

A CLOSER LOOK AT

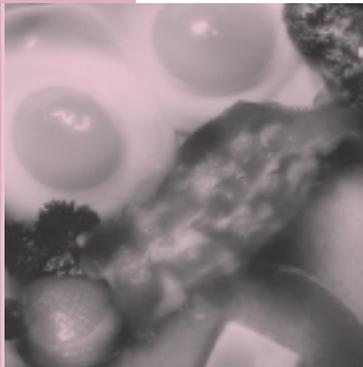
High Cholesterol



Americans pay \$53.4 billion each year for medical care of heart disease. An additional \$47.4 billion is lost due to premature death and lower productivity.

A JOINT PROJECT BETWEEN
THE AMERICAN HEART ASSOCIATION AND
THE NATIONAL PHARMACEUTICAL COUNCIL

Hear disease is the leading cause of death in the United States, claiming the lives of nearly 460,000 Americans each year.¹ Americans pay \$53.4 billion each year for medical care related to heart disease.¹ Another \$47.4 billion is lost in costs related to reduced workplace productivity and premature death.¹ High cholesterol is a major risk factor, along with age, family history, cigarette smoking, high blood pressure, and diabetes.²



Cholesterol is a soft, waxy substance found among the fats in the bloodstream and in all of the body's cells. It is an important part of a healthy body because it is used to form cell membranes, some hormones, and other needed tissues. People get cholesterol in two ways. The body—mainly the liver—produces varying amounts, usually about 1,000 milligrams a day. Another 400 to 500 milligrams (or more) can come directly from foods. The average American man consumes about 337 milligrams of cholesterol a day. The average American woman consumes about 217 milligrams a day.³



Some of the excess dietary cholesterol is removed from the body through the liver. Still, the American Heart Association recommends that cholesterol intake be limited to less

than 300 milligrams per day. Those with heart disease should limit dietary cholesterol to 200 milligrams daily. Foods high in saturated fat—such as egg yolks, meat, poultry, fish, seafood and whole milk dairy products—generally contain substantial amounts of dietary cholesterol. Foods from plants (fruits, vegetables, grains, nuts and seeds) do not contain cholesterol. Typically the body makes all the cholesterol it needs, so people don't need to consume it.³

For patients with moderate cholesterol levels and few risk factors for heart disease, guidelines recommend attempting to control cholesterol levels by maintaining a healthy weight and by reducing intake of total fat, saturated fat, and cholesterol.² Treatment with prescription medications is necessary if adjustments to diet and exercise are ineffective, initial cholesterol levels are too high, or several risk factors for heart disease are present.

Recently released guidelines for treating cholesterol include several new criteria and are expected to increase the number of Americans being treated for cholesterol-related problems. The number of patients on prescribed low-cholesterol diets is expected to increase from 52 million to about 65 million, and the number of patients prescribed a cholesterol-lowering drug is expected to increase from 13 million to about 36 million.⁴

Evidence suggests that cholesterol-lowering therapy should be standard practice for patients with heart disease and those at high risk for developing it. In all, more than one-third of the U.S. population may benefit from some form of cholesterol-lowering therapy, leading to potential savings of one billion dollars per year.^{5,6} However, the translation of scientific advances into better practice patterns and greater treatment has been only partly successful. Because high cholesterol does not cause obvious symptoms and detection requires a blood test, as few as 42 percent of those affected by it have been diagnosed.^{7,8} In fact, as recently as 1998, several surveys found that most patients discharged from the hospital after a heart attack were not taking the most effective cholesterol-lowering drugs.⁹ A study from the University of Michigan Medical Center found that most physicians failed to prescribe cholesterol-lowering medications, even in patients with diagnosed heart disease. Although cardiologists were more likely to prescribe these drugs than other doctors were, usage was still low: 17 percent for cardiologists vs. 11 percent for other physicians.¹⁰

Since the introduction in 1987 of the first of a new class of cholesterol-lowering drugs, there have been remarkable advances in cholesterol therapy. Large-scale clinical trials have confirmed the link between high cholesterol and heart disease. One study found that for every 10 percent reduction in cholesterol levels, the risk of death from heart disease fell by 15 percent.¹¹ Despite their higher price relative to other therapies, recent research has shown that the newest class of cholesterol-lowering therapies (statins) are cost-effective for the prevention of heart attacks and suggests that these therapies are more cost-effective than older therapies.^{12,13}

Over half of the observed increase in expenditure for cholesterol-lowering drugs from 1994 to 1997 was due to the increased rate of medication use. One likely explanation is the growing awareness of the benefits of cholesterol screening and cholesterol-lowering therapy. Practice patterns are still lagging behind available evidence, however, and there is room for substantial improvement.



Public health initiatives and disease management programs may increase the use of drug therapy by encouraging people to have their cholesterol tested. The U.S. strategy and goals for improving the health of the American people, stated in *Healthy People 2000: National Health Promotion and Disease Prevention Objectives*, included specific goals for cholesterol reduction:

- Reduce mean serum cholesterol;
- Reduce prevalence of high blood cholesterol;
- Increase blood cholesterol screening; and
- Increase initiation of appropriate diet and/or drug therapy for high blood cholesterol.¹⁴

THE PROPORTION OF ADULTS TAKING ACTION TO REDUCE THEIR HIGH BLOOD CHOLESTEROL INCREASED FROM 30 PERCENT IN 1988 TO 60 PERCENT IN 1995.

“GOOD” CHOLESTEROL VERSUS “BAD” CHOLESTEROL

Cholesterol and other fats cannot dissolve in the blood. They have to be transported to and from the cells by special carriers called lipoproteins. There are several kinds, but the ones to be most concerned about are low-density lipoprotein (LDL) and high-density lipoprotein (HDL).

Low-density lipoprotein is the major cholesterol carrier in the blood. If too much LDL cholesterol circulates in the blood, it can slowly build up in the walls of the arteries feeding the heart and brain. Together with other substances it can form plaque, a thick, hard deposit that can clog those arteries. A clot that forms in the region of this plaque can block the flow of blood to the heart causing a heart attack, or to the brain causing a stroke. A high level of LDL cholesterol reflects an increased risk of heart disease. That's why LDL cholesterol is often called “bad” cholesterol. Lower levels of LDL cholesterol reflect a lower risk of heart disease.

About one-third to one-fourth of blood cholesterol is carried by high-density lipoprotein or HDL. Medical experts think HDL tends to carry cholesterol away from the arteries and back to the liver, where it's passed from the body. Some experts believe HDL removes excess cholesterol and slows plaque growth. HDL cholesterol is known as “good” cholesterol because a high level of HDL seems to protect against heart attack. The opposite is also true however. A low level of HDL cholesterol indicates a greater risk for heart attack. For some people, exercise increases HDL cholesterol. Alternately, smoking has been shown to lower HDL cholesterol levels.

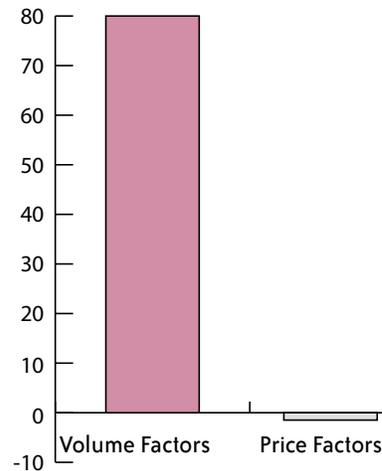
Source: American Heart Association (AHA).
http://www.americanheart.org/Heart_and_Stroke_A-Z_Guide/chol.html, 2001.

FACTORS INFLUENCING DRUG SPENDING FOR HIGH CHOLESTEROL 1994-1997

METHODOLOGY

This study separately analyzed prescription drug spending growth for two large national claims databases, one representing managed care plan enrollees and the other representing those covered by large employer-provided health benefit plans. The study defined and assessed several factors affecting the price per day of therapy and the volume of therapy — the number of days of therapy received and the number of patients receiving drug therapy. The analysis also examined the effects of price and volume changes for established drugs on the market during the entire period of analysis and for new drugs that were first marketed during this period.

Spending on pharmaceuticals was analyzed for individuals who received health benefit coverage from large employers in 1994 and 1997. The sample included individuals who received cholesterol-lowering drugs and those who were diagnosed with another condition for which these drugs are often prescribed. A similar analysis was conducted for individuals enrolled in private managed care plans from 1997 to 1999.



Spending for cholesterol-lowering drugs rose 80 percent from 1994 to 1997. Volume factors (increased numbers of people with high cholesterol receiving cholesterol-lowering prescriptions, and increased intensity and duration of drug therapy) far outweighed price factors, which had almost no net impact in influencing spending growth.

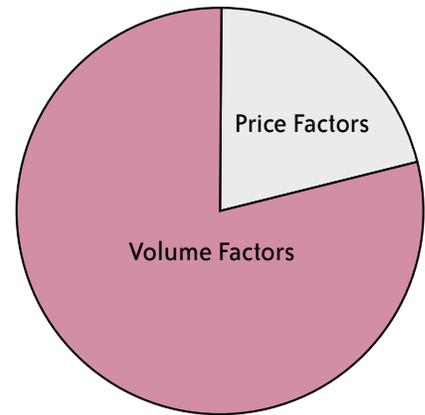
Sixty-seven percentage points of the overall 80 percent spending growth came from an increase in the percentage of patients who filled prescriptions for cholesterol-lowering drugs. This increase is consistent with efforts by employers and managed care organizations to encourage identification and treatment of people with undiagnosed high cholesterol.

Factors Influencing Growth in Rx Expenditures:	% Positive Impact	% Negative Impact
Total Growth in Expenditures	+80	
Growth Due to Volume Factors	+81	
Changes in the Number of Prescriptions per Person for Established Drugs		-55
Changes in the Number of Prescriptions per Person for New Entrants	+55	
Changes in Days of Therapy for Established Drugs	+16	
Changes in Days of Therapy for New Entrants		-1
Patients per 1000 Health Care Enrollees	+67	
Growth Due to Price Factors		-1
Inflation		-7
Changes in Mix of Established Drugs	+10	
Price of New Entrants		-4

Source: MEDSTAT's Marketscan database

FACTORS INFLUENCING DRUG SPENDING FOR HIGH CHOLESTEROL 1997-1999

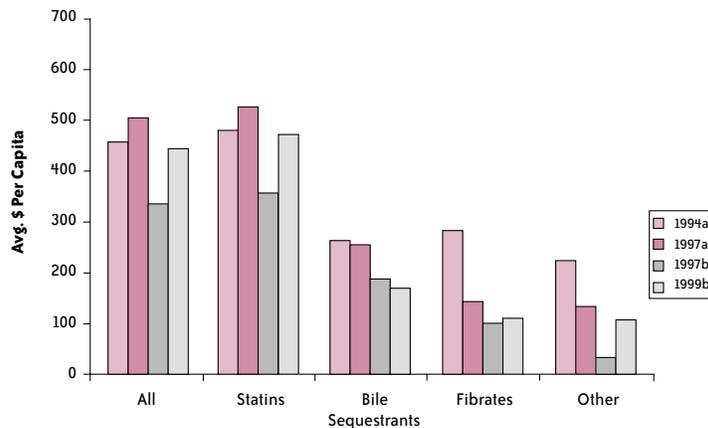
Spending for cholesterol-lowering drugs increased 127 percent between 1997 and 1999. Again, volume factors (increased numbers of people receiving cholesterol-lowering prescriptions, and increased intensity and duration of drug therapy) accounted for the majority of the increase. Increased numbers of patients being treated alone accounted for nearly two-thirds of the overall increase in spending. In contrast to data from 1994 to 1997, combined price factors contributed approximately 21 percent of total spending growth. Almost all of the price growth (24 percentage points) was due to a shift in the mix of drugs prescribed among the established drugs.



Factors Influencing Growth in Rx Expenditures:	% Positive Impact	% Negative Impact
Total Growth in Expenditures	+127	
Growth Due to Volume Factors	+100	
Changes in the Number of Prescriptions per Person for Established Drugs	+4	
Changes in the Number of Prescriptions per Person for New Entrants	+4	
Changes in Days of Therapy for Established Drugs	+8	
Changes in Days of Therapy for New Entrants	+0.1	
Patients per 1000 Health Care Enrollees	+84	
Growth Due to Price Factors	+27	
Inflation	+3	
Changes in Mix of Established Drugs	+24	
Price of New Entrants	+0.5	

Source: Protocare Sciences managed care database

EXPENDITURE PER CAPITA FOR CHOLESTEROL-LOWERING MEDICATIONS



In each of the databases analyzed, drug spending per patient was dominated by drugs in the treatment class statins. There was a substantial drop in per patient spending for drugs in the classes of bile sequestrants and fibrates. These shifts in spending are most likely due to the increased availability of the more effective statins.

Source: a - MEDSTAT's MarketScan database; b - Protocare Sciences managed care database

ABOUT THIS PUBLICATION:

"A Closer Look at High Cholesterol" is a joint publication of the American Heart Association and the National Pharmaceutical Council.

The American Heart Association spent about \$337 million during fiscal year 1999-2000 on research support, public and professional education, and community programs. Nationwide, our organization has grown to include more than 22.5 million volunteers and supporters who carry out our mission in communities across the country. The association is the largest voluntary health organization fighting heart disease, stroke and other cardiovascular diseases, which annually kill about 950,000 Americans.

Since 1953, the National Pharmaceutical Council (NPC) has sponsored and conducted scientific, evidence-based analyses of the appropriate use of pharmaceuticals and the clinical and economic value of pharmaceutical innovation. NPC provides educational resources to a variety of health care stakeholders, including patients, clinicians, payers and policy makers. More than 20 research-based pharmaceutical companies are members of the NPC.

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FOR MORE INFORMATION ABOUT HIGH CHOLESTEROL, PLEASE CONTACT:

The American Heart Association (AHA)
www.americanheart.org
1-800-AHA-USA1

The National Institutes of Health (NIH)
www.nih.gov
301-496-4000

The National Heart, Lung and Blood Institute (NHLBI)
www.nhlbi.nih.gov
1-800-575-9355

The National Institute of Neurological Disorders and Stroke (NINDS)
www.ninds.nih.gov
1-800-352-9424

American College of Cardiology (ACC)
www.acc.org
1-800-253-4636

¹ American Heart Association (AHA). 2001 Heart and Stroke Statistical Update. Dallas, TX: AHA, 2001.

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