Lowering Blood Cholesterol to Prevent Heart Disease

Coronary heart disease is responsible for more than 500,000 deaths each year in the United States. It is responsible for more deaths than all forms of cancer combined. There are more than 5.4 million Americans with symptomatic coronary heart disease and a large number of others with undiagnosed coronary disease; many of them young and highly productive. It has been estimated that coronary heart disease costs the United States more than $60 billion a year in direct and indirect costs.

Coronary heart disease is caused by atherosclerosis, a slowly progressive disease of the large arteries that begins early in life but rarely produces symptoms until middle age. Often the disease goes undetected until the time of the first heart attack, and this first heart attack is often fatal. Modern methods of treatment have improved greatly the outlook for patients having heart attacks, but major progress in our battle against this number 1 killer must rest on finding preventive measures.

A number of risk factors have been identified as strongly associated with coronary heart disease, Cigarette smoking, high blood pressure, and high blood cholesterol levels are the most clearly established of these factors. Risk is greater in men, increases with age, and has a strong genetic component. Obese, diabetes mellitus, physical inactivity, and behavior patterns are also risk factors.

A large body of evidence of many kinds links elevated blood cholesterol levels to coronary heart disease. However, some doubt remains about the strength of the evidence for a cause-and-effect relationship. Questions remain regarding the exact relationship between blood cholesterol and heart attacks and the steps that should be taken to diagnose and treat elevated blood cholesterol levels.

To resolve some of these questions, the National Heart, Lung, and Blood Institute of the National Institutes of Health Office of Medical Applications of Research convened a Consensus Development Conference on Lowering Blood Cholesterol to Prevent Heart Disease from December 10 to 12, 1984. After hearing a series of expert presentations and reviewing all of the available data, a consensus panel of lipoprotein experts, cardiologists, primary care physicians, epidemiologists, biostatisticians, and officials of the Food and Drug Administration, lay representatives, and representatives of other risk factors (hypertension, cigarette smoking, physical inactivity, and obesity) agreed on answers to the following questions:

1. Is the relationship between blood cholesterol levels and coronary heart disease causal?
2. Will reduction of blood cholesterol levels prevent coronary heart disease?
3. Under what circumstances and at what level of risk should blood cholesterol be reduced by diet or drug treatment be started?
4. Should an attempt be made to reduce the blood cholesterol levels of the general population?
5. What research directions should be pursued regarding the relationship between blood cholesterol and coronary heart disease?

Panel's Conclusions

Elevation of blood cholesterol levels is a major cause of coronary artery disease. It has been established beyond a reasonable doubt that lowering definitively elevated blood cholesterol levels (specifically, blood levels of low-density lipoprotein [LDL] cholesterol) will reduce the risk of heart attacks caused by coronary heart disease. This has been demonstrated most conclusively in men with elevated blood cholesterol levels, but much evidence justifies the conclusion that similar protection will be gained in women with elevated blood cholesterol levels. After careful review of genetic, experimental, epidemiologic, and clinical trial evidence, we recommend treatment of individuals with blood cholesterol levels above the 90th percentile (upper 25% of values). Furthermore, we are persuaded that the blood cholesterol levels of most Americans are undesirably high, in large part because of our high dietary intake of saturated fats, saturated fat, and cholesterol. In countries with diets lower in these constituents, blood cholesterol levels are lower and coronary heart disease is less common. There is no doubt that appropriate changes in our diet will reduce blood cholesterol levels. Epidemiologic data indicate that more than a dozen clinical trials allow us to predict with reasonable assurance that such a measure will afford significant protection against coronary artery disease.

For these reasons we recommend the following:

1. All individuals with high-risk blood cholesterol levels (above the 90th percentile) should be treated appropriately by dietary means under the guidance of a physician, dietitian, or other health professional; if that fails to lower cholesterol drugs should be added to the treatment regimen. Guidelines for children are somewhat different, as discussed below.

2. Adults with moderate-risk blood cholesterol levels (between the 75th and 90th percentiles) should be treated intensively by dietary means, especially if additional risk factors are present. Only a small proportion should require drug treatment.

3. All Americans (except children younger than 2 years of age) should be advised to adopt a diet that reduces total dietary fat intake from the current level of about 40% of total calories to 30% of total calories, reduces saturated fat intake to less than 10% of total calories, increases polyunsaturated fat intake but not saturated fat intake, increases dietary cholesterol but not saturated fat intake by more than 10% of total calories, and reduces daily cholesterol intake to 250 to 300 mg or less. Intake of total calories should be reduced, if necessary, to correct obesity and adjusted to maintain real body weight. A program of regular moderate-level exercise will be helpful in this regard.

4. In individuals with elevated blood cholesterol levels, special attention should be given to the management of other risk factors (hypertension, cigarette smoking, obesity, and physical inactivity). These dietary recommendations are similar to those of the American Heart Association and the Inter-Society Commission for Heart Disease Resources.

We further recommend the following:

1. New and expanded research should be planned and initiated soon to educate physicians, other health professionals, and the public to the significance of elevated blood cholesterol levels and the importance of treating them. We encourage NIDDK and NHBLI to provide a research agenda for the purpose of development of plans for a National Cholesterol Education Program that will enlist participation by all segments of society and address all aspects of the problem of elevated blood cholesterol levels.

2. Efforts to focus development of plans for a National Cholesterol Education Program that will enlist participation by all segments of society and bring about real change are expensive and may require a federal appropriation of $3 million per year for 5 years.

3. We further recommend the following:

a. All physicians should be encouraged to include, whenever possible, a blood cholesterol measurement on every adult patient when that patient is first seen; to encourage parents and physicians to include, whenever possible, a blood cholesterol measurement on every child when that patient is first seen.

b. Information. The public should be educated on how to assess the risk of coronary artery disease. The goal of education is to ensure that individuals with elevated blood cholesterol levels will make it easier for individuals to adhere to the dietary recommendations described above.

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4. Intake of total calories should be reduced, if necessary, to correct obesity and adjusted to maintain real body weight. A program of regular moderate-level exercise will be helpful in this regard.

5. The food industry should be encouraged to continue to provide nutritious, low-calorie, low-sodium, and vitamin-enriched foods that will make it easier for individuals to adhere to the recommended diets, and school food services and protection agencies should help to ensure meals consistent with these dietary recommendations.

6. Food labeling should include the specific source or source of fat content in food and the amount of polyunsaturated fat and cholesterol content as well as other nutritional information. The public should be educated on how to read the food labels to make informed choices.

7. All Americans should be encouraged to include, whenever possible, a blood cholesterol measurement on every adult patient when that patient is first seen; to ensure that individuals with elevated blood cholesterol levels will make it easier for individuals to adhere to the dietary recommendations described above.

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prehensive evidence, which includes information derived from
pathophysiologic, experimental, epidemiologic, and clinical evi-
dence, makes it reasonable to presume that the reduction in coronary heart disease incidence will be accompanied by a moderate reduction in overall mortality.

The magnitude of the reduction in coronary heart disease risk can be estimated from these clinical trials; particular attention to whether the blood cholesterol yields approximately a 2% reduction in coronary heart disease rates. This is remarkably similar to the 2% reduction in blood cholesterol level resulting from the major observational epidemiologic studies. Thus, for example, a reduction in blood cholesterol level resulting from the preventive intervention should reduce coronary heart disease rates by 10%. The absolute magnitude of this benefit should be greater in patients at high risk because the absolute risk of coronary heart disease is high. Thus, the presence of other risk factors such as cigarette smoking and hypertension
in diseases of death rates as high as 50% may be achievable in patients in the high-risk-cholesterol categorization, thus adhering well to a combination of effective drug treatment and a fat-controlled diet.

Under What Circumstances and at What Level of Blood Cholesterol Should Dietary or Drug Treatment Be Started?

What is Hypercholesterolemia? An precise definition of hypercholesterolemia (an abnormal high blood cholesterol level) is difficult to establish. An abnormally high level of a biologic substance is typically defined to be the upper limit of the established reference range for the population (the 95th percentile). However, the concept of defining "normal" values for blood cholesterol level is not always straightforward. In premenopausal women, the upper limit of normal for total cholesterol is higher than for men. This difference in definition is based on the observation that coronary heart disease is an important cause of death in men, whereas death rates from coronary heart disease in women are generally lower. Thus, one approach to defining "normal" values for blood cholesterol level is to use the median value in the premenopausal age group and the 95th percentile for men. This approach is based on the observation that coronary heart disease is more common in men than in women. However, there is a large range of total cholesterol values in the population and the cutoff value for defining hypercholesterolemia is arbitrary. Therefore, it is recommended that levels be measured and that the decision to treat be based on the individual's clinical situation and the presence of other risk factors.

Epidemiologic Evidence

A large body of epidemiologic evidence supports the direct relationship between blood cholesterol levels and coronary heart disease:

- Populations experiencing severe dietary (especially fat) limitations and weight loss have been shown to have less coronary heart disease and fewer heart attacks.
- Prospective studies such as the Framingham study have shown that elevated blood cholesterol levels in healthy people predict the future occurrence of coronary heart disease. 
- Evidence emerging from multiple clinical trials, reviewed in the next section, clearly indicates that lowering blood cholesterol levels in patients with hypercholesterolemia decreases the likelihood of fatal and nonfatal coronary heart disease.
- Thus, the evidence obtained from genetic, experimental, epidemiologic, and clinical intervention investigations overwhelmingly supports a causal relationship between blood cholesterol levels and coronary heart disease.
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The presence of high-risk and moderate-risk blood cholesterol values should be confirmed by a repeated analysis. Although the initial sample may be obtained without the subject's fasting, the repeated analysis should be obtained after an overnight fast so that a valid triglyceride level can also be determined.

After the secondary causes for hypercholesterolemia (eg, hypothyroidism, nephrotic syndrome, dysproteinemias, diabetes mellitus, and obstructive liver disease) have been excluded, the primary cause should be evaluated. This includes family screening to detect the hereditary forms of elevated blood cholesterol level. Other causes include other family members needing treatment. Measurement of LDL cholesterol is often helpful to determine if the elevated total cholesterol level is due to high levels of LDL, which is associated with a higher risk of coronary heart disease. In addition, a low HDL cholesterol level (an independent risk factor) may guide a physician to be more aggressive in the treatment of individuals with high or moderately high blood cholesterol levels.

Diet Therapy

The first step in the treatment of persons with high-risk and moderate-risk blood cholesterol levels is diet therapy and caloric restriction for weight normalization. Weight loss may reduce blood cholesterol levels, and a moderate level of physical exercise may be helpful in this regard. The American Heart Association's and the Atherosclerosis Study Group of the Inter-Society Commission for Heart Disease Resources. We recommend a diet composed of approximately 30% of the calories intake from fats and no more than 20% 300 mg of cholesterol per day. An essential consideration is a reduction of the total saturated fat intake to 10% or less of total calories. It is recommended that polyunsaturated fat intake be increased but no to more than 10% of total calories. These changes can be readily made while intake of protein, vitamins, and minerals is well maintained. The American Dietetic Association is also recommended for additional information on the Food and Nutriti

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The dietary cholesterol intake should be lowered to 150 to 200 mg/day (equivalent to the American Heart Association recommendation) for men and 100 to 150 mg/day for women. It is estimated that 150 to 185 mg/dL in the population. In fact, recent epidemiologic studies have shown that the relationship between the 75th and 90th percentile (170 to 185 mg/dL) and reduced risk of coronary heart disease.

Drug Therapy

Drug therapy should be used only after a careful trial of diet modification using the most rigorous diet appropriate for the particular individual. Even when use of drugs seems appropriate, it is important to stress that maximal diet therapy should be continued. Several drugs, used singly or in combination, are available. These include the bile-acid sequestrants (cholestyramine and colestipol), nicotinic acid, probucol, and the fibrates (clofibrate and gemfibrozil). Of these, bile-acid sequestrants and nicotinic acid have been shown to reduce the incidence of coronary heart disease in individuals with a high blood cholesterol level but normal triglyceride level. Moreover, a recent study has reported a beneficial effect on coronary heart disease risk in individuals with high triglyceride levels but normal cholesterol levels.

Special Guidelines for Management of Children

Identifying and treating children with elevated cholesterol levels is a subject for special consideration. It is desirable to begin prevention in childhood because patterns of lifestyle are developed early in life. To modify children's lifestyles, including dietary habits and physical activity, is easier than attempting to modify adult lifestyles. The evidence justifies for men, women, and children a reduction in dietary cholesterol intake of 150 to 200 mg/day (equivalent to the American Heart Association recommendation) for men and 100 to 150 mg/day for women. It is estimated that reducing the intake of total fat, saturated fat, and cholesterol and by increasing intake of polyunsaturated fat. This has been accompanied by a substantial reduction in the average blood cholesterol level of the population.

Conclusions

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Recomme
Atherosclerotic plaque measurement using safe, precise enhanced radiography. Effects of regimens to lower blood cholesterol levels and to pharmacologic interventions to reduce blood cholesterol concentration is needed regarding their biochemical and biologic metabolism and about the mechanisms of the atherosclerotic process remains unknown.

Cellular and Molecular Biology.—A better understanding of lipoprotein production and removal, lipoprotein receptors, and the metabolism of high density lipoprotein (HDL) and its role in preventing coronary heart disease should be periodically evaluated. This should be the case for other factors controlling the risk factors in major population subgroups, including blacks. As nutritional practices of the population change and as health professionals improve management of elevated blood cholesterol levels, ongoing monitoring of nutritional patterns, blood cholesterol levels, and disease outcomes is essential. An important corollary will be monitoring to assess disease incidence, prevalence, and case fatality rates. Research to assess the effects of blood cholesterol lowering on a major public health issue, namely coronary heart disease mortality is needed. Overall safety of long-term intervention with diet and drugs should be investigated and a major public health issue, namely coronary heart disease mortality is needed. Overall safety of long-term intervention with diet and drugs should be investigated and a major public health issue, namely coronary heart disease mortality is needed. Overall safety of long-term intervention with diet and drugs should be investigated and a major public health issue, namely coronary heart disease mortality is needed. Overall safety of long-term intervention with diet and drugs should be investigated and a major public health issue, namely coronary heart disease mortality is needed. Overall safety of long-term intervention with diet and drugs should be investigated and a major public health issue, namely coronary heart disease mortality is needed. Overall safety of long-term intervention with diet and drugs should be investigated.

Community Applications.—Community demonstration research to test the effectiveness of nutritional education strategies that influence food choices and other risk-factor behaviors of the healthy free-living population is needed.

Pharmacologic Research.—New compounds that are more effective, economical, and safe for the reduction of blood cholesterol levels and other products that are high in nutritional quality and taste and in fat and cholesterol content. These products should include total calories, fat, saturated fat, polyunsaturated fat, and cholesterol content as well as other essential nutritional information. If necessary, appropriate statutory or other changes to require such labeling should be seriously considered.

National cholesterol education program should be implemented for physicians, other health professionals (including those in training), and the public; its effectiveness should be periodically evaluated. Thus, the recommended diet should be available nationwide. The food industry should accelerate its current efforts to develop, produce, and market leaner meats and other foods, including dairy products, with reduced total fat, saturated fat, polyunsaturated fat, and cholesterol content. More food products that are high in nutritional quality and taste yet low in fat and cholesterol must also be developed.

Recent reports of the effectiveness of lipid lowering in the primary prevention of coronary artery disease morbidity and mortality indicates that major effort to decrease plasma cholesterol levels. The cholestyramine drug trial (Lipid Research Clinical Program) lipoproteins of low density cholesterol by diet or drugs. The implications of these studies have been buttressed with evidence that hygienic measures can be as effective as drugs. Butterfat with possible positive results from interventional studies and acknowledging the overwhelming biologic and epidemiologic associations between serum cholesterol and coronary heart disease, it seems rational, if not imperative, to mount a major educational effort to lower plasma cholesterol levels. Primary prevention is most appropriate from the health perspective and, intuitively, should be the most cost-effective approach. This sequence of logic is formidable and leaves unresolved only the implementation strategy and the degree of diligence that should be applied. However, this suggests that the health care professional will also need to understand and can orchestrate the social and medical changes necessary to achieve a national goal of lower plasma lipid levels. The proponents of a lipid reduction campaign point to the success of the national effort to identify and treat hypertension in the United States following the reports of the Veterans Administration Collaborative Trial and the Hypertension Detection and Follow-up Program. Significant increases have occurred in personal awareness of high blood pressure and in initiation and persistence of treatment. The lowering of blood pressure in all segments of the US population are well documented in national surveys from 1960 through 1980. The National High Blood Pressure Education Program and the American Heart Association can be considered to be as important as the remarkable change. Their strategy was primarily educational and directed simultaneously to the public and to medical providers. By logical extension, an analogous educational effort, along with further studies of lipid reduction should be similarly effective, if the same factors operate. However, our thesis is that the educational and medical approaches to lipid reduction differ considerably from those related to blood pressure reduction. This discussion examines this premise from an educational perspective and identifies differences that necessitate different educational and practice strategies. These differences encompass the traditional educational components (knowledge, attitudes, and skills) and extend to the complementary intervention strategies of public health and of medical care.

Public Education, Societal Change, and the Public Health Approach

The educational program for high blood pressure was addressed initially and primarily to the public, rather than to professionals. The strategy was to focus public attention on blood pressure as a personal health problem that requires attention by both the public health and of medical care. The stra tegy for high blood cholesterol was directly the opposite. An analogous educational approach would be required to achieve a national goal of lower plasma lipid levels. The proponents of a lipid reduction campaign point to the success of the national effort to identify and treat hypertension in the United States following the reports of the Veterans Administration Collaborative Trial and the Hypertension Detection and Follow-up Program. Significant increases have occurred in personal awareness of high blood pressure and in initiation and persistence of treatment. The lowering of blood pressure in all segments of the US population are well documented in national surveys from 1960 through 1980. The National High Blood Pressure Education Program and the American Heart Association can be considered to be as important as the remarkable change. Their strategy was primarily educational and directed simultaneously to the public and to medical providers. By logical extension, an analogous educational effort, along with further studies of lipid reduction should be similarly effective, if the same factors operate. However, our thesis is that the educational and medical approaches to lipid reduction differ considerably from those related to blood pressure reduction. This discussion examines this premise from an educational perspective and identifies differences that necessitate different educational and practice strategies. These differences encompass the traditional educational components (knowledge, attitudes, and skills) and extend to the complementary intervention strategies of public health and of medical care.

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