NATIONAL
CHOLESTEROL
EDUCATION
PROGRAM

Summary Report:

THE NATIONAL CHOLESTEROL EDUCATION PROGRAM COORDINATING COMMITTEE MEETING

October 12, 1999
Bethesda Marriott Hotel
Bethesda, Maryland

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HIGHLIGHTS

National Cholesterol Education Program (NCEP) Coordinating Committee Meeting

October 12, 1999

- Dr. Lawrence Friedman of the National Heart, Lung, and Blood Institute (NHLBI) reported on the National Conference on Cardiovascular Disease (CVD) Prevention: Meeting the Healthy People 2010 Objectives for Cardiovascular Health, which was held in September 1999. He highlighted the following findings presented at that conference:

  - There is recent evidence that declines in CVD mortality have slowed and that CVD mortality and the presence of CVD risk factors varies greatly by race/ethnicity, education, income, and region.

  - Although community programs exist, not enough is known about their impact on high-risk populations or areas.

  - Secondary prevention treatments vary by region and are underutilized in some regions.

  - Conference participants identified the need for better coordination of CVD control efforts, more training in prevention and rehabilitation, policy implementation at the population level, and new systems for evaluation of preventive services.

- Dr. Elizabeth Ofili reported on the NHLBI Working Group on Adherence to Medical and Lifestyle Interventions. She reviewed recommendations made by the Applications Group regarding how the Adult Treatment Panel III (ATP III) guidelines might address adherence issues in four areas:

  - Systems: Use of performance measures such as HEDIS (Health Plan Employer Data and Information Set), clinical pathways, and multidisciplinary approaches such as lipid clinics, reminders, lipid graphs, and so on.

  - Providers: Link physician education tools, such as pocket guides, with patient education; provide critical pathways and decision trees for patients with varying risk; make the guidelines user friendly and easy to implement.

  - Patients/consumers: Develop educational messages to be used on the Internet, television, and radio and in print media.

  - National, State, and local partnerships: Work together to disseminate information and distribute patient education materials.

- Dr. Linda Van Horn described the Nutrition Academic Award (NAA) program which is intended to provide a better awareness and understanding of the role of nutrition in prevention and treatment, with a focus on CVD. The objectives include developing medical education curricula and training opportunities and providing training models for dissemination to other medical and health professional schools. Ten medical schools currently have NAA programs. It is hoped that the modules developed as part of the NAA program will be used by other schools and that the program will lead to the addition of nutrition-related questions on medical boards.

- Dr. James Cleeman reported on National Cholesterol Education Month (September, 1999). The three foci were cholesterol lowering in primary prevention, in coronary heart disease (CHD) patients, and in older Americans. This year's theme was "Keep the Beat: Cholesterol Counts for Everyone." Cholesterol month activities and products included a community kit, a Web-based version of the community kit, a media kit, and major enhancements and updates to the "Live Healthier, Live Longer" Web site. Preliminary feedback on Cholesterol Month was quite positive; additional feedback will be available from a survey of users of the community kit. A total of 1,400 community kits were produced and distributed, with many more users accessing the kit on the Web. The "Live Healthier, Live Longer" Web site received more than 50,000 hits through the end of September.

- Dr. Scott Grundy reported on the initial meeting of ATP III. He outlined the major issues that are being addressed. These issues and areas of emphasis were derived from previous input from the Coordinating Committee. They include the following:

  - Implications of recent clinical trials for primary and secondary prevention.
  - Low-density lipoprotein cholesterol (LDL-C) target in patients with established CHD.
  - Integration of hypertriglyceridemia into cholesterol management.
  - High-density lipoprotein cholesterol (HDL-C): should it be a target of therapy.
  - Reemphasis of primary prevention in ATP III.
  - Role of CHD risk assessment.
  - Reaffirmation of the significance of dietary therapy.
  - Adherence/compliance to drug therapy and life habit modifications.
  - Recommendations for patients with diabetes mellitus.
  - Special considerations for different population groups.

  Dr. Grundy gave a brief overview of the guidelines development process. The major product will be the ATP III final report. Other products will include an executive summary of the full report, a pocket card for practitioners, and a PowerPoint slide set.

- In the agenda segment dealing with selected ATP III issues, Dr. Grundy discussed recommendations for patients with CHD. Two questions to be considered are (1) What is the optimal LDL-C reduction for lowering CHD risk? and (2) What is the LDL-C goal for patients with established CHD? How the LDL-C goal is applied in clinical practice will need to be considered as well.

- Dr. Van Horn discussed new aspects of dietary therapy that will be considered by the panel. These include reaffirming the overall significance of dietary therapy, the role of dietary fat and fatty acids, the ratio of refined to complex carbohydrates, dietary fiber in cholesterol lowering, soy proteins and isoflavones, the role of antioxidants, dietary supplements, alcohol recommendations, and the role of fat-free foods, adherence, and weight control. She noted that some of the emphasis in ATP III may be food-oriented rather than nutrient-oriented.

- In a discussion about improving adherence, Dr. James McKenney stressed that nonadherence to lipid modifying therapy is a major public health challenge. The ATP III recommendations will have to address patients, providers, and the health care system. He reviewed potential strategies for each of these areas and stated that the panel will examine the utility of an implementation kit that could serve as a resource tool for implementing the guidelines.

- Dr. Luther Clark discussed the impact of different population group considerations on the ATP III recommendations and the applicability of risk assessment and stratification instruments for these groups. ATP III is considering the following issues affecting population groups:

  - Women: HDL-C levels and the role of hormone replacement therapy.

  - Elderly patients: Appropriate risk group, the role of subclinical atherosclerosis, stroke, and the safety of drug therapy.

  - Young adults: Screening recommendations and risk assessments.

  - Racial/ethnic groups: Whether left ventricular hypertrophy (LVH) is a CHD risk equivalent for African Americans, and impact of baseline population risks.

- Committee members divided into four small groups to further discuss selected ATP III issues and areas of new emphasis.

- The next Coordinating Committee meetings will be held on May 23, 2000, and December 5, 2000.

WELCOME AND REPORT FROM THE COORDINATOR

Dr. James Cleeman

Dr. Cleeman called the meeting to order at 8:30 a.m. He reported that Dr. Claude Lenfant, Chairman of the National Cholesterol Education Program (NCEP) Coordinating Committee, regretted that he could not attend the meeting because of an international commitment.
Dr. Cleeman welcomed Coordinating Committee members and guests. He introduced two new members:

- Ms. Pamela King, representing the American Association of Occupational Health Nurses
- Ms. Jill Gross, representing the American Red Cross

He also introduced five substitute representatives:

- Ms. Elaine Auld, of the Society for Public Health Education, substituting for Dr. Donald O. Fedder
- Ms. Jan Bodner, of the U.S. Department of Agriculture, substituting for Ms. Alanna Moshfegh
- Dr. Harry Preuss, of the American College of Nutrition, substituting for Dr. Stanley Wallach
- Dr. Elizabeth Castro, of the Office of Disease Prevention and Health Promotion, substituting for Dr. Linda Meyers
- Dr. Sue Ann Anderson, of the U.S. Food and Drug Administration, substituting for Dr. Darla Danford

See Attachment A for a complete list of participants.

Dr. Cleeman reviewed the agenda (Attachment B), which included presentations on the National Conference on Cardiovascular Disease (CVD) Prevention, the Working Group on Adherence to Medical and Lifestyle Interventions, the Nutrition Academic Award program, Coordinating Committee feedback on Cholesterol Month materials and Web offerings, the initial meeting of Adult Treatment Panel III (ATP III), and a discussion of selected ATP III issues and areas of new emphasis.

Dr. Cleeman directed participants to materials in their meeting packets, including the agenda for the National Conference on CVD Prevention, a list of principal investigators in the Nutrition Academic Award program, the charge to the ATP III panel, and a copy of a recent NCEP article entitled "Cholesterol Lowering in the Elderly Population." [Citation: Grundy SM, Cleeman JL, Rifkind BM, Kuller LH. *Arch Intern Med*. 1999;159:1670–1678]

Dr. Cleeman noted that the next NCEP Coordinating Committee meetings will be held on May 23, 2000, and December 5, 2000.

REPORT ON THE NATIONAL CONFERENCE ON CVD PREVENTION
Dr. Lawrence Friedman

Dr. Friedman reported on the National Conference on CVD Prevention: Meeting the Healthy People 2010 Objectives for Cardiovascular Health, which was held in September. The goal of this transagency conference was to assess the magnitude and causes of trends in CHD, stroke, and other cardiovascular diseases, including evidence that declines in CVD morbidity and mortality have slowed. A major challenge to reaching the Healthy People 2010 Objectives is concern about reversals in declines in CVD morbidity and mortality of specific subgroups defined by socioeconomic status, race/ethnicity, and region. A review of the needs and opportunities to reestablish the CVD decline will allow development of a more comprehensive and effective research and prevention agenda for the 21st century.

Dr. Friedman said that the planning group for the conference will assemble the recommendations into a paper to be submitted for publication. He reviewed the conference's objectives and some recommendations that were made by individual speakers.

1. Examine trends in levels of CVD mortality (and morbidity, if possible) in the U.S. population as a whole and in selected subpopulations, the degree of disparity among subpopulations, and the potential reduction of the disparity as a means to attain the projected 2010 objectives.

    - The percent reduction in CVD mortality has slowed from 2.6 percent in the 1980s to 1.5 percent in the 1990s. The rate of CHD mortality continues to fall, but not as rapidly as before. Heart failure prevalence, incidence, and mortality have continued to increase.

- CVD mortality is related to income inequality in U.S. cities. Rural areas have a higher CVD mortality rate than central cities or suburbs.
- Rates of stroke mortality remain unchanged since 1990. Regional patterns for stroke are heterogeneous; the Stroke Belt shows additional clusters in the south-central United States and possibly the Pacific Northwest.

2. Describe trends in the levels of CVD risk factors, both behavioral (e.g., diet, exercise, tobacco use) and physiological (e.g., serum lipids, blood pressure, obesity, diabetes) in the U.S. population as a whole and in selected subpopulations.

    - The steady decline in tobacco use since 1964 has leveled off since 1990; there are large differences in smoking trends by education, income, and race/ethnicity. There has been a rise in smoking among high school students.
    - Food consumption patterns include increases in grains and fruit, a slight increase in meats and dairy products, less consumption of milk and more soda intake, less dietary cholesterol and less saturated fat as percentage of calories, and increased carbohydrate and caloric intake.
    - Only 27 percent of adults meet recommended levels of physical activity, with large differences by race/ethnicity, education, income, and region. Among adolescents, there is less attendance at physical education classes.
    - The prevalence of obesity has risen steadily from 1960 to 1994 (currently, about 39 percent of men and 25 percent of women ages 20 to 74 are considered obese), with variations by education, income, and race/ethnicity.
    - The prevalence of diagnosed diabetes rose since 1958 to about 7 percent of adults and is associated with education levels and race/ethnicity.

3. Estimate trends in levels of health services, including primary prevention, secondary prevention, and rehabilitation, paralleling CVD mortality trends.

    - Policy regulations, guidelines, and risk factor control programs seem to be increasing but there is little coordination among them. Not enough is known about the impact of community programs in high-risk populations or areas.

- State health department funding is not proportional to the disease burden.
- Surveys of primary care physicians show positive attitudes toward preventive services, but less than 50 percent of patients receive routine screening/counseling.
- Secondary prevention varies by region, and proven therapies are underutilized.
- Coronary artery bypass surgery and other revascularization rates vary markedly by geographic region.

4. Identify areas where new or better data are needed to attain the Healthy People 2010 Objectives, so as to target these areas as part of the strategic research agenda for the 21st century. Recommendations included the following:

    - Establish a national surveillance system for CVD to provide data to monitor levels and trends in population subgroups and to allow differences in mortality, morbidity, incidence, and risk factors within the population to be better understood.
    - Explore new data opportunities afforded by managed care and other computerized medical record linkage systems.
    - Establish community trials in selected high-risk groups.
    - Identify interventions that change behavior and maintain those changes.
    - Within high-risk populations, improve identification of individuals who are eligible for intensive interventions.

5. Develop a more effective strategy agenda for CVD prevention programs and policies to reduce CVD in the Nation as a whole and disparities among subpopulations in CVD mortality, morbidity, risk factors, and health care services. Conference participants identified the need for the following improvements:

    - Better coordination of CVD control efforts
    - New collaborations/partnerships
    - More training in CVD prevention and rehabilitation
    - Implementation of policy and environmental strategies (e.g., nutrition, physical activity, tobacco control) at the population level, in primary care systems, and in secondary prevention systems

- New systems for evaluation of performance of preventive services
- New mechanisms to support prevention programs

Dr. Friedman stated that a planning group will compile the recommendations and develop a paper for possible publication.

Coordinating Committee members made the following comments:

- Data must be age specific because age adjustment reflects differences in medical care for the very old. The real interest is in cohorts born after World War II who have been exposed to prevention efforts.
- The 10-percent increase in calorie intake is a concern, but changes in consumption of categories of food groups may be more important.

REPORT ON THE NHLBI WORKING GROUP ON ADHERENCE TO MEDICAL AND LIFESTYLE INTERVENTIONS

Dr. Elizabeth Ofili

Dr. Ofili reported on the NHLBI Working Group on Adherence to Medical and Lifestyle Interventions, which comprised two groups: Applications and Research. The Applications Group, which included representatives from academic medicine and industry, provided input for the development of guidelines and interventions by examining issues within the health care system that are limiting clinical intervention and considering how to work with community organizations and develop market strategies. The group identified four focus areas: systems (health care organizations), providers, patients/consumers, and partnerships.

Dr. Ofili provided an outline of the Applications Group recommendations and their possible application for ATP III (noted below in italics).

Systems

- Promote accountability within the system.
  Use performance measures such as HEDIS versus the NCEP goal.
- Promote adherence to clinical guidelines.

Provide a target for monitoring (critical pathways).

- Identify and disseminate good practice models.

  Use a multidisciplinary approach, e.g., lipid clinics, reminders, and lipid graphs.

Providers

- Promote patient-provider communication. Consider the patient environment interactions.

  Link physician education, such as pocket guides, with patient education.
- Look at disease management strategies. Give how-to examples.

  Provide case studies and critical pathways for decision trees for high-, low-, and intermediate-risk patients.
- Provide practical algorithms that are easy to implement.

  Solicit provider input regarding user-friendliness of guidelines.

Patients/consumers

- Market to patients as consumers. Regard patients as a "provider model." Involve them in self-monitoring.

  Provide patient messages via the Internet, television, radio, and magazines.
- Self-monitor progress.

  Identify who, what, and how.

Partnerships (National, State, local)

Potential partners for prevention initiatives include community groups, academic centers, payors (government, employers), managed care organizations (MCOs), and the pharmaceutical industry. Issues include access to prescriptions/lab tests, increased coverage for preventive services, and FDA medication packaging (e.g., information on decreased benefits for nonadherers).

Support the evaluation and dissemination of information regarding the impact of payor mix and other variables on guideline implementation.

Partner with pharmaceutical companies to help distribute patient education materials.

Committee members offered the following comments:

- Information from the adherence workshop will be important to ATP III.
- Examine best practice models to disseminate critical pathways or algorithms.
- ATP III needs to go an extra step to provide a practical approach to implementing the guidelines.
- Look at research recommendations that are important to behavioral/social sciences.

In response to a question about the Adherence Group's future role, Dr. Ofili said that its recommendations will be published and smaller groups will focus on particular aspects of the recommendations. Dr. Cleeman added that adherence issues will be addressed in ATP III. He also noted that the NHLBI has conducted market research with physicians regarding their attitudes toward various guidelines. Results from this research showed that physicians want guidelines that are user friendly and practical, that depict critical pathways, and that use visual presentations. This information will be used when developing ATP III. Dr. Ofili called attention to the NHLBI *Practical Guide to the Management of Asthma* (which includes several critical pathways) as a model publication.

REPORT ON THE NUTRITION ACADEMIC AWARD PROGRAM

Dr. Linda Van Horn

Dr. Van Horn expressed appreciation to the NHLBI and Dr. Lenfant for supporting the Nutrition Academic Award (NAA) program, which is intended to provide a better awareness and understanding of the role of nutrition in prevention and treatment, with a focus on CVD. The objectives of the NAA are to (1) develop and enhance undergraduate and graduate medical education curricula and training opportunities to learn clinical principals and clinical practice skills and (2) provide training models for dissemination to other medical schools and other health care professional schools.

The 10 medical schools with current NAAs are Brown University, Northwestern University, Tufts University, the University of Alabama, University of Iowa, University of Pennsylvania, University of Rochester, University of Texas Southwestern Medical Center, University of Washington, and Yeshiva University. Awards will be made to an additional 7 to 10 schools by April 2000. To be eligible for an NAA, a U.S. institution must have an accredited school of medicine and support from the dean; principal investigators must have a doctoral degree and faculty appointment in medical school with a rank of associate or full professor.

Training opportunities within the NAA include undergraduate clerkships, residencies, fellowships, faculty development, and continuing medical education. The NAA Steering Committee comprises the principal investigators and NHLBI representatives and has four subgroups: Curriculum, Medical Education Strategies Evaluation, Patient and Practice Resources, and Research.

In describing the NAA program at Northwestern University, Dr. Van Horn gave credit to Dr. Jeremiah Stamler for his nutrition elective course that was the school's second most popular elective. When the school eliminated its electives, nutrition was integrated into the core curriculum because of increased interest.

Dr. Grundy, principal investigator at the University of Texas Southwestern Medical Center's NAA, said he would like to see the NAA closely linked with the Office of Prevention, Education, and Control's (OPEC) educational programs and brought to medical schools. Dr. Grundy also voiced support for creating Web sites for nutritional programs developed locally so that they can be available nationally.

Dr. Van Horn said the NAA program has funding for 5 years; additional funding would be needed for continuation. It is hoped that the modules developed will be used by other schools and that the NAA program leads to the addition of nutrition-related questions on medical boards. Cross-school implementation and raised awareness will help all schools build a support system to add nutrition education to their curricula.

COORDINATING COMMITTTEE FEEDBACK ON CHOLESTEROL MONTH MATERIALS AND WEB OFFERINGS

Dr. James Cleeman

Dr. Cleeman reported that National Cholesterol Education Month 1999 had three foci: cholesterol lowering in primary prevention, in CHD patients, and in older Americans. The theme for the month was "Keep the Beat: Cholesterol Counts for Everyone." Vehicles to garner attention included a community kit (both hard copy and Web versions), a press kit, and an expanded, enhanced Web site.

Preliminary feedback on Cholesterol Month activities has been quite positive to date, with user respondents indicating that they implemented many activities using the kit. More feedback will be available from a survey of users of the community kit. The NHLBI produced 1,400 hard copy kits, and when the supply was depleted, users were directed to the Web version.

Dr. Cleeman gave a brief demonstration of the Web version of the kit and the enhanced "Live Healthier, Live Longer" Web site. The "Live Healthier, Live Longer" site was designed initially for CHD patients but now also includes a module for primary prevention. The message is "Cholesterol counts for everyone: whether you want to prevent heart disease or whether you have heart disease." A popular feature of the site is "Create a Diet," which allows users to enter their values for weight, height, sex, age, and activity level to obtain a customized allowance for calories and levels of saturated fat, total fat, and cholesterol. Users can choose foods for meals and snacks and evaluate how they did with respect to their allowances. There were more than 55,000 "hits" to the Web site in September.

Dr. Cleeman noted that the Web-based kit was available in mid-August, and the enhancements to "Live Healthier, Live Longer" were completed in mid-September. Members noted that hard copies of the kit are needed because not everyone has access to the Internet. Low literacy issues also must be addressed. Asked about policies for linking to the Web site,

Dr. Cleeman replied that it is easy for other organizations to link to the NHLBI site, but the reverse—linking the NHLBI site to non-Federal sites—is a problem because of implied endorsement of the site.

REPORT ON THE INITIAL MEETING OF ADULT TREATMENT PANEL III (ATP III)

Dr. Scott Grundy

Dr. Grundy stated that the Coordinating Committee is an important part of the ATP III process. The Committee's review of draft documents and input from the members are critical elements in developing the document. The following major issues and areas of new emphasis were derived from previous Coordinating Committee input and will be thoroughly evaluated:

- What are the implications of recent clinical trials for primary and secondary prevention? How will the guidelines be modified in light of the large amount of new data from statin trials, fibrate trials, and angiographic trials?
- What should be the LDL-C target in patients with established CHD?
- How should treatment of hypertriglyceridemia be integrated into cholesterol management? Hypertriglyceridemia is a marker for the metabolic syndrome. Should triglyceride-rich lipoproteins be a direct target of therapy? Can statin therapy be combined with triglyceride-lowering drugs such as fibrates and nicotinic acid?
- Should HDL-C be a target of therapy? How is HDL-C linked to CHD? Will the results of the statin and fibrate trials lead to a change in the ATP position on HDL-C?
- Should ATP III reemphasize primary prevention? What are the roles for dietary therapy, drug therapy, and LDL-C targets?
- What is the role of CHD risk assessment? (An NHLBI workshop on risk assessment was held in January 1999; results will be published shortly.)
    - Is Framingham scoring transportable to other populations? The current NCEP method to measure risk adds categorical risk factors and is more qualitative than the Framingham scoring, which uses more graded, quantifiable variables. Should both the methods be used? Is one better than the other?

- Consider the concept of CHD risk equivalent. Should patients without established CHD but at high calculated risk be treated as if they had coronary disease?

- Dietary therapy. Will ATP III reaffirm the significance of dietary therapy? What is the role of dietary fat, dietary adjuncts, obesity/weight reduction, and physical activity? (See Dr. Van Horn's presentation below.)
- Adherence/compliance. How can ATP III improve adherence and compliance to life habit modifications and drug therapy? (See Dr. McKenney's presentation below.)
- Diabetes mellitus. Is type 2 diabetes a CHD risk equivalent? What should be the LDL-C goal in diabetes patients? How should high triglyceride levels and low HDL-C levels be managed in these patients? Should they be classified in the same high-risk category as CHD patients? Is there a role for combined drug therapy in addition to weight control and exercise?
- Special considerations for different population groups (women, middle-aged men, the elderly, young adults, racial/ethnic groups, and others). (See Dr. Clark's presentation below.)

Dr. Grundy said that ATP III will assess the large amount of new data using an evidence-based approach and will then rigorously evaluate the evidence. The major product will be the ATP III final report; other products will be an executive summary (20 to 30 pages), a pocket card, and a PowerPoint slide set. The ATP III report will include issues/new areas of emphasis, guidelines for clinical management, identification of evidence for the recommendations, and references.

The panel will prepare issue papers, which will be the basis for incorporating major issues into the final report. Each paper will describe the nature of the issue, key evidence, and recommendations. There will be three sources of supporting literature: panel-nominated literature related to the major issues; a formal literature search; and a meta-analysis of major questions, conducted by a meta-analysis subgroup, which will examine relevant clinical trial data. The evidence will be displayed by type (major controlled clinical trials, smaller controlled trials, observational studies, or clinical experience) and by strength.

Panel members will draft subsections of the report, and the section chairs will merge the sections into a draft report. The report will be reviewed by the full panel, Coordinating Committee, senior advisors, and selected reviewers.

Dr. Grundy outlined the timetable for the report, from the first panel meeting (which was held September 22, 1999) to the literature search (September–December), meta-analysis subgroup activities (October–February), development of issue papers (3 months), the second meeting (January 2000) to review issue papers and literature and set preliminary panel positions, development of subsection drafts (January–March), internal first draft of the full report (end of March), and the review process, which will lead to several drafts during the spring and summer. The entire process will take approximately 18 months, with projected completion in Spring 2001.

Participants discussed the role of primary prevention and the need to reemphasize the population approach to preventing the development of high LDL-C levels. An important simple message is to prevent the rise in LDL-C with age, recognizing that risk factors occur over the lifetime. It was noted that physical inactivity and obesity were not independent risk factors in ATP II but will be carefully examined during the ATP III development process.

Dr. Grundy summarized the discussion by noting the following suggestions to include in the report:

- Identify high-risk individuals and recommend appropriate therapy.
- Examine the issue of long-term versus short-term risk.
- Extend primary prevention to moderate-risk people—mesh with the public health approach. (Clinical management and the public health approach are complementary.)
- Focus on the elderly since there is a great deal of disease in this group. Risk algorithms are not good predictors in the elderly. Which people ages 65 and older should be put on cholesterol-lowering drugs?
- Address the role of lipid abnormalities other than elevated LDL-C.
- Include a section on cost-effectiveness. (Cost-effectiveness analyses may have to be revised now that the price of statins is lower.)
- Incorporate physical inactivity and obesity into a high-risk strategy.

DISCUSSION OF SELECTED ATP III ISSUES AND AREAS OF NEW EMPHASIS

Patients With Coronary Heart Disease

Dr. Scott Grundy

Dr. Grundy noted that one measure of the effectiveness of managed care established by the National Committee for Quality Assurance (NCQA) HEDIS guidelines is the percentage of CHD patients with LDL-C levels <130 mg/dL, but NCEP guidelines call for a level of ≤100 mg/dL. After discussions with NCQA, it was agreed that NCQA supports the NCEP clinical goal of an LDL-C of ≤100 mg/dL as the appropriate target for LDL-lowering therapy, but for practical reasons, the <130 mg/dL goal will be used to make initial judgments about the quality of secondary prevention in managed care.

Dr. Grundy addressed two questions:

1. What is the optimal LDL-C reduction for lowering CHD risk?

   The current consensus supports the NCEP recommendation of a target LDL-C ≤100 mg/dL as optimal.

   - Epidemiologic studies. Early studies suggested a threshhold effect with no clear benefit of lowering total cholesterol to <200 mg/dL (LDL-C <130 mg/dL). Later studies, such as the Multiple Risk Factor Intervention Trial (MRFIT), revealed a curvilinear relationship and demonstrated benefits of lowering total cholesterol to 150 mg/dL or less (LDL-C <100 mg/dL). A summary of worldwide studies indicates that persons with LDL levels ~100 mg/dL have lower rates of CHD than those with levels ~130 mg/dL.
   - Angiographic trials. The Familial Atherosclerosis Treatment Study (FATS), the Program on the Surgical Control of the Hyperlipidemias (POSCH), and the post-CABG (coronary artery bypass grafting) study all demonstrated better outcomes with lower LDL-C levels, close to or below 100 mg/dL.
   - Clinical trials. The Cholesterol and Recurrent Events (CARE) trial found an apparent threshold effect at an LDL level around 125 mg/dL; however, the subgroup was quite

small. The Scandanavian Simvastatin Survival Study (4S) demonstrated a curvilinear effect with observed benefits to approximately 100 mg/dL.

2. What is the LDL-C goal for patients with established CHD? How is the goal applied in clinical practice?
   Among the ideas for discussion that will be considered by the panel are the following categories of patients, based on LDL-C levels:
   - Baseline ≥130 mg/dL.
   - Baseline 100 to 129 mg/dL.
   - On-treatment 100 to 129 mg/dL.
   - Baseline ≤100 mg/dL.

New Aspects of Dietary Therapy
Dr. Linda Van Horn

Dr. Van Horn briefly discussed some of the issues that will be considered by the Panel in the development of the dietary therapy section of the ATP III report.

- Diet Therapy. Reaffirm the significance of dietary therapy. Identify how to maximize the impact of diet on lipid lowering, with a focus on the Step II diet (which emphasizes saturated fat and cholesterol reduction). Consider the research since the ATP II report, including qualitative and quantitative data on carbohydrates.
- Dietary fat and fatty acids. Consider the research on total fat, saturated fatty acids, transfatty acids, monounsaturated fatty acids, and polyunsaturated fatty acids.
- Carbohydrates. Evaluate the significance of the ratio of refined to complex carbohydrates because of the sharp increase in their consumption as fat intake has declined.
- Dietary fiber. Examine the role of psyllium, oat bran, and other foods rich in dietary fiber.

- Soy. Examine the potential lipid-lowering benefits of soy proteins and isoflavones. A recent meta-analysis on this topic has been conducted. Consider labeling issues and the role of soy in chronic disease.
- Antioxidants. Examine the role of vitamins C and E and beta carotene. Compare supplements and food sources.
- Dietary supplements. There is great consumer interest in dietary supplements such as garlic. Examine the lipid-lowering role of phytosterols and stanols.
- Moderate alcohol. Determine what recommendations should be made about moderate intake of alcohol. Examine the red wine question.
- Other. Examine the role of fat-free foods, adherence, and weight control. Consider both qualitative and quantitative issues, energy balance, and the significance of physical activity.

Dr. Van Horn noted that some of ATP III's emphasis may be food-oriented rather than nutrient-oriented.

Participants made the following comments:

- Give prominence to obesity and adherence issues. Simplify and translate messages to make them user friendly. Give practitioners hands-on tools to help them implement the guidelines' recommendations.
- Provide a compelling case for the impact of diet on cholesterol levels. Link messages to the idea of preventing a rise in LDL-C and development of atherosclerosis. Link diet to other diseases (e.g., the relationship between low-fat diets and cancer incidence).
- Recognize increased requirements for certain nutrients because of other intakes (e.g., those who consume a great quantity of soda may need extra calcium).
- Use caution when recommending moderate alcohol consumption because of the negative aspects involved. Alcohol can be viewed as a carbohydrate or a drug.
- Identify the need to develop a universally accepted, simple, accurate tool to assess diet.
- Address popular diet books; many people believe the diets are "approved."

- Address the role of supplements in CHD because large numbers of people are taking them. Examine the roles of homocysteine, folic acid, and vitamins B6 and B12.

Improving Adherence

Dr. James McKenney

Dr. McKenney stressed that nonadherence to lipid-modifying therapy is a major public health challenge. The ATP III will assess the literature and provide practical recommendations for ways to increase adherence. These recommendations will have to address patients, providers, and the health care system. An implementation kit with best-practice guidelines may be a useful resource to help integrate the guidelines into clinical practice.

Dr. McKenney mentioned the following potential strategies for patients, providers, and systems.

Strategies for patients

- Patient education (positive messages, active listening)
- Contracting
- Self-monitoring
- Social support
- Telephone followup
- Tailoring
- Feedback and prompting
- Goal-setting
- Rewards
- Problem-solving
- Relapse prevention

Strategies for providers

- Use best practice models.
- Identify a patient “champion” in the office.
- Develop a plan for patient education.
- Support patient education through a Web site.

- Manage appointments and followup.
- Structure care plans.
- Make use of other health professionals, such as dietitians, pharmacists, and nurse case managers.

Strategies for systems

- Proclaim noncompliance a major health problem.
- Develop ICD-9 codes for nonadherence services.
- Develop a public-private public education initiative. Make messages about lipid-lowering drugs more positive.
- Articulate a standard of care for lipid management.
- Advocate a broader involvement of nurses, dietitians, and pharmacists in patient care.
- Recommend research on adherence issues.

Committee members made the following comments:

- Examine what has worked in the past to improve compliance, using community collaboration models and supportive networks. Review the literature on disease management programs.
- Provide patients with positive feedback for adherence. For example, have patients calculate their baseline risk, then recalculate it after treatment to demonstrate benefit.
- Make patients responsible for their care. Give them a dietary assessment tool and a checklist of things they are responsible for (e.g., weight control).
- Pay attention to patients' "stages of readiness," and target interventions appropriately. Recognize the diversity of the population; do not take a one-size-fits-all approach.
- Recognize the need for health professionals whose major function is to manage and provide support for patients who need long-term adherence to therapies such as lipid-lowering drugs. The physician cannot do this in a 10-minute office visit. The health care system does not pay for these services and resources. HEDIS measures should include patient interventions and education. ("What gets measured gets done.")

- Make implementation kits vignette-based rather than didactic. For example, illustrate ways to implement changes in the office.
- Provide physicians with a self-assessment tool to help them determine the percentage of their patients who are provided with dietary assessment and counseling and treated to NCEP goal levels.
- Determine how to improve care delivery through reminder systems, audit/feedback, system change incentives, and financial incentives.
- Successful adherence/compliance studies use daily education and contact with participants.

Special Considerations for Population Groups
Dr. Luther Clark

Dr. Clark said that the underlying question is the impact of different population group considerations on the ATP III recommendations and the applicability of risk assessment and stratification instruments for these groups. The ATP II position is that the guidelines and algorithms are applicable to the population, with special considerations for some groups. It recommends that the same algorithm be used in men and women, with some special considerations. For example, ATP II has a different definition of age as a risk factor by sex (55 in women versus 45 in men), and it recognizes that a protective HDL-C level (≥60 mg/dL) is more common in women.

Questions to be addressed by ATP III for population groups include the following:

Women

- Should the definition of low HDL-C (<35 mg/dL) be changed? Should it be the same for males and females?
- Should HDL-C be a target of intervention, when is it appropriate to intervene?
- What should be the goal of HDL-raising therapy?
- What is the role of hormone replacement therapy in light of the recent findings of the Heart and Estrogen/Progestin Replacement Study (HERS)?

Elderly Patients

- Should persons ages 60 and older be in the highest risk group (as in the Framingham risk assessment)?
- What is the role of subclinical atherosclerosis?
- Should the issue of stroke be addressed?
- Is drug therapy sufficiently safe so that elderly patients can be treated with the same intensity as younger patients?

Young Adults

- Should risk assessment instruments consider 5- and 10-year risk or lifetime risk?
- What should be the screening recommendations for males ages 20 to 35 years and premenopausal women?

Racial/Ethnic Groups

- Should left ventricular hypertrophy (LVH) be considered a risk factor in African Americans? Should it be considered a CHD risk equivalent?
- What is the impact of the fact that Hispanics and Pacific Islanders have a lower baseline population risk, whereas Native Americans have a higher baseline population risk?

During a discussion that followed, it was noted that the big challenge is to integrate the pieces into a whole and to build on what has already been done. Because risk stratification will be impacted by population baseline, there is a need to identify the reference group (which has been middle-age men in the past). Should the reference population be women? Which risk assessment instrument should be used? Should there be a global risk score?

Dr. Cleeman thanked the presenters and noted that the discussions would be continued in the small groups.

REPORTS FROM THE SMALL-GROUP DISCUSSIONS (in the order presented)

Group 2 Report
Dr. Linda Van Horn

Members of Group 2 continued discussing new aspects of dietary therapy. Some of the points that were made during the session included the following:

- Relative to dietary assessment, methods can be technologically advanced or not, depending on the intended use and target audience.
- The NCEP "Live Healthier, Live Longer" Web site should be emphasized. Perhaps it should serve as a national model.
- ATP III needs to address access issues such as underserved populations.
- A dietary assessment tool that could be used in the primary care setting is important.
- Dietary assessment should somehow incorporate the food guide pyramid. This may help physicians perform a dietary assessment.
- In some populations, videos are a better educational medium than computer-based applications.
- ATP III needs to clearly show the evidence for its recommendations. Many popular diets on the market that consumers are exposed to are not evidence based.
- ATP III needs to consider how to package its messages for maximal effectiveness.
- The metabolic syndrome needs more specialized dietary intervention.
- What appears to be average in a population is not necessarily normal.

Group 4 Report
Dr. James McKenney

Group 4 continued discussing the topic of improving adherence. System, provider, and patient issues were considered. Members discussed the following:

- An implementation kit that includes tools is needed for ATP III.
- The Cochrane Collaboration Group is an example of an organization that tests and validates tools.
- Regarding health maintenance organizations (HMOs), it is important to emphasize a strong message (e.g., know your goal).
- HEDIS is important in the managed care arena.
- Consideration needs to be given about how we will or will not incorporate other guidelines (such as the European guidelines).
- It is important to have a validated risk assessment tool.
- ATP III needs to address the HDL issue because patients ask their physicians about it.
- Health care professionals other than physicians (e.g., nurses and pharmacists) need to play a major role in implementing the guidelines.
- There needs to be a mechanism for measuring outcomes.
- Health care professionals need to work with patients to help them set goals.
- Patients can be given tools and responsibility in their care; empowering them is important.
- Web-based educational applications are good but are not currently widely accessible.
- There may be a role for remote access tools via telephone.

In response to a brief discussion about risk assessment tools, Dr. Grundy invited Coordinating Committee members to submit risk assessment tools that they are familiar with or that are being used in clinical practice. In addition, members were invited to submit any pertinent literature on this topic and other guidelines that they would like the panel to consider. Materials for consideration should be forwarded to Dr. Cleeman, who will ensure that the panel members receive it.

Group 3 Report
Dr. Luther Clark

In its discussion about special populations, Group 3 considered the following areas:

- Overall, members are pleased with the issues that ATP III will consider.
- ATP III should build on ATP I and ATP II.
- Efforts should be made to integrate the new guidelines with existing guidelines (e.g., obesity, blood pressure, and diabetes).
- Public health messages need to be considered. The population report has not been updated recently.
- ATP III should reaffirm dietary therapy.
- ATP III should recognize that some population groups may respond differently to messages, therapies, and so on.
- The source of the guidelines (i.e., the NHLBI) is more important to practicing physicians than a display of the graded evidence.
- Practicing physicians do not have much time for cholesterol education.
- HDL recommendations need to be clear.

As part of a discussion that followed, Dr. Grundy invited members to offer comments on the general evidence-based approach to be used in the development of ATP III. A member stated that weighting evidence often is a controversial issue and suggested that outside assistance be used in the process. Dr. Grundy replied that the panel comprises a heterogeneous group that represents a variety of areas and disciplines. Members briefly discussed grading the strength of the evidence. Dr. Cleeman noted that there will be many opportunities for the Coordinating Committee to offer input and comments on the strength of evidence.

Group 1 Report
Dr. Scott Grundy

Members of Group 1 discussed whether diabetes should be considered a CHD risk equivalent. Members acknowledged that this is a controversial issue. Some authorities recommend treating diabetic patients like CHD patients relative to setting the LDL goal at less than 100 mg/dL, whereas others do not believe there is enough evidence to make that recommendation. Diabetic patients also have other lipid abnormalities, which may need to be addressed with combined drug therapy.

Another topic area discussed by Group 1 was whether enough attention is being paid to physical inactivity as a separate concern from obesity. Some suggestions regarding physical activity included the following:

- Reinforce the exercise (physical activity) message.
- Incorporate physical inactivity into the risk factor assessment.
- Highlight discussion about physical activity in the text.

A third area considered by Group 1 was how ATP III could link to and reinforce public health messages. The group agreed that perhaps the report of the population panel could be examined in this context. A question to consider is whether to separate out high-risk patients or stratify them into categories similar to ATP II.

A member asked that the panel consider merging the high-risk clinical approach with the primary prevention approach so that an LDL level of 120 mg/dL does not become an LDL level of 160 mg/dL some years later. A member commented that the aim of the guidelines is to help Americans improve their health over time and reduce the burden of disease. A member stated that JNC VI has prevention as part of its title for the first time. Should we do the same with ATP III and allow the integration of two approaches?

OPEN FORUM—COMMENTS FROM INVITED GUESTS

A comment was made by a member of the audience that there are several different types of risk and that knowing risks and odds can be empowering to both practitioners and patients. ATP II does not deal indepth with risk, and ATP III should go into more detail. Dr. Grundy agreed that ATP III needs to be clear on different types of risk. A Committee member commented that there is absolute risk and attributable risk, and caution needs to be used until physicians and patients know what the different types of risk mean.

ADJOURNMENT

Dr. Cleeman thanked members for a very productive meeting. He told members to expect to be engaged in the guidelines development process in a continuous way. Dr. Cleeman invited Committee members to forward ideas, suggestions, or other guidelines to be reviewed by the panel. The next Coordinating Committee meetings will be on May 23, 2000, and December 5, 2000.

ATTACHMENT A

PARTICIPANT LIST

National Cholesterol Education Program
Coordinating Committee Meeting
October 12, 1999

Participant List

COORDINATING COMMITTEE

Members Present

AMERICAN ACADEMY OF FAMILY PHYSICIANS
Theodore G. Ganiats, M.D.

AMERICAN ACADEMY OF INSURANCE MEDICINE
Gary D. Graham, M.D.

AMERICAN ASSOCIATION OF OCCUPATIONAL HEALTH NURSES
Pamela King, R.N.

AMERICAN COLLEGE OF CHEST PHYSICIANS
Gerald T. Gau, M.D.

AMERICAN COLLEGE OF NUTRITION
Harry Preuss, M.D. (Substituting for Stanley Wallach, M.D.)

AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE
Ruth Ann Jordan, M.D.

AMERICAN COLLEGE OF PREVENTIVE MEDICINE
Lewis H. Kuller, M.D., Dr.P.H.

AMERICAN DIABETES ASSOCIATION, INC.
Alan Garber, M.D., Ph.D.

AMERICAN DIETETIC ASSOCIATION
Linda Van Horn, Ph.D., R.D.

AMERICAN HEART ASSOCIATION
Scott M. Grundy, M.D., Ph.D.

AMERICAN HOSPITAL ASSOCIATION
Sandra Cornett, R.N., Ph.D.

AMERICAN OSTEOPATHIC ASSOCIATION
Michael Clearfield, D.O.

AMERICAN PHARMACEUTICAL ASSOCIATION
James M. McKenney, Pharm.D.

AMERICAN PUBLIC HEALTH ASSOCIATION
Stephen Havas, M.D., M.P.H., M.S.

AMERICAN RED CROSS
Jill K. Gross, M.P.H., CHES

ASSOCIATION OF BLACK CARDIOLOGISTS
Elizabeth Ofili, M.D., M.P.H.

CITIZENS FOR PUBLIC ACTION ON BLOOD PRESSURE AND CHOLESTEROL
Gerald J. Wilson, M.A., M.B.A.

NATIONAL BLACK NURSES ASSOCIATION
Linda Burnes-Bolton, Dr.P.H., R.N., M.S.N., F.A.A.N.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
James I. Cleeman, M.D.

NATIONAL MEDICAL ASSOCIATION
Luther T. Clark, M.D.

SOCIETY FOR NUTRITION EDUCATION
Darlene Lansing, M.P.H., R.D.

SOCIETY FOR PUBLIC HEALTH EDUCATION
Elaine Auld, M.P.H., CHES (Substituting for Donald Fedder, Dr.P.H., M.P.H.)

Members Absent

AMERICAN ACADEMY OF PEDIATRICS
Ronald E. Kleinman, M.D.

AMERICAN COLLEGE OF CARDIOLOGY
Richard C. Pasternak, M.D., F.A.C.C.

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS
Thomas E. Nolan, M.D.

AMERICAN MEDICAL ASSOCIATION
Yank D. Coble, Jr., M.D.

AMERICAN NURSES ASSOCIATION
Joan E. Watson, R.N., Ph.D., F.A.A.N.

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS
Joanne Mitten, M.H.E.

Associate Member Absent

AMERICAN ASSOCIATION OF OFFICE NURSES
Joyce Logan

Liaison Representatives Present

AGENCY FOR HEALTH CARE POLICY AND RESEARCH
Francis D. Chesley, Jr., M.D.

DEPARTMENT OF AGRICULTURE
Jan Bodner, M.S. (Substituting for Alanna Moshfegh, M.S., R.D.)

DEPARTMENT OF DEFENSE
Col. Robert Dana Bradshaw, M.D., M.P.H.

FOOD AND DRUG ADMINISTRATION
Sue Ann Anderson, Ph.D. (Substituting for Darla Danford, M.P.H., D.Sc.)

HEALTH RESOURCES AND SERVICES ADMINISTRATION
Celia Hayes, M.P.H., R.D.

NATIONAL CANCER INSTITUTE
Carolyn Clifford, Ph.D.

NATIONAL CENTER FOR HEALTH STATISTICS
Clifford Johnson, M.P.H.

OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION
Elizabeth Castro, Ph.D. (Substituting for Linda Meyers, Ph.D.)

Liaison Members Absent

CENTERS FOR DISEASE CONTROL AND PREVENTION
William H. Dietz, M.D., Ph.D.

COORDINATING COMMITTEE FOR THE COMMUNITY DEMONSTRATION STUDIES
Thomas M. Lasater, Ph.D.

DEPARTMENT OF VETERANS AFFAIRS
Pamela Steele, M.D.

NHLBI AD HOC COMMITTEE ON MINORITY POPULATIONS
Yvonne L. Bronner, Sc.D., R.D., L.D.

GUESTS

Charles M. Alexander, M.D.	Merck & Co., Inc.
Marianne Andreach	Bristol-Myers Squibb Company
Robert Ashton	Parke-Davis
Allison Barnes, M.D.	University of Maryland
David Bilheimer, M.D.	Merck & Co., Inc.
James W. Blasetto, M.D., M.P.H.	Novartis Pharmaceuticals
Douglas A. Boyd	National Institutes of Health
Meredith Carter, Pharm.D.	Parke-Davis
Carola P. Friedman, M.D., F.A.C.C.	Bristol-Myers Squibb Company
Elizabeth Haybron, M.B.A.	Warner-Lambert
Ann Heller, R.N., M.P.H.	Maryland Dept. of Health & Mental Hygeine
Richard Kahn, Ph.D.	American Diabetes Association
Ann Kenny	Prospect Associates
Patricia Kriger	Bristol-Myers Squibb Company
Stuart Kupfer, M.D.	Searle
Craig Lustig, M.P.A.	National Institutes of Health
Carol McCormick	Ketchum
Linda Min, M.S., R.D.	Egg Nutrition Center
Charles E. Olech, R.P.H.	LipoMed, Inc.
James Otvos, Ph.D.	North Carolina State University
Natan Polster	The HLB Newsletter
Elizabeth M. Puckett, M.S., P.T.	North Carolina Division of Public Health
Kristine Soechting	Warner-Lambert
Jennifer Weber, R.D., M.P.H.	N. Chapman Associates, Inc.
Peter W.F. Wilson, M.D.	Framingham Heart Study

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Ellen Sommer, M.B.A.
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SUPPORT CONTRACT STAFF
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Joanne Karimbakas, R.D.
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Damian Maeyaert
Elaine Murray
Alexandra Sharnoff

ATTACHMENT B

MEETING AGENDA

National Cholesterol Education Program
Coordinating Committee

Tuesday, October 12, 1999
Bethesda Marriott Hotel - Bethesda, Maryland

AGENDA

8:30	Welcome and Report from the Coordinator	Dr. James Cleeman
8:45	Report on the National Conference on CVD Prevention	Dr. Lawrence Friedman
9:10	Report on the Working Group on Adherence to Medical and Lifestyle Interventions	Dr. Elizabeth Ofili
9:30	Report on the Nutrition Academic Award Program	Dr. Linda Van Horn
9:45	Coordinating Committee Feedback on Cholesterol Month Materials and Web Offerings	
10:00	BREAK	
10:15	Report on the Initial Meeting of Adult Treatment Panel III (ATP III)	Dr. Scott Grundy
11:00	Discussion of Selected ATP III Issues and Areas of New Emphasis:	
	Patients With Coronary Heart Disease	Dr. Scott Grundy
	New Aspects of Dietary Therapy	Dr. Linda Van Horn
	Improving Adherence	Dr. James McKenney
	Special Considerations for Population Groups	Dr. Luther Clark
12:15	LUNCH Small Group Discussions: ATP III Issues and Areas of New Emphasis	
1:30	Reports from the Small Group Discussions	
2:45	Open Forum: Comments from Invited Guests	
3:00	Adjournment	

ATTACHMENT C

SUMMARIES OF SMALL-GROUP DISCUSSIONS

National Cholesterol Education Program
Coordinating Committee Meeting
October 12, 1999

Small-Group Discussion—Group 1

Dr. Scott Grundy (Chairperson/Facilitator)
Dr. Elizabeth Castro (substituting for Dr. Linda Meyers)
Dr. Alan Garber
Dr. Stephen Havas
Dr. Clifford Johnson
Dr. Lewis Kuller
Dr. James Cleeman (NHLBI)
Dr. Nancy Ernst (NHLBI)
Dr. Basil Rifkind (NHLBI)
Ms. Sue Shero (Contractor Staff)

Members discussed a variety of topics related to the ATP III guidelines, including whether to consider diabetes a CHD risk equivalent, how the guidelines could link to public health messages, and the role of physical inactivity as a separate risk factor from obesity. In a discussion about treatment of diabetic patients, the following comments were offered:

- A recent review by S. Haffner, M.D., showed that event rates in patients with diabetes are similar to those with CHD. Although this would favor aggressive treatment in diabetics, supporting epidemiologic data are sparse. In trials such as the Air Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS) and the Honolulu Heart Study, treatment benefits of cholesterol lowering were not statistically significant. In secondary trials with diabetic cohorts, some have shown positive effects of treatment while others, such as LIPID (Long-Term Intervention with Pravastatin in Ischaemic Disease), which had a large diabetic cohort, did not demonstrate a statistically significant reduction in events. Based on the evidence to date, can the guidelines recommend a target LDL of ≤100 mg/dL for persons with diabetes?

- Dr. Grundy stated that the NCEP needs to consider the American Diabetes Association (ADA) guidelines for cholesterol.

- The diabetic population has a great deal of premature atherosclerosis. The extent of disease appears to be different among persons with diabetes. An additional problem is that they also have small vessel disease, which may mitigate the effects of cholesterol-lowering drugs.

- There is a high correlation between triglyceride levels and LDL particles as a predictor of atherosclerosis, but physicians do not measure LDL particles. Perhaps there is an advantage to lowering triglycerides in this population.

- The cost of treatment will soon decrease as the prices of older statins fall, but we must consider that adding drugs to lower cholesterol will increase an already complex treatment regimen.

- How safe is it to use a fibrate and a statin together? In general, the drug companies do not support combining them, but there seems to be more openness to combined drug therapy now, even in the FDA.

Some members supported setting an LDL target of ≤100 mg/dL for persons with diabetes, whereas others supported a target of <130 mg/dL. A member noted that there will always be residual events. In discussing public health considerations, the following comments were made:

- We are missing opportunities to lower risk if the LDL level gets to 160 mg/dL. From there, it is hard to get it to 100 mg/dL.

- A message could be crafted to convey the idea that people should know their LDL level.

- In a sense, ATP II "allows" low-risk patients to have a higher LDL. ATP III should address this differently.

- We need to develop specific messages—people do not respond well to general messages.

- Should ATP III address noninvasive assessments such as electron beam computerized tomography and carotid intimal thickness? These may be good motivational tools for change.

- ATP III is mainly a high-risk strategy. How do we incorporate and link to the larger public health messages?

The following comments were made during a discussion about physical inactivity as a risk factor for CHD:

- Physical inactivity is probably different from obesity. Obesity operates through other risk factors.

- The prevalence of physical inactivity is possibly 70 percent to 80 percent of the population.

- Physical activity is part of the process to slow the development of disease.

- Physical activity and diet need to be used in addition to cholesterol-lowering drugs.

- Some members agreed that in ATP III, physical inactivity should be separated from other risk factors such as obesity.

National Cholesterol Education Program
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Small-Group Discussion—Group 2

Dr. LindaVanHorn (Chairperson/Facilitator)
Dr. Linda Burnes-Bolton
Dr. Michael Clearfield
Dr. Carolyn Clifford
Ms. Darlene Lansing
Ms. Eileen Newman (NHLBI)
Ms. Joanne Karimbakas (Contractor Staff)

Group 2 discussed areas related to dietary assessment and dietary recommendations to be considered for ATP III. Members agreed that it is important to emphasize assessment. Suggestions included using technology to make available a standardized assessment tool. The NHLBI Web site could serve as a global source of information. Members of Group 2 discussed the following:

- The need to examine ways in which a dietary assessment tool could be incorporated into the health care system. An example would be if the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) required that an organization have a dietary assessment tool in order to obtain accreditation. Reimbursing health care providers for dietary services would increase the likelihood of implementation.

- The need to identify methods to target various multicultural groups and underserved populations who do not have access to current technology.

- Physician-directed dietary intervention with patients was thought to be unlikely, but a video that teaches the fundamentals could be an effective educational tool. Instructional videos could address different patient needs and allow a self-assessment to be completed by the viewer.

- Physicians should be educated in the fundamentals of nutrition with an easy, concise message, such as the food guide pyramid. Physicians should also encourage patients to follow up with registered dietitians and other qualified health care providers.

- Dietary recommendations need to be based on the most recent scientific evidence and should address popular fads such as Sugar Busters, The Zone, and the Atkins diet. Group members thought that an effective way to address these fad diets is to point out the lack of scientific evidence to substantiate claims as well as to emphasize the current science base.

- Dietary recommendations should emphasize long-term life habit change rather than focus on a specific diet. Messages should include risk factor reduction and improved health in addition to weight loss.

- ATP III should address special populations for which the step II diet might not be the best and only recommendation (e.g., those with hypertriglyceridemia, insulin resistance syndrome, and diabetes).

- Recommendations regarding physical activity and alcohol consumption should be included in the dietary therapy section of ATP III.

- ATP III should address population-based primary prevention.

National Cholesterol Education Program
Coordinating Committee Meeting
October 12, 1999

Small Group Discussion—Group 3

Dr. Luther Clark (Chairperson/Facilitator)
Dr. Sue Ann Anderson (substituting for Dr. Darla Danford)
Dr. Theodore Ganiats
Ms. Jan Bodner (substituting for Ms. Alanna Moshfegh)
Ms. Terry Long (NHLBI)
Ms. Elaine Murray (Contractor Staff)

Members of Group 3 expressed support for the ATP III issues and suggested approaches presented during the morning session. They felt that ATP III should (1) build upon ATP I and II and (2) seek to integrate its recommendations with those for obesity, high blood pressure, and diabetes. Other points discussed by members of Group 3 included the following:

- The public health message stemming from the guidelines' recommendations is a major issue that needs to be addressed. A central focus should be on primary prevention among those groups most in need of intervention.

- It is important to recognize that the benefits of cholesterol lowering vary among different population groups and are not clearly established for some groups. An important issue to settle is what the LDL level should be for each population group. In general, recommendations specific to special populations will be better received if they are educational, not directive.

- The guidelines should be user friendly and, regardless of drug therapy issues, reaffirm the importance of diet. Additional information about HDL-C needs to be part of ATP III. The information needs to be as clear as possible since it may add some complexity to the overall document.

- Issues related to the accuracy of risk assessment tools among different populations need to be resolved. For example, some risk assessment tools appear to underestimate risk in blacks and overestimate it among Puerto Ricans and older Asian men with diabetes.

- The impact of cholesterol reduction on diverse populations needs to be determined. More data will be available in 2003, but that is a long time to wait.

- There are essentially three categories of women that need to be addressed: premenopausal, postmenopausal, and postmenopausal on hormone therapy.

- Because they have to deal with the whole body, general practitioners do not have much time to devote to cholesterol education. Practicing physicians want to know that information comes from a credible source but do not want to be provided with the details. Accordingly, the recommendations issued to physicians should be clear and concise.

- To avoid the perception that the report is biased, controversial issues should be tackled now to show that they have been addressed.

National Cholesterol Education Program
Coordinating Committee Meeting
October 12, 1999

Small-Group Discussion—Group 4

Dr. James McKenney (Chairperson/Facilitator)
Col. Robert Dana Bradshaw
Dr. Sandra Cornett
Dr. Gerald Gau
Dr. Gary Graham
Dr. Ruth Ann Jordan
Ms. Pamela King
Dr. Harry Preuss (substituting for Dr. Stanley Wallach)
Mr. Gerald Wilson
Ms. Mary Hand (NHLBI staff)
Mr. Alexander Kuhn (Contractor Staff)

Dr. McKenney reviewed some possible strategies to improve adherence including using health professionals to educate patients, instituting reminder systems, developing problem-solving skills, involving spouses, and making adherence a topic in the patient/provider dialog. Dr. McKenney opened the discussion for suggestions and comments. Members of Group 4 offered the following:

- An implementation kit seems to be needed. Providers want protocols, forms, and so forth that can be easily adapted to meet institutional needs. The implementation kit should include pieces for providers, the health care system, and patients.

- The components of the kit need to be developed on the basis of strategies that have been shown to work. A literature review to identify evidence-based strategies may be appropriate.

- A review of other guidelines, such as the European guidelines, should take place during the development of ATP III.

- Implementation tools are needed that can be used in physician practice and involve the entire health care team. Suggested tools included a wall chart, pocket guide, and standing orders.

- Tools could be developed that are especially designed for health fairs.

- Managed care is a large player in the implementation of guidelines and recommendations. The main motivator for managed care organizations (MCOs) is cost containment. In some MCOs, preventive medicine is not a priority. HEDIS measures and NCQA accreditation may help address these issues to some extent.

- An issue to be addressed in this section is that there appears to be some reimbursement difficulty if the patient does not have an initial diagnosis of hyperlipidemia.

- Web-based patient education is a useful tool but will not reach a substantial portion of the population. At the present time, Web-based applications should complement audio-video and paper-based systems of education. It is important to determine the validity of any tool before its use.

- Ms. Hand discussed medical informatics and how it may be used in the future for treatment, adherence, and followup of patients.

- It may be useful to evaluate existing assessment tools (such as those from the AHA, ACC, Framingham, Diamond, and Kaiser) and incorporate the strongest parts of each tool into an NCEP tool.

- Nurses and other health care providers will have increasingly important roles in adherence/compliance in the future.

- Physicians and other health care providers will need to work together to make the greatest impact on adherence/compliance issues.