GTE Corp.: HEDIS is a work in progress. When this system was initiated, there was plenty of resistance from just about everyone. Someday there will be a HEDIS 27.0. We are further along than we were a few years ago, however, and we are headed in the right direction.

LURYE: HEDIS was constructed for a purpose very different from that of NCEP. If HEDIS came out with a requirement that nobody was going to be able to meet, nobody would spend the $30,000 to administer the HEDIS survey plus the $1 million or so in indirect costs that a typical organization spends in getting ready for HEDIS accreditation.

MENDES: When you start throwing out different numbers for the same population, the potential exists for confusion. I'm concerned about the practicing physician out there who sees different numbers coming in from different sources.

CHD AND DIABETES

MENDES: How about coronary disease and diabetes? What challenges are involved in treating this high-risk population? These patients probably are going to be on multiple medications, which complicates treatment options. However, this is a subpopulation we need to be aggressive with.

CRESPIN: Challenges exist in treating patients for previously diagnosed CHD. A patient who has diabetes and CHD represents a three- to sixfold increase in risk.[10] Before the first heart attack, American diabetic patients have somewhere between two- to fourfold greater risk. Once a diabetic patient has manifested CHD, the risk increases by another factor of three. This patient population has an enormous amount of CHD. A diabetic patient who comes to see you for the first time, newly diagnosed and with no heart disease, is as likely to have a first coronary event as any other patient of yours who has already had an angioplasty but doesn't have diabetes. Virtually every diabetic patient has to be seen as someone with CHD risk, just like the established CHD patient. Recognizing this fact, the American Diabetes Association has just advised reducing LDL cholesterol to less than 100 in all diabetic patients regardless of CHD risk status.[11]

MENDES: Are there opportunities for pharmaceutical companies to help us publish guidelines? It is important that your P&T committee de-

velop those guidelines independently, and this is not a problem so long as decisions are made without regard to funding. By definition, a guideline will ultimately promote somebody's product; if this is the case, the drug manufacturers are having work done for them. I see no conflict in having them pay for production and distribution of these materials, provided the guidelines were developed independent of potential funding consideration by a pharmaceutical company. It is a different story, however, if a P&T chairperson approaches the pharmaceutical company and asks for money to develop a guideline.

LURYE: We plan to get the assistance of a couple of different pharmaceutical companies in different areas to help us study our own population. That requires funding that we don't necessarily have. The drug company representatives I've been dealing with understand that the funding does not guarantee that their product is going to be promoted in some specific way. However, these types of initiatives will raise the general level of dyslipidemia awareness. There will also be a higher drug spend, but we hope that we will keep these members long enough to see the benefit.

BUSCH: At our last P&T committee meeting, we addressed the funding issue for pharmaceutical companies. Several pharmaceutical companies have asked us whether we would be interested in their making some charts and handouts that had our name on them. They offered to distribute them for us. It seemed like a pretty convenient thing, but we have decided that we want our funding to come to us centrally. We will produce and distribute appropriate handouts, not the pharmaceutical company, even though it offers lots of manpower to get the information out to our doctors.

MENDES: Is there a role for pharmaceutical companies in the management of dyslipidemia?

KHOURY: There has been a backlash against pharmaceutical companies using guidelines as a promotional tool. It has come to the point where medical groups like ours, which are dealing with HMOs on a more frequent basis, have concluded that drug representatives are not allowed in the partners' offices. There is a trend toward keeping pharmaceutical companies out of doctors' offices and away from the P&T committee. In my opinion, it's a shame. Pharmaceutical companies have an important role to play in developing disease management programs.

GEIERMAN: Our big problem was counter-detailing products that the drug companies' representatives were promoting. We faced a dilemma: whether to eliminate all samples and all pharmaceutical representatives, or to limit the products the representatives can talk about and the number of samples we keep. I have limited the number of samples that we keep. We have a preferred formulary list (those are the samples we keep) and the representatives are allowed to talk only about the samples on our formulary. The only time they can talk about new drugs or any drugs not on our formulary is on "drug day," which is held once a month.

COST-EFFECTIVE APPROACHES

DANIEL E. HILLEMAN, PHARM.D., Professor & Chair, Department of Pharmacy Practice, Creighton University School of Pharmacy: Why use statins to treat hypercholesterolemia? These drugs represent first-line therapy. Their advantages include efficacy in terms of lowering LDL cholesterol and a relatively benign adverse-effect profile.[12] These are easy to administer and have a substantial effect on mortality. In addition, the relative risk reduction of the statin class is greater than that of niacin, bile acids, or fibric acid derivatives.[11]

The primary concern with the statin class is not efficacy, but cost. How are we going to pay for these drugs? If we are treating a substantial percentage of the population, who is going to cover the cost? All of these drugs cost over a dollar per day average wholesale price (AWP); the least expensive typically costs about $1.30 a day AWP. If we were talking about a drug that cost 30 cents or 20 cents a day, we wouldn't be so concerned.

MEASURING COST-EFFECTIVENESS

In measuring cost-effectiveness, per-unit drug cost must be viewed in the context of acute events avoided. Statins, although they require front-end investment, reduce the cost of treating CAD and other types of vascular disease by preventing adverse events such as heart attack and stroke.

Cost-effectiveness is the most common type of pharmacoeconomic evaluation in the literature. Typically, cost-effectiveness means that on one hand you have cost, and on the other you want to know how many dollars it takes to effect a particular change in a naturally occurring outcome parameter. For instance, what's the cost per milligram change in LDL cholesterol? What's the cost per percentage change in LDL cholesterol? Cost or dollars per percentage reduction of LDL cholesterol is the most common evaluation tool used in lipid-lowering therapy analyses. Incremental cost-effectiveness is used with a more expensive statin to calculate how much more it would cost for every percentage reduction of LDL cholesterol.

Cost per successfully treated patient is another measure of cost-effectiveness. Last, and probably most important, what is the cost per life-year gained? If mortality data are available, an economic model can be applied to demonstrate dollars spent per life-year gained. Traditional pharmacoeconomic experts would tell you that over $75,000 spent per life-year gained is no longer considered cost-effective. This tool has been applied to all kinds of interventions (e.g., hemodialysis for end-stage renal disease; automobile seat belts); it can be applied to a variety of public health interventions and certainly to lipid-lowering ther-

apy, as well (Figure 7).

Cost benefit is similar to cost-effectiveness, but whatever parameter you are impacting must be converted to dollars.

The last method of cost-effectiveness analysis is cost utility. Typically, cost utility is a cost-effectiveness analysis that determines dollars spent per life-year gained and reaches a quality-of-life assessment. You end up with what is called a utility index.

Regardless of analysis tool, most decision-makers, when looking at the numbers, concur that the use of statins in both primary and secondary prevention is cost-effective. This is a simple cost analysis looking at dollars spent per year/per percentage LDL cholesterol reduction.[13]

STATIN COST-EFFECTIVENESS

A recent study compared existing statins on a head-to-head basis to determine which member of the class would be most cost-effective. Researchers estimated the percentage of patients that would get to target at different doses, and then calculated the cost of getting those patients to target. Since low-risk patients only need a 16–20 percent reduction in LDL cholesterol, any statin at its starting dose can get these patients to target, because all doses studied yielded more than a 20-percent reduction in LDL cholesterol.

In moderate-risk group patients, atorvastatin 10mg per day, despite its higher annual cost ($664 per year compared to about $430 for fluvastatin, based on 1997 AWP), was found to be equally cost-effective. The reason is there is no dose titration needed with atorvastatin. Atorvastatin 10mg, with a 37 percent reduction in LDL cholesterol, gets everybody in the moderate-risk category to target without additional drugs or titration. Therefore, in the moderate-risk group of patients, atorvastatin 10mg is as cost-effective as using fluvastatin.[14]

It costs approximately $95,000 to treat 100 patients with atorvastatin for a year based on duration of therapy and severity of LDL levels. The low-risk group costs more to treat, but, particularly in the high-risk group, savings are the end result because monotherapy is efficacious for all patients. From an overall cost-effectiveness standpoint, if you were looking to select one drug, atorvastatin would be that drug.

COST VS. THERAPEUTIC VALUE

TAYLOR: I look at just the cost per day of therapy. We're pretty easy. I had thought it was pretty straightforward, but you're saying, in essence, that it's really not cost per mile that's important; it's whether the bus is taking you in the right direction.

HILLEMAN: I'm saying that looking simply at the price per pill is going to shortchange a substantial percentage of the patients if you believe that we should be aggressively lowering LDL cholesterol to the NCEP target.

If you want to look at the bottom line, there are other options that may cost less per pill per patient, per day, or per year. However, what is important (and the data back this up) is that if we treat aggressively, particularly the CAD patients, and get their LDL cholesterol to 100 mg/dL or lower, the number of cardiovascular events in those patients will be substantially reduced compared with patients with less aggressive LDL cholesterol reduction. In my opinion, the NCEP guidelines represent the best treatment guidelines out there.

My economic analysis is predicated on the assumption that those guidelines will be followed. Let's apply those guidelines; then we'll look at the cost and efficacy concerns. Some patients will do fine with lower-priced drugs. There is also a percentage of patients, particularly in the high-risk category, that ends up costing less on atorvastatin because of the drug's efficacy.

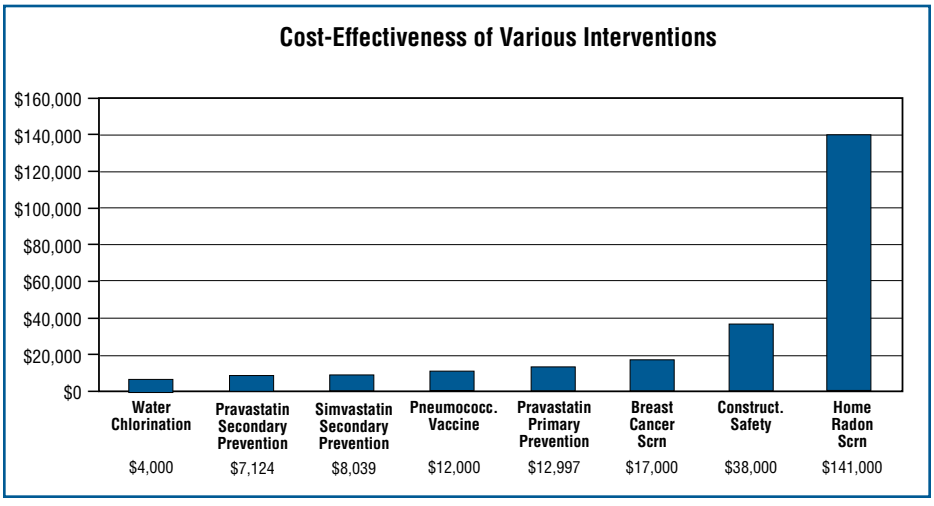
COMPELLING DATA?

MENDES: Do research results and economic evaluations of various studies influence decision making when a physician selects a drug for a specific patient?

LURYE: I'm not sure whether the economic results are in the forefront when the doctor is in the exam room. If you sit on a P&T committee or are trying to decide what drugs to include as alternatives, I'm sure the results are a factor.

BUSCH: In Massachusetts, 80 percent of our work force is in managed care. Managed care probably makes up more than 50–60 percent of our outpatient business. We're trying to educate our doctors

FIGURE 7



about cost-effectiveness. Part of the problem is the patient. Patients don't care about cost-effectiveness; they care about effectiveness. They want to know what the best drug is.

As I understand the data, all of these drugs have similar side-effect profiles. Side-effect profiles are probably the same once you reach the target as defined by NCEP LDL levels. As more data come in, we're beginning to believe that it's a class effect. Once the class effect is accepted, it's easier to look the patient in the eye and say, "Any of these drugs will work. The drug that I'm going to pick for you is a drug that we think will do this quickest, with the least amount of dose titration."

These data are critical. We're trying to give this information to patients through the physicians. In fact, we have offered two drugs on our formulary: fluvastatin and atorvastatin. Most people are using atorvastatin. They don't want to be troubled with a lot of other details.

CLASS EFFECT?

MENDES: Do you believe that the efficacy of individual statins is due to a class effect and that product decisions should be based on the LDL reduction issue?

LAWLOR: Yes.

MENDES: That's what we think as well. Does the analysis of percentage of patients achieving a goal influence your decision regarding which statin you recommend?

GEIERMAN: Depending on what the patient's LDL or total cholesterol is, we'll pick a dose that will effectively decrease it to target.

GOLDSTEIN: Monotherapy is important in a busy practice, for reasons other than those that were already mentioned. It's hard to keep too many medicines in your head. Also, if you're busy and your patients are busy, you can give them something that means they have to come in less often to get titrated and need less monitoring before they get to goal. There is benefit there, as well.

MENDES: Most of us agree that treating patients to goal is, in fact, our ultimate goal in giving patients statins. That is, not just putting them on statins, but treating them aggressively to get them to goal. What about adverse effects? How significant are the adverse effects of the different statins?

KHOURY: The adverse-effects profile is pretty much the same for all the statins.

MENDES: Does anybody disagree? I have yet to take a patient off of a statin because of adverse effects.

LURYE: Are the monitoring regimens for any of the statins substantially different?

CRESPIN: No, all are about the same.

The adverse-effects issue is difficult. As we push people to get to goal and use higher doses of statins, we see more patients complain of vague aches and pains. When these same patients are tested for liver function, no abnormalities are found. Some patients try every statin and still complain of aches and pains. It's frustrating.

Occasionally, someone will do better on one drug than on others, although I doubt that can be predicted. No single statin has a monopoly on the lowest incidence of adverse effects.

PHARMACOECONOMIC ANALYSIS

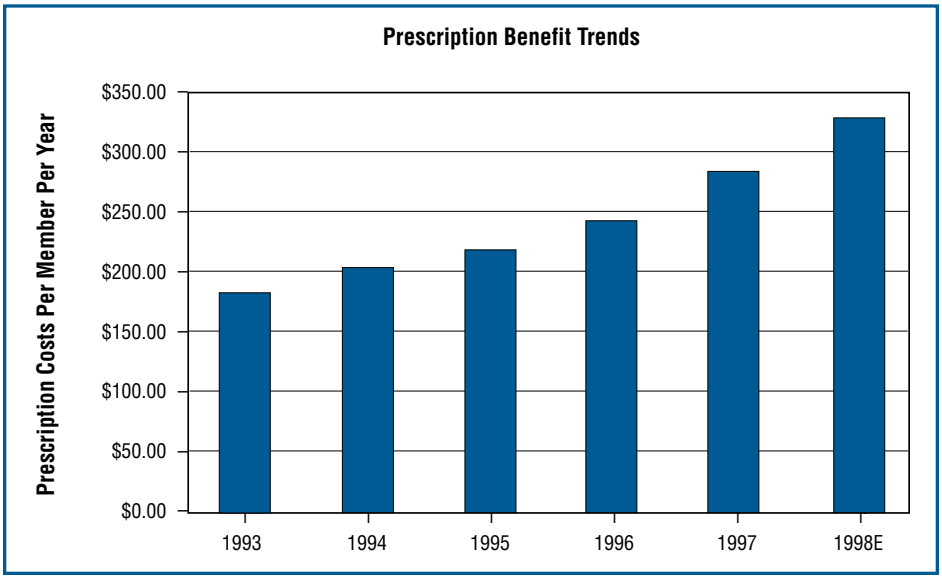
MENDES: Can we adequately understand and utilize pharmacoeconomic data to make decisions? Do P&T committees look at this kind of analysis? Are we, in fact, capable of evaluating our total medical costs in our own patient populations?

GEIERMAN: We receive claims data from several of our HMOs in order to conduct evaluations of different drugs. The bottom line is the cost per day to get our patients to their goal.

MENDES: When you do P&T committee reviews for a given product, do you evaluate available pharmacoeconomic data?

GEIERMAN: To a point. We don't go extensively into it because there are

FIGURE 8



too many things to discuss. Physicians are the ones who are actually treating patients. They have experience with most of the drugs; they know which ones are effective and which are not.

Atorvastatin was not on the PacifiCare formulary in Southern California, but physicians realized how efficacious a drug it was and started using it. It didn't have to be on the formulary to succeed. If a drug is good, it will push itself.

MENDES: It doesn't seem that many decision makers are utilizing pharmacoeconomic outcomes data in P&T committee meetings. I've been involved in prelaunch consultancy work for pharmaceutical companies in the managed care arena. In these meetings, MCO executives tell pharmaceutical companies that they must do outcomes and pharmacoeconomic studies. Yet you're telling us that you don't use these studies for your P&T reviews. What's the answer? What is a pharmaceutical company supposed to do in this area?

GEIERMAN: When you are comparing more than one drug in the same class, outcomes studies are needed to show cost benefit. In order to demonstrate a difference or assert that one drug should be used over other drugs, evidence of benefit and cost savings must be provided. If a class effect exists, cost-effectiveness is the determinant.

MENDES: I don't think it's accurate to say that P&T committees never look at pharmacoeconomic data. Certain studies influence the way we think. It is extremely helpful to have data that compare drugs head-to-head. That's probably the most beneficial type of research; however, it is expensive and seldom done.

BUSCH: We do use pharmacoeconomic data produced in studies. In fact, that's the kind of data we need. We depend on larger trials as a means to assess our own direct costs.

REISSMAN: I agree. The P&T committees do look at the data. However, the data that committees currently get tend to compare products against placebo, not against other products. Actions are many times thought to be class effects so we end up looking at cost instead of being able to compare outcomes between products.

MENDES: Is there a particular outcome metric that is most helpful? Is there something that a pharmaceutical company ought to be looking at in its research that would be more useful for us?

BUSCH: It depends on who is looking at the data. Integrated health care systems, insurance companies, and large groups may be looking at quality per life-year saved or quality-adjusted life-year. They may use these data to demonstrate success and win contracts with employers. If doctors understand that the goal is to get the LDL to a certain level, however, they're going to want to know the cost for reaching the goal and what the proper dosages are. Some of the data presented today addressed that.

Once physicians accept guidelines, they must understand how to pick the drug end dose to reach the goals set forth by the guidelines. Correct dose is almost as important as the correct drug. Slide rules and calculators are useful. Most physicians don't care about quality-adjusted life-year measures; they are irrelevant.

LURYE: A cost-effectiveness ratio would be meaningful. Quality of life is going to be perceived without study data. On a periodic basis, share general information, such as cost-effectiveness ratios. Disseminate the kind of information that individual physicians can use. For example, conduct a blinded peer-based comparison. Physicians don't like being below average.

LAWLOR: Cost-effectiveness ratios sound good if they feature drug-to-drug comparisons. However, they are big numbers and not necessarily meaningful when you are considering an individual patient. I like to look at cost per year per successfully treated patient. That indicator demonstrates that if I use a given drug, it will successfully treat the patient at a definable, comparable cost.

SELECTING A STATIN

MENDES: Can the selection of a statin be simplified? Can a P&T committee simplify its recommendations? Are currently available research trials adequate to help us decide which statins are best for us to include in a formulary or a recommendation?

GOLDSTEIN: I think that the trials are adequate for statins. It appears that a consensus on class effect exists. Most plans probably have an easier time of picking a preferred statin than they do with many other drug classes.

LURYE: The pharmaceutical companies tend to present bundles of products to the P&T committee. We end up making deals that cover a variety of things. If the committee selects out on one agent, then it loses its advantage on the other drugs in the bundle. These are not pure decisions.

MENDES: That's true in this class. After seeing these data, does anybody here think that there isn't a place for atorvastatin?

LURYE: Our concern is that it is not on formulary, but is the most prescribed agent. It's an exception that keeps coming up.

RISK IN MEDICAL GROUPS

REISSMAN: Health plans are mandating that pharmacy risk be taken on by medical providers, whether they want it or not. Why is this happening? The inflationary trend of the pharmaceutical benefit is frequently cited as the reason that pharmacy risk is being passed from health plans to medical groups. Over the past five or six years, almost without exception, every plan in the United States has experienced an increase of 15 percent or more in its pharmacy benefit.

This trend is a combination of inflation of the actual drug price, a shift to newer products, and increased utilization. More people are taking more drugs. (Figure 8)

UTILIZATION DRIVERS

There are a variety of reasons for increased drug utilization, many of them beneficial in general. Some of these reasons include:

1) The number of products being approved by the FDA. In the last two years, the FDA approved more products than it had approved in the previous five. Improved therapies also have come to market, products that are more efficacious and have fewer adverse effects.

2) More emphasis is being placed on prevention. As a result, patients are slowly starting to improve compliance.

3) The health care system is identifying and treating disease earlier. When people begin taking drugs earlier in their lives, increased inflation results. Direct-to-consumer advertising is leading patients not only to ask for specific products, but also to get to the physician's office earlier, and is raising disease awareness. The aging population also plays a role: With the average age of the U.S. population in its 30s, we use fewer medications than we will as average age increases.

Health plans have been unable to affect the utilization of prescriptions. The management techniques used by health plans are aimed primarily at the unit cost of individual prescriptions, not at how many prescriptions are being written or consumed. Cost equals prescription cost times the number of prescription units. Both price and utilization must be affected in order to affect overall costs. None of the current management techniques (including working with network pharmacies to get a better percentage off AWP, mandating generics, increasing copayments, putting in formularies and therapeutic substitutions) are really getting at units; they get only at cost per prescription.

RISING COST, RISING RISK

In a typical model, pharmacy may be 10–11 percent of the total medical dollar that is spent by a given health plan. However, as health plans carve out medical costs, through either shared risk or global capitation, pharmacy costs are no longer 10 percent of the whole; they are 40 percent of what's left to manage by the health plan. Suddenly, pharmacy becomes a much more significant portion of a health plan's variable expenses.

On the other end, many medical groups are requesting pharmacy capitation or pharmacy risk in higher percentages than even the health plan initially wants to share. Medical groups are saying: "Let us control that total dollar. Get out of our way, give us the money, and we'll do our thing. You channel the patients to us and we'll take care of the medical costs and medical utilization."

What does the marketplace for pharmacy risk look like? There's no set standard. There are probably more exceptions than rules on how pharmacy-risk arrangements are put together. Generally, in Medicare programs, the richer the benefit, the higher the percentage being pulled out of the HCFA premium to fund the pharmacy risk pool. In commercial programs, however, the pharmacy risk budget tends to be a flat per-member, per-month (PM/PM) budget, not a percentage of premium. The interesting thing about the flat budget is that many times it is never explained to the medical provider how the number was developed or how it compares to actual group cost patterns.

Settling the risk program is another issue. Generally, the cost that plans pay to the pharmacy (usually some discount off AWP plus a dispensing fee, minus the member copay) is deducted from the pharmacy budget pool. Other plans may just use the AWP of the drug. Some plans also deduct an administrative fee from the pharmacy funds. However, very few health plans pass on the rebate to the medical group in the settlement. Unless your contract specifically states that you are getting a rebate, you probably are not. This is true of the statin class, as well.

Many groups have been successful in negotiating certain products out of their pharmacy risk agreements. Targets for exclusion include products that treat rare diseases. If one of your patients contracts a rare and expensive disease, that patient could spend your entire pharmaceutical budget. Exclusions for these types of products can be negotiated or risk can be shared under a stop-loss or catastrophic-risk pool.

REBATES

It is important to understand how rebates are being calculated in your contracts. What do you think you should get back in rebates? Generally, health plans should get back between 3 percent and 9 percent. Plans with open formularies run closer to 3 percent, and those with tightly closed formularies obtain as much as 9 percent. Medical groups contracting with health plans may not have any of this rebate netted against the budget. This may be okay if the budget was adjusted upward to compensate for the rebate funds.

MENDES: Can you break that down in a PM/PM range?

REISSMAN: If your average PM/PM is $10, your rebate should be between 30 and 90 cents. If you are not getting close to 5 percent back, you are probably not getting the entire rebate, or else there is a lot of utilization of nonformulary drugs which will not be rebated. Very rarely is anything over 9 percent negotiated. A health plan would have to have an exceedingly tight formulary to get more than that.

GEIERMAN: Is the rebate split between the HMO and medical groups? It should be split fairly. Fair is fifty-fifty.

REISSMAN: Yes, I believe in shared risk. It should be split fifty-fifty. The reality, however, is that rebates are not

shared. Most of the time, the groups are not getting the rebates due them for making cost-effective therapeutic decisions.

MENDES: Has the rebate percentage been trending up or down in the last couple of years?

REISSMAN: Overall, rebate percentages have decreased. Unless you are driving market share, MCOs don't get the maximum 15 percent or 17 percent on any individual product. Only health plans with very restrictive formularies are getting 9 percent. The majority of health plans are probably closer to the 5-percent level. Open formularies are probably running at 3 percent. The point is that groups, by and large, are not getting rebates at all. They have to look at their own unique situations. A statin that is cheaper for an MCO may not be cheaper to a medical group.

DRUG UTILIZATION DATA ARE KEY

MENDES: How quickly does the pharmacy benefit manager (PBM) get rebate data to the drug company for rebates of the medical group for review?

REISSMAN: The PBM has the data; it's just a matter of getting it in a usable format. The usual turn-around time for rebates is about six months. Your plans can tell you what standards they have in place for sending data to each medical group.

GEIERMAN: There are minimum criteria. The MCO might not give a DEA number, which makes it impossible to find out which physicians prescribed what. In one health plan, we had 800 physicians. Only 9 percent of the physicians were tied to a DEA number; the other 91 percent had no DEA numbers. How could you tell which prescriptions were yours?

LURYE: Yet you are at risk for the total 100 percent.

MENDES: We refuse to accept risk if the MCO can't give us the data.

GOLDSTEIN: For us, the infrastructure is largely nonexistent. There is no data reporting. The concept of shared risk for pharmacy is in the contract, but there will be no shared risk until we see some data and also share in the rebate with the HMO from its PBM.

RECREATING THE FORMULARY

REISSMAN: Many medical groups have found it useful to throw out individual health-plan formularies and develop their own, which is a cross product of all the health plans with which they work.

LURYE: We tried to do that. The problem is that our big payer offers four different delivery-system options. If we threw out the formulary, our members would have a different benefit than the people using the other systems. We are obligated to respect the formulary.

REISSMAN: Developing your own group formulary is something to consider. It can be a subset of the products that are on the health-plan formularies. You may even include some products that are not on the health-plan formulary if they are more financially beneficial for your group than what the health plan offers.

The sample cabinet should correlate directly to the group formulary. If it doesn't, money will be lost. Samples are especially good for starting patients on products and ensuring that they are going to respond well. Nonformulary samples, however, make overall drug budget management very difficult.

OUTCOMES IN THE COST EQUATION

MENDES: When calculating an AWP cost for percentage LDL reduction, keep in mind what the ceiling is in terms of the maximum reduction that the various products can provide.

REISSMAN: Obviously, you can't calculate a 60-percent reduction in LDL with fluvastatin; it's never going to get you there.

LURYE: That's not how you buy it (you buy it by the pill).

REISSMAN: Correct. However, the bottom line is getting the patient to goal. What is it going to cost to get him to goal? Drug cost is not the only issue. Titration and monitoring costs must be factored in. When you are at risk for pharmacy, you are generally also at risk for medical. Very few plans are going to pass on pharmacy risk and not pass on medical risk.

Therefore, one must consider how many times the patient is going to be seen; how many lab tests will be given, and so on. What are the offsets to other medical costs that your organization is at risk for? Can we measure that? That, of course, is an ongoing issue.

We also have to consider the patient copay. It is much more difficult to convince patients to use a nonformulary agent if they are on a triple-tier copay plan and their copay for that product is $35, versus a formulary agent that has a copay of $10. That becomes a concern.

We want to use the most cost-effective product. However, that does not always mean the least expensive product in a category. This is a unique category. Atorvastatin is a perfect example of the best of both worlds. It is the most efficacious agent at the best price. That occurs in few categories.

THE IMPACT OF RISK

MENDES: At the physician or medical group level, how does being at increased risk affect prescribing patterns? Does it influence prescribing?

KHOURY: Our group is at full risk for Medicare pharmacy. We look at every physician in our group, whether a partner or a provider. The partners have a stake; their average cost is about 50 percent lower than the average provider. When we see a provider who is out of the range, we simply educate. We do not have a big stick to force anything to be done, simply because we do not want to see our patients on TV news magazines. At present, the provider unfor-

tunately has no downside for prescribing whatever he or she wants to prescribe. As a result, we cannot base our payment to the provider on pharmacy utilization.

LURYE: In our group, risk hasn't yet started to affect prescribing, although it will soon. Some level of cost containment occurs. Our drug spend is lower than average, to a large extent because we operate with a closed formulary. The exception process is tedious enough that the patient or physician really must be committed. Whether this is good from a patient-care perspective is an open question.

BUSCH: Being at risk influences physicians' prescribing and is good for cost containment. Some degree of risk assumption probably is necessary to stop runaway pharmacy costs. For the first time, physicians are being forced to consider more cost-effective ways to meet their goals. They should be doing this. They shouldn't be rationing health care at the bedside, but when equal or nearly equal options exist, cost savings should be examined.

Risk has a positive impact. Problems arise when an arbitrary number of dollars is assigned to the pharmacy. That scenario is not based on reality; it hurts patient care.

RISK AND INDIVIDUAL PHYSICIANS

MENDES: Are individual physicians sharing in the risk? Does anybody here financially penalize physicians for poor performance or reward them for good performance?

BUSCH: We try to divide primary care physicians into small units. They have a piece of the risk for total medical expenses. Pharmacy is a major component of that. It's a complicated economic system but, in the end, doctors can look at their performance reports and get a sense of where they can make improvements.

MENDES: It appears that you use peers to try to monitor one another.

BUSCH: I'm under the assumption that two things that drive doctors are money and competition. They want to be the best group, not the worst group. It's partly a financial reward and partly peer competition.

MENDES: Do perverse incentives exist when physicians are at risk for drugs? Are there conflicts, incorrect incentives, or disincentives?

GOLDSTEIN: There is concern about perverse incentives when physicians are at risk for drugs. It may even go beyond perverse incentives; the physicians may be getting mixed messages. They may be hearing about a disease management program that tells them that patients are underidentified, underdiagnosed, or undertreated, all of which implies higher utilization. At the same time, they're being told that they will be financially penalized for the aggregate cost of their prescribing. Depending on the model, the risk model for individual physicians can go too far.

BUSCH: We are involved with disease management programs, and want our patients to be treated. That's what we're here for. We have a preferred formulary, and we want effective drugs on it. If the drug doesn't work, physician visits increase. We don't want that. If a drug doesn't work, it's off the formulary. We are increasing utilization because of the disease management programs.

KHOURY: When individual physicians are put at risk for pharmacy costs, they will choose the cheapest product, unless outcomes are integrated into the utilization assessment. In our medical group, we have attempted to do that. We look at not only the physician's drug cost, but also the number of hospital days used by the physician's patients. The most expensive care is hospitalization. Both risk and outcomes must be considered.

MENDES: If you simply incentivize physicians based on a cost-per-prescription basis, you will drive them to use less expensive products. That will not always yield the outcome you want. Quality parameters help eliminate perverse incentives.

TREATMENT HURDLES

REISSMAN: Are your existing risk contracts or risk arrangements preventing you from getting hypercholesterolemia patients to goal?

MENDES: In my experience, yes. Suppose that a physician has a patient who needs a 40-percent reduction or more. The MCO won't cover an atorvastatin prescription until that physician has tried 40 mg pravastatin and proved that it has failed. There are ways around this, such as using samples to get the patient to goal. Once the patient is at goal on a particular drug, the MCO will pay for it. It's absurd that physicians at risk for the outcomes of patients have to play games in order to prescribe the most cost-effective drugs, especially when the rebates received by the HMO for a less effective drug are not even passed on to the medical group.

LURYE: We have the same concern, but a far bigger problem is underdiagnosis and undertreatment, regardless of the agent.

SHARING THE BURDEN

MENDES: Patients need to take a little more responsibility for the cost of these drugs. We're all going to go broke unless we share the burden.

TAYLOR: Higher copays tend to result in higher compliance. When people get stuff for free or for a couple of dollars, they stick it in a drawer and forget about it. If they have to pay $25 or more for it, the value goes up.

MENDES: My experience with that phenomenon was confirmed when nicotine patches were covered as a health plan benefit. I wasn't able to get many people to quit smoking. Now that people have to pay for the patches, those patients that purchase them are more highly motivated, and a greater percentage of them actually quit smoking.

REISSMAN: A $10-$15 difference is usually enough to get a person to switch from one product to another. The problem with triple-tier copays is that the top tier is being placed fairly high. When you start putting three or four products together at $35-$45 copays, patients start to say, "Which of these products will I *not* get, because I can't pay for all of them." That's one of the things I'm concerned about.

MENDES: Do pharmaceutical companies have a role in financial risk relationships for medical groups? One obvious means of involvement is the rebate mechanism. How do you feel about rebates?

GEIERMAN: Rebates should be done away with so that we can work with MCOs to provide our patients with cost-effective, efficacious products. Until rebates disappear, we're always going to be adversarial, especially since the MCO rarely shares the rebate with the medical group.

LURYE: Rebates tend to confuse things. Some pharmaceutical deals are for four or five products. You take it all or you take nothing. That has nothing to do with science.

MENDES: What can pharmaceutical companies do? They're in a no-win situation. If one company decides that it's not going to pay a rebate, but a competitor does, that company is at a competitive disadvantage. If all the pharmaceutical companies get together to stop paying rebates to change the system, that's collusion. What can we expect pharmaceutical companies to do, given this scenario?

GEIERMAN: If rebates disappear, pharmaceutical companies will start becoming more cost-effective with arrangements. If drugs are too high-priced, they won't be utilized. They'll lower the cost, and the cost will decrease all around.

REISSMAN: A lot of pharmacy directors would agree with what Dr. Geierman just said. There's a lot of talk at the health plan level that if rebates were done away with, everybody's life would be a whole lot easier. The problem is that, for MCOs that are getting close to 9 percent back in rebate and keeping it all, it's a tough sell to the chief financial officer. How does one explain that costs next year will increase by 10 percent due to loss of rebates plus additional inflation increases?

One of the interesting things I've seen is that a couple of pharmaceutical companies are now putting into their health plan contracts a mandate that a certain percentage, or all, of the rebate goes back to the medical groups if the medical groups are at risk for pharmacy, in order to get the discount. This may be a way to help level the playing field.

FINAL THOUGHTS

MENDES: On behalf of Parke-Davis and Pfizer, I would like to extend sincere thanks to all the participants of today's roundtable. We believe that forums such as this one make a real difference. If we can continue to figure out ways to work together, win-win scenarios will replace adversarial relationships in the marketplace. The real winner, however, will be the patient who benefits from improved efficiencies in CHD therapy. Together, we can save money and save lives.

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