Summary Report

THE NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM COORDINATING COMMITTEE MEETING

December 5, 2003
Sheraton Reston Hotel
Reston, Virginia

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HIGHLIGHTS

- Dr. Barbara Alving, acting director of the National Heart, Lung, and Blood Institute (NHLBI), welcomed Coordinating Committee members and introduced the following new members:

  – Dr. Oscar Carretero, American Society of Hypertension

  – Dr. Stuart Linas, American Society of Nephrology

  – Mr. Kevin Rebeck, American Academy of Physicians Assistants

- Dr. Larry Fields described the Secretary of Health and Human Service's Stroke Belt Initiative, which aims to increase the number of individuals whose blood pressure is controlled. The initiative will include funding for studies in one community in each of three core States. A Stroke Belt community action team will provide activities directed at individuals, health care providers, and health systems and health plans.

- Dr. Daniel Levy presented data from the Framingham Heart Study (FHS) on rates of hypertension, treatment, and control for persons in three age groups: <60, 60–79, and ≥80 (the "old old"). Current rates of control in the "old old" are unacceptably low (especially in women), indicating that treatment for this group should be a national priority.

- Dr. Bruce Psaty reviewed data on high blood pressure from the Cardiovascular Health Study (CHS) for patients <80 years of age and for those >80. In 1990–99, levels of hypertension awareness, treatment, and control increased in all CHS participants.

- Drs. Jerry Cohen, Carlos Vallbona, and Marvin Moser led a discussion to review the implications of the data for public health policy. The group discussed realistic blood pressure goals, messages for physicians, and ways to increase treatment levels.

- Mr. Chuke Nwachuku provided an overview of a plan to jointly disseminate the results of the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack (ALLHAT) study and the "Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure" (JNC 7). The project will target health care providers, formulary systems, and patients, using traditional dissemination approaches as well as academic detailing.

- Ms. Vicki Burt reviewed data on blood pressure from the National Health and Nutrition Examination Survey (NHANES), and indicated that new NHANES data will include estimates of hypertension awareness, treatment, and control.

- In his coordinator's report, Dr. Edward Roccella presented data on media outreach for JNC 7, including print and broadcast coverage, e-mail messages, a Web site, and materials for physicians and patients.

- The next Coordinating Committee meeting will be held in September 2004.

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WELCOME AND INTRODUCTION OF NEW MEMBERS
[Dr. Barbara Alving]

Dr. Alving, acting director of the National Heart, Lung, and Blood Institute (NHLBI), welcomed the National High Blood Pressure Education Program (NHBPEP) Coordinating Committee (CC) members. She noted that the former director Dr. Claude Lenfant, remains busy and is about to receive a Lifetime Award from the American Society of Hematology. An announcement for a new permanent director will be open until February 6, 2004.

Dr. Alving introduced the following new CC members: Dr. Oscar Carretero, representing the American Society of Hypertension (replacing Dr. Barry Materson); Dr. Stuart Linas, representing the American Society of Nephrology; Mr. Kevin Rebeck, representing the American Academy of Physicians Assistants (replacing Mr. John Davis); and Dr. Charles Curry, representing the American College of Cardiology (substituting for Dr. Suzanne Oparil).

Dr. Alving said that she is particularly interested in guidelines for hypertension in the "old, old" (age 80 and older) and the need to make home monitoring devices more available.

THE STROKE BELT REVISITED
[Dr. Larry Fields]

Dr. Fields, the senior executive advisor to the assistant secretary for health, Department of Health and Human Services (DHHS), began by recognizing a mentor, Dr. H. Mitchell Perry, Jr., for his contributions to understanding and treating high blood pressure (BP).

Dr. Fields provided background on the Stroke Belt. While there were 11 original Stroke Belt States, 7 States in the Southeast are in the top quintile relative to the U.S. national average. Causes of excess stroke-related deaths in the Stroke Belt are unknown, though a clustering of risk factors in the Southeast is considered to be at least partially responsible. In 1997, the South had the highest percentage of the population living with a stroke (2.6 percent). Dr. Fields showed geographic information system (GIS) maps illustrating States with high rates of stroke hospitalization, in-hospital stroke death, adults with self-reported obesity, self-reported diabetes, high BP, and recommended level of physical activity. Many of these maps overlapped, indicating that risk factors were related.

Dr. Fields then focused on the Secretary's Stroke Belt Initiative, which began when a group of representatives from each DHHS agency/office decided to address risk factors for priority conditions—heart disease, stroke, hypertension, and peripheral vascular disease.

Hypertension is the most powerful risk factor for stroke, and this risk increases with age. Initiatives addressing healthy behaviors will impact stroke levels. The goal is to increase the number of individuals with normal endogenous BP control and to also increase the number with optimal exogenous BP control. While it is not known what is driving excess stroke deaths in the Stroke Belt, what is known is if there is an average BP reduction (e.g., 3–5 mmHg over time), there will be significant improvement.

Key elements of the Stroke Belt Initiative include:

- **Requests for applications and proposals (RFAs/RFPs)**. Phase 1 will focus on one community in each of three core States. Funding awards will be for 2–3 years.

- **Core community activities**. A Stroke Belt community action team will provide collaboration at the community level and will emphasize activities directed at individuals, health care providers, and health systems/health plans. The initiative will include several communitywide programs: an "Enabling Ring of Collaboration" with existing high BP/stroke reduction efforts; a "Check Blood Pressure, Stop Stroke" campaign; and a volunteer network for free BP checks and referral to care. It will also include the "Blood pressure CONTROL IS THE GOAL" program for health providers and a program for health systems and health plans.

- **An effort to optimize future funding.** This effort will bring resources at national, regional, subregional, and other levels to sustain the program in the future.

Recognizing the CC's accomplishments in increasing awareness, prevention, and control of BP, Dr. Fields invited CC members to join the Initiative, on behalf of the DHHS secretary, assistant secretary, and surgeon general.

Discussion

Participants made the following suggestions:

- Consider the benefit of policy changes, such as efforts to reduce sodium levels in food. The CC has been involved in the sodium issue since 1993, and the American Public Health Association (APHA) passed a resolution in 2002 recommending that sodium in the food supply be reduced by 50 percent over the next 10 years. The United Kingdom (U.K.) is actively working with the food industry to reduce sodium levels in food. We must work with industry and educate the public about the amount of salt they are consuming. Sodium consumption in the Japanese population has gone from of 35 gm/day to 13 gm/day over the last 15 years, and the average systolic blood pressure (SBP) in Japan has dropped 8 mmHg. Dr. Field said that the Initiative is discussing the sodium issue, and he noted that the RFA will require that people in the community know about the efforts of other organizations.

- Make a distinction between thrombotic strokes and hemorrhagic strokes.

- The level of proteinuria is a good prognostic indicator for hypertension.

- Look at existing cohorts (e.g., the Jackson Heart Study) as a good resource for tracking mean BP. Dr. Field said the Initiative has looked at the Jackson study and the REGARD trial and will align with ongoing efforts.

- Provide consistent messages for practicing physicians. Much medical education comes from industry; there should be efforts to ensure a balanced approach.

- Consider the effect of physical activity in reducing BP in the population. The 10,000 Steps program encourages people to walk more and to use a pedometer to measure their progress. Small Steps, Big Rewards is another successful program to encourage physical activity.

- The Initiative should think big and address policy approaches. It should also be planned with reference to physical activity, diet, weight loss, diabetes prevention and treatment, and BP checks. Dr. Field said that the Initiative plans to focus on hypertension first—then to build and expand the Initiative.

- We must fully understand the data. For example, Louisiana has a high hospitalization rate for stroke but not a high stroke mortality.

EPIDEMIOLOGY OF HYPERTENSION IN THE "OLD OLD" DATA FROM THE FRAMINGHAM HEART STUDY
[Dr. Daniel Levy]

Dr. Levy shared information on hypertension from the Framingham Heart Study (FHS). This study included the original cohort (starting in 1948) and the Framingham offspring cohort (starting in 1971). He presented data on all exams from January 1990 through December 1999 for persons in three age groups: <60, 60–79, and >80 (the "old old")? for a total of more than 14,000 clinical exams. SBP is a risk factor that increases with age, while diastolic blood pressure (DBP) decreases in persons older than age 60.

Dr. Levy reviewed the BP categories in the "Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure" (JNC 7) as well as treatment and control rates, drugs used for treatment, and hypertension and risk for cardiovascular disease (CVD) in the three age groups, concentrating on the "old old." In the latter group (mean age 84), 71 percent had hypertension as defined by JNC 7 (>140/90 mmHg); only 9 percent fell in the normal category (<120/80 mmHg); and 71 percent had stage 1 or stage 2 hypertension.

Effective BP control is a problem of the elderly. Among treated hypertensives, the rates of control are 70 percent in patients younger than 60, compared with 45 percent in oldest men and 33 percent in the oldest women. In the "old old," we deal with isolated systolic

hypertension; the younger groups more often have combined systolic/diastolic hypertension and occasionally isolated diastolic hypertension.

The use of diuretics for treatment increased slightly with increasing age. At all ages, more women than men were on diuretics. In the "old old," only 22 percent of men and 32 percent of women received diuretics. Use of beta-blockers (BBs) was quite level across age groups, with about one-third of patients receiving a BB. Calcium channel blockers (CCBs) were used in 19 percent of men and 25 percent of women in the "old old" group. Use of angiotensin converting enzyme inhibitors (ACEIs) declined with age, with about 30 percent of the "old old" on these drugs. Use of angiotensin receptor blockers (ARBs) was very low during the period of the study in all age groups. Alpha-blockers are used more in older men (these drugs are also used to treat prostate problems).

Dr. Levy made the following points about those older than 80 years:

- More than 70 percent are hypertensive; only 10 percent have normal BP.
- Only 32 percent of men and 24 percent of women are controlled to target BP levels. Very few were on more than one medication.
- The proportion of hypertensive subjects receiving treatment increased with advancing age. More than 70 percent of those with hypertension were receiving drug treatment. Two-thirds were on one drug (even though the ALLHAT [Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack] study showed that more than one drug is needed to treat hypertension). Only 22 percent of men and 32 percent of women were on diuretics (even though diuretics were the preferred choice during this period).
- Hypertension carries increased risk for all forms of CVD, and risks were consistently greater for stage 2 hypertension than for stage 1. Contrary to other studies, the relative risks did not decline with age, and the absolute risks increased consistently with advancing age.
- Current rates of control in the "old old" are unacceptably low (especially in women). In light of the excess risk of CVD associated with hypertension, treatment in older people should be a national priority.

Data From the Cardiovascular Heart Study [Dr. Bruce Psaty]

Dr. Psaty reviewed data on high BP from the Cardiovascular Health Study (CHS) for patients <80 years of age and those >80. The CHS is known for its measures of subclinical disease (using carotid ultrasound and cerebral magnetic resonance imaging) and for its ability to track the effects of high BP and lipids across time.

Dr. Psaty said that data from the National Health and Nutrition Examination Study (NHANES) indicate changes in awareness, treatment, and control of BP (defined as <140/90 mmHg) during the period from 1976 to 2000. Awareness increased 19 percent, treatment

increased 28 percent, and control increased 24 percent. The JNC recommendations for first-line treatments changed from 1988 to 2003, with "JNC 4" (1988) recommending any of four major classes of drugs; "JNC 5" (1993) recommending diuretics or BBs (based on the 1991 Systolic Hypertension in the Elderly Program-SHEP and other studies); and JNC 7 (2003) recommending low-dose diuretics in uncomplicated hypertension (based on the ALLHAT study).

The CHS recruited 5,201 older adults (>65) in 1989–90 and 687 additional African Americans in 1992–93. These cohorts had to have treated hypertension (a self-report of a history of hypertension plus use of antihypertensive mediation) and BP >140/90. The subjects age 80 and older included 709 in the original cohort and 121 in the African-American cohort. Dr. Psaty reviewed the baseline characteristics of both cohorts, noting that about half of those in the original cohort reported a history of hypertension, and they had much higher BP than the subjects who did not report a history. About 35 percent in both groups had a history of heart disease.

Dr. Psaty made the following points about the CHS study:

- From 1990 to 1999, awareness rose from 75 percent to almost 90 percent in the entire cohort; treatment rose from 65 percent to 80 percent; and control rose from 38 percent to 49 percent. The subset of older patients was small and only half survived to 1999. Treatment and control levels in this group were similar to the rates for the entire cohort.

- Among treated patients, more than 95 percent had a controlled DBP <90. Most who were not controlled had mild elevations of SBP. (The importance of SBP was recognized only in the 1990s.)

- The number of patients on a single medication declined from about 60 percent to 50 percent. The mean number of medications in patients who were controlled and not controlled was the same—1.7.

- At baseline, 38 percent of all CHS participants had treated hypertension. By 1998–99, 51 percent of surviving participants had treated hypertension. The mean number of medications per treated participant increased from 1.5 to 1.7.

- Among patients without coronary heart disease (CHD) who were age 80 and older, there was no change in BB use with time. In patients with CHD, there was higher use of CCBs and BBs.

- The incidence of CVD in patients ≥80 was substantial—about 30–40 percent in women and 56–68 percent in men. Based on age, many of these people might qualify for a statin.

- As BP rises from optimal levels to stage 2+, the rate of myocardial infarction (MI) triples, stroke rates quadruple, and mortality rates double in the older adults. The association between SBP and stroke was flat among treated hypertensives.

Dr. Psaty made the following conclusions:

- Awareness, treatment, and control improved during followup in all CHS participants, including those ≥80 years.
- Informing participants about elevated BP probably served as an intervention.
- By 1999, half of CHS participants were taking antihypertensive medications.
- Despite clinical trial evidence and national guidelines, the use of recommended drugs (diuretics and BBs) declined from 1989 to 1999 in all participants, including the cohort ≥80 years. The use of ACEIs, CCBs, and loop diuretics increased in all participants, including those ≥80.
- CVD incidence rates are high in adults 80 years or older.
- SBP is a better predictor of CVD events than DBP or pulse pressure.
- The associations with CVD events are generally linear and are similar in those younger and older than 80 years.
- Among those ≥80, 41 percent of hypertensives had BP <140/90, and 55 percent of treated hypertensives had SBP <140. In the ALLHAT trial, 61.2 percent to 68.2 percent of subjects (treated with lisinopril and chlorthalidone, respectively) achieved BP <140/90 mmHg.

Dr. Psaty suggested that the CC consider treatment based on absolute CVD risk. He noted that the level of risk qualifies many people for treatment despite other risk factors.

Discussion

The following comments were made during the discussion:

- The CHS collected some data on diet and physical activity. The FHS has some dietary information, and patients occasionally were asked if they were receiving drugs for conditions other than hypertension.
- There were no major differences in the use of medications in the CHS across communities or regions.
- The FHS looked at differences in SBP, DBP, and pulse pressure across age groups. In young people, DBP was a good predictor of risk, but it is a poor predictor in the elderly (it is inversely related to risk when considered with SBP). Low DBP is an indicator of vascular stiffness, but Dr. Levy doubts that low DBP causes the outcome. In the FHS, pulse pressure in the elderly was the best predictor of outcome.

- In the FHS, cases of heart failure in the younger patients were mostly in males; among older patients, women begin to catch up, but never catch up fully.

- The FHS looked at family history (parent age of death). A study taking into account the parent's history of risk of CHD and CVD found that this improves risk prediction.

- Half of the exams in the FHS are conducted in the home or nursing home (not the clinic).

- The results of the FHS do not relate to the number of drugs used; there were small differences by drug class. Dr. Levy speculated that it might be due to the coexistence of CHD, leading to slightly more aggressive treatment in men.

- Dr. Psaty agreed that we can change physician inertia in prescribing drugs by addressing a BP goal rather than which drugs to use. He said that the half of people who are not treated might do well with modest treatment levels.

Implications of the Data for Public Health Policy: Panel Discussion [Drs. Jerry Cohen, Carlos Vallbona, and Marvin Moser]

The panel reviewed some of the issues. To begin, Dr. Cohen said that the population is aging, and the prevalence and treatment of isolated systolic hypertension (ISH) is the major problem. The SHEP study, supported by NHLBI and the National Institute on Aging, included 650 octogenarians (the group that benefited most in terms of stroke prevention). Low-dose diuretics in the treatment group reduced stroke 7.5 percent. Stroke and heart failure are common in the "old old." We have a problem convincing the "old old" that ISH should be treated aggressively. Getting patients on treatment is more important than achieving the goal of <140 mmHg SBP.

Dr. Moser said that meta-analyses indicate that treating the "old old" clearly reduces the rate of strokes and heart failure—a strong argument for treatment. Most physicians believe that they cannot achieve the goal; many are poor adherers, but even those who try hard find that many patients cannot reach goal. Patients may develop side effects that lead them to drop out of treatment. The guidelines should be more in tune with what clinicians are experiencing; otherwise we risk losing patients and physician credibility.

Dr. Moser suggested changing the message to a two-stage approach:

- Stage 1: Get the SBP down from 180 mmHg to 160 mmHg. Patients who reduced their risk of stroke and heart failure achieved a decrease of 15–20 mmHg in SBP. We cannot achieve the goal in more than 60–70 percent of patients.

- Stage 2: Get BP as close to 120/80 mmHg as possible. The two-stage approach could be over a period of 6–8 weeks.

Dr. Moser said that he believes in getting SBP <140 mmHg, but we have to modify the goal from a practical point of view. There should be a strong message to treat the elderly and use multiple drugs (based on meta-analysis data) to get SBP as low as possible. About 60 percent of the elderly can get BP pressure to goal, but for others we may have to settle.

Dr. Vallbona said that in his experience in Houston, a SBP of 150 mmHg is the best that can be accomplished even though the primary care physicians (PCPs) try their best. He suggested that the elderly regularly monitor their pressure at home. We should also emphasize lifestyle change—including reducing sodium intake and increasing physical activity. This may help achieve goal BP.

During the course of the discussion, some participants agreed with Drs. Cohen, Moser, and Vallbona about the difficulty in achieving the BP goal, but others did not and thought that we can expect more. The following comments were made:

- We must set the best goal—but not everyone is expected to meet the goal. We should also aim for better drug control of BP during the first year.

- Most likely two or more drugs will be needed to achieve goal BP. In the ALLHAT group without severe BP, half needed three drugs to meet goal. Several trials (e.g., Action to control Cardiac Risk in Diabetes [ACCORD]) show that when the right drugs are used, most patients will tolerate them. Nine of 10 patients do not get the treatment that they would tolerate.

- Physicians are doing a better job controlling BP than 5 years ago, but there is unwillingness to add diuretics. ALLHAT showed that physician inertia was the reason—not patient unwillingness.

- One ALLHAT subanalysis found that patients who did not get additional drugs (average two drugs) were mostly African American and older patients. The investigators looked at patients referred for resistant hypertension and its causes. The most common reason (for 58 percent of the cases) was the wrong regimen. The study ended up controlling 60 percent of these patients. The message has to include unambiguous endorsement of lifestyle modification plus enough drugs to get people to goal.

- All clinicians have patients they cannot control. The issue is to start low and go slow. Start low and stop is the problem. The message should be that you can clearly achieve BP goals in the vast majority of patients. Don't be content with less.

- There is a good reason for inertia—the lack of evidence that therapy in the "old old" with stage 1 hypertension is beneficial. More data are needed on outcomes, pharmacokinetics, and treatment acceptability, to show that reaching the goal is likely to be beneficial.

- Most studies of doses and regimens have been conducted in young White men. The Food and Drug Administration and industry should be asked to conduct pharmacokinetic studies and to test the right doses and regimens in persons age 80 and older.

- A chronic care model is needed. Practitioners have to tailor treatment to every patient on a daily basis. The goal is to achieve both short- and long-term goals.

- The issue of the "old old" must take into consideration compliance and family issues. How are they taking medication? Who is helping them with that? How are they paying for treatment?

ALLHAT AND JNC 7 DISSEMINATION PLAN
[Mr. Chuke Nwachuku]

Mr. Nwachuku provided an overview of a plan to disseminate the ALLHAT and JNC 7 recommendations. He began by quoting from a recent article in Lancet that said that 10,000 new clinical trials are indexed in MEDLINE annually and the Cochrane Collaboration has identified 350,000 trials. Internists would have to read 20 articles a day for a year to keep abreast of research results. Guidelines such as the JNC 7 synthesize the research and make the science more clinically relevant.

Clinicians are slow to apply the evidence in their practices. For example, the benefit of hand hygiene has been known for over 100 years, yet compliance is a problem. Knowledge and awareness are not the same as doing. About 76 percent of clinicians are familiar with "JNC 6" and usually follow the recommendations. About 61 percent report satisfaction with control of BP, but only 35 percent of patients have SBP <150 mmHg.

Factors that influence dissemination and implementation of innovation are at the levels of the care system, provider, and patient. Marketing influences figure in each category; this topic was discussed in a 2003 commentary in "Lancet" titled "The Statin Wars: Why AstraZeneca Must Retreat."

Because traditional dissemination approaches have not been fully effective, the NHLBI identified a need for a detailed dissemination plan with a requirement for evaluation. It suggested a dissemination plan that would meld the efforts of the ALLHAT Steering Committee (which published recommendations based on the trial in the "Journal of the American Medical Association" ["JAMA"] in 2002) with NHBPEP efforts to disseminate the JNC recommendations. The project is called, Improving Blood Pressure Treatment in the Community: A Joint Project of the NHBPEP and ALLHAT Collaborative Research Group.

This joint project will further the use of traditional dissemination approaches and will also use academic detailing approaches based on the behavioral theory of intervention mapping. The project will target health care providers, formulary systems, and patients. A goal is to have 200 ALLHAT investigators act as educators who will inform groups of their colleagues, reaching 39,000 providers. Office posters and script cards will provide messages. Public service announcements will encourage patients to approach providers about their BP level and use of

diuretics. The formulary system modification approach will rely on persuasion through personal contact, targeting 10 major health plans as well as Medicaid/Medicare. Professionals will be reached through peer contact, personal letters, and association newsletters. The new dissemination policy requires prespecified measures of success, a process evaluation (to determine deliverable program components), and an outcomes evaluation that will analyze trends of prescribing practices and BP pressure control rates.

Mr. Nwachuku presented an update on current ALLHAT dissemination activities, which include 200 presentations; 15 published manuscripts (37 in progress); and dissemination aids such as slides, reprints, newsletters, dear colleague letters, and frequently asked questions. Media outreach will include print, radio, TV, and Internet messages. Input to the ALLHAT guidelines has come from JNC 7, Canadian BP guidelines, and the National Kidney Foundation (NKF) experts. ALLHAT Web sites have had more than 2 million hits. The NHLBI Web site links to ALLHAT and NHBPEP CC member organizations help to disseminate the guidelines.

The ALLHAT Dissemination Committee and the ALLHAT Clinical Trials Center are revising the proposal for the dissemination plan. The next steps will include the Steering Committee's review of revisions, the NHLBI's review of the proposal, and the JNC 7 Executive Committee's review of the proposed core messages. Finally, the plan will be implemented.

Discussion

Mr. Nwachuku said that staff at 10 regional locations will be independent physicians who participated in the ALLHAT trial. The 200 ALLHAT investigator-educators will be volunteers who will receive modest honoraria for serving as educators. There will be small pilot tests.

Dr. Jay Merchant of the Center for Medicare and Medicaid Services (CMS) said that staff at CMS regional offices might be able to help.

Dr. James Reed said that the plan makes it look like JNC 7 depends only on ALLHAT, when in fact, JNC 7 reviewed all the evidence. Another participant said that the CC should not endorse a clinical trial and promote it in conjunction with JNC 7. Mr. Nwachuku asked them to hold judgment until they see the plan's messages, which will be reviewed by the JNC 7 Executive Committee. He said that the common goal of ALLHAT and JNC 7 is to reduce CVD and that both sets of recommendations have congruent messages.

Dr. Roccella said that ALLHAT will not be the only trial promoted. He added that the NHBPEP saw an opportunity to disseminate JNC 7 messages because the ALLHAT investigators are in the field. The NHLBI Office of Prevention, Education, and Control held discussions with the ALLHAT Dissemination Committee and agreed that the use of ALLHAT investigators to disseminate the JNC 7 approach would be worthwhile. One common goal is BP control.

Other suggestions were to explore ways to partner with industry, to focus on overall response rates in ALLHAT rather than just the drug results, and to not back off from disseminating trial results because of how people perceive them.

NHANES DATA FOR 1999/2000 AND 2001/2002
[Ms. Vicki Burt]

Ms. Burt reviewed the NHANES data on BP data collection. She noted that the National Center for Health Statistics (NCHS) has not yet released the data for 2001/2002.

The objective of NHANES is to assess the health and nutrition status of adults and children in the United States. Surveys have been conducted since 1960 (though the names have changed). While the surveys used to be periodic, they are now conducted annually with data released in 2-year batches. Each year, a national sample of 5,000 people of all ages is surveyed. Some subgroups are oversampled (e.g., African Americans, Mexican Americans, adolescents ages 12–19, persons age 60 and older, pregnant women, low-income non-Hispanic Whites). Because the sample is too small to oversample other minority groups, special studies are conducted for these groups in certain geographic areas. For example, there are plans to collect data in New York City in 2004. NHANES will make available public access data.

NHANES goals relate to the NHLBI education program—e.g., to monitor trends in the prevalence, awareness, treatment, and control of selected diseases. Survey topics include the following:

- **Dietary intake.** This is the only national survey that includes diet (done in collaboration with the U.S. Department of Agriculture).
- **CVD.** Data on BP and lipids are included.
- **Diabetes.** The survey will re-add the glucose tolerance test in 2005. A suggestion has been made to start this test at age 12.
- **Environmental exposure.** A large proportion of 300 laboratory tests included in the survey relate to these exposures.
- **Physical fitness and activity.** A treadmill test on people ages 12–49 has been included since 1999 (4-year data will be released in 2004). Starting in 2003, all survey participants ages 6 years and older wear a physical activity monitor for a week.
- **Kidney disease.** The data include creatinine levels.
- **Obesity and body composition.** This will be a central theme in the 2000/2001 data.
- **Respiratory disease.** Spirometry is not currently included, though the NHLBI has proposed including it.
- **Other topics.** These include hearing and balance, infectious disease, mental health, oral health, reproductive health, risk behaviors, skin disease, and vision.

The data are collected at the two mobile exam centers. The staff include two physicians who measure BP. The centers travel around the country, moving every 6 weeks. Half of the trailer is a laboratory where more than 300 tests are conducted, including tests on blood, urine, saliva, nasal swabs, and vaginal swabs. The other half is exam rooms and offices.

Ms. Burt showed data for age-adjusted prevalence of overweight/obesity among U.S. adults age 20 and older. This has increased dramatically over the last 15 years—both in adults and children. Other slides showed median serum and red blood cell folate concentrations in women of childbearing age for 1988–94 and 1999–2000, indicating a major increase in folate in the years after this vitamin was added to foods. Spina bifida rates for 1991–99 show a decrease since food fortification began.

Turning to BP measurements over the last 40 years, Ms. Burt said that BP was measured in a variety of ways. Surveys before 1980 did not use large BP cuffs or include standardized training, which may account for falsely high prevalence in early years. Standardized training was used for NHANES III (1988–94), the current survey (1999–2000; 2000–2001), and surveys in Mexican Americans.

Ms. Burt reviewed data on BP prevalence that were presented by Dr. Edward Sondik at a CC meeting in April 2002, as well as an article published in "JAMA" in July 2003 (Hajjar). Dr. Sondik compared NHANES III (1988–94) with NHANES data for 1999–2000. The study published in "JAMA" took up to six measures of BP in household and mobile exam centers and used only 1988–91 data. Dr. Sondik said that there was an improvement in treatment and control for men but no statistically significant change in prevalence. For women, there may have been an increase in prevalence, but it was not statistically significant. The "JAMA" article concluded that contrary to earlier reports, hypertension prevalence is increasing in the United States. Hypertension control rates, though improving, tend to be low. Ms. Burt said that based on the authors' confidence levels, she was not sure what Dr. Hajjar based his conclusions on.

Dr. Sondik hypothesized that increasing overweight may be a reason for the increasing prevalence of hypertension. The prevalence estimates—adjusted for obesity—explained about half of the difference in prevalence between NHANES III and 1999–2000. Based on a covariance analysis, the "JAMA" article came to a similar conclusion: 2 percent of the 3.6 percent increase in hypertension prevalence was attributed to an increase in body mass index (BMI).

Ms. Burt closed by saying that the new NHANES (1999–2002) data will include new estimates of hypertension awareness, treatment, and control.

Discussion

The following points were raised during the discussion:

- The authors of the "JAMA" article used public data access. The NCHS feels strongly that the data should be available to all.

- Responding to a comment that treadmill testing should be done in persons older than 49, Ms. Burt said that this age was selected for safety reasons (the test is

done in the trailer). Muscle strength was measured in people ages 50 and older for 4 years. All tests must be done in a 2-hour interval; there may be a need to choose between the treadmill test and the glucose tolerance test. The NCHS is considering raising eligibility criteria for the study.

COORDINATOR'S REPORT
[Dr. Roccella]

Dr. Roccella presented data on media outreach for JNC 7. The Express version was printed in "JAMA" on May 14, 2003, and the long version was printed December 6, 2003 in "Hypertension." The guidelines were discussed on 17 national broadcasts and 9 networks, including the major news shows, and reached more than 26 million people on May 14–15. Print coverage reached more than 60 million people, with articles in national newspapers, major daily newspapers, magazines, and international coverage. Several national consumer magazines and medical professional publications also developed stories on the guidelines.

Results of JNC 7 dissemination efforts included the following:

- An e-mail message was sent out through NHLBI's Health Information Network (which has 50,000 people on its e-mail list).

- More than 340,000 materials were disseminated in 6 months. "JNC 7 Express" was sold out in 8 weeks, and almost 100,000 clinician reference cards have been distributed (sold on a cost-recovery basis).

- A JNC 7 Web site was launched (http://www.nhlbi.nih.gov), including guidelines, information for patients, information for health professionals, and media and press materials. "JNC 7 Express" can be downloaded from the Web site. The materials are in the public domain and can be reproduced.

- The SCISEARCH database indicated that "JNC 7 Express" was cited 68 times from May to October 2003.

- Forthcoming is a JNC 7 wallet card, a PalmOS application to help physicians easily retrieve the key JNC 7 messages, and widespread dissemination of the JNC 7 campaign materials with integration of its messages into member organization programs. There are plans to partner with the ALLHAT group to ensure that the messages reach the public.

Dr. Roccella asked member organizations to tell NHLBI what they are doing in terms of program promotion and integration. He noted that 2,000 family physicians attended a meeting of the American Academy of Family Physicians (AAFP) for a presentation on JNC 7. The AAFP will put JNC 7 questions on its Board exam. Many CC organizations include discussions of JNC 7 on their Web sites.

Dr. Roccella announced that Dr. Moser is the recipient this year of the Dr. Stevo Julius Award for Continuing Medical Education. He will be presented with the award in February in Brazil.

ADJOURNMENT

Dr. Roccella said that the next meeting of the CC will be in September 2004. He thanked the participants and adjourned the meeting.

Attachment A

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM
COORDINATING COMMITTEE

Sheraton Reston Hotel
Reston, Virginia
December 4–5, 2003

Participant List

Members Present

Lee A. Green, M.D., M.P.H.
American Academy of Family Physicians

Howard Weiss, M.D., M.P.H.
American Academy of Ophthalmology

Kevin Rebeck, P.A.-C.
American Academy of Physician Assistants

Lynn Kirby, R.N., N.P., C.O.H.N.-S.
American Association of Occupational Health Nurses

Charles L. Curry, M.D.
American College of Cardiology

Sheldon G. Sheps, M.D.
American College of Chest Physicians

Jerome D. Cohen, M.D.
American College of Physicians—American Society of Internal Medicine

Ron Stout, M.D., M.P.H.
American College of Occupational and Environmental Medicine

Carlos Vallbona, M.D.
American College of Preventive Medicine

Michael Glick, D.M.D.
American Dental Association

Stephen Havas, M.D., M.P.H., M.S.
American Public Health Association

Laurie Willshire, M.P.H., R.N.
American Red Cross

Barry L. Carter, Pharm.D.
American Society of Health-System Pharmacists

Oscar Carretero, M.D., M.B.A.
American Society of Hypertension

Stuart Linas, M.D.
American Society of Nephrology

Jackson T. Wright, Jr., M.D., Ph.D.
Association of Black Cardiologists

Marvin Moser, M.D.
Hypertension Foundation

James W. Reed, M.D., F.A.C.P., F.A.C.E.
International Society of Hypertension in Blacks

Rita Strickland, Ed.D., R.N.
National Black Nurses Association, Inc.

William Manger, M.D., Ph.D.
National Hypertension Association, Inc.

Daniel W. Jones, M.D.
American Heart Association

Henry R. Black, M.D.
American Hospital Association

Nancy Houston Miller, R.N., B.S.N.
American Nurses Association

Leonard M. Steiner, M.S., O.D.
American Optometric Association

William A. Nickey, D.O.
American Osteopathic Association

Mark J. Cziraky, Pharm.D.
American Pharmaceutical Association

George L. Bakris, M.D.
National Kidney Foundation, Inc.

Otelio S. Randall, M.D., F.A.C.C.
National Medical Association

Edwin C. Marshall, O.D., M.P.H., M.S.
National Optometric Association

Keith C. Ferdinand, M.D., F.A.C.C.
NHLBI Ad Hoc Committee on Minority Populations

Joseph L. Izzo, Jr., M.D.
Society of Geriatric Cardiology

Kathryn M. Kolasa, Ph.D., R.D.
Society for Nutrition Education

Federal Agencies Present

Jay Merchant, M.H.A.
Centers for Medicare and Medicaid Services

William C. Cushman, M.D.
Department of Veterans Affairs

David Snyder, R.Ph., D.D.S.
Health Resources and Services Administration

Vicki Burt, R.N., Sc.M.
National Center for Health Statistics

Barbara Alving, M.D., and Edward J. Roccella, Ph.D., M.P.H.
National Heart, Lung, and Blood Institute

Thomas Hostetter, M.D.
National Institute of Diabetes & Digestive & Kidney Diseases

Members Absent

James R. Sowers, M.D.
American Diabetes Association

Jack P. Whisnant, M.D.
American Academy of Neurology

Mary C. Winston, Ed.D., R.D.
American Dietetic Association

Ray W. Gifford, Jr., M.D.
American Medical Association

Pamela J. Colman, D.P.M.
American Podiatric Medical Association

Gerald Wilson, M.A., M.B.A
Citizens for Public Action on High Blood Pressure and Cholesterol, Inc.

Rita Strickland, Ed.D., R.N.
National Black Nurses Association, Inc.

Attachment B

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM
COORDINATING COMMITTEE MEETING

Sheraton Reston Hotel
Reston, Virginia
December 5, 2003

Meeting Agendas

8:30 a.m.	**Welcome and Introduction of New Members**	Dr. Barbara Alving
	The Stroke Belt Revisited	Dr. Larry Fields
	Epidemiology of Hypertension in the "Old Old"	
	• Data from Framingham Study	Dr. Daniel Levy
	• Data from the Cardiovascular Heart Study	Dr. Bruce Psaty
	Break	
	Implications of the Data for Public Health Policy: Panel Discussion	Dr. Jerry Cohen Dr. Carlos Vallbona Dr. Marvin Moser
	ALLHAT and JNC 7 Dissemination Plan	Mr. Chuke Nwachuku
	NHANES Data for 1999/2000 and 2001/2002	Ms. Vicki Burt
	Coordinator's Report	Dr. Edward Roccella
1:00 p.m.	**Adjournment**	

NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM JOINT SUBCOMMITTEES MEETING

Sheraton Reston Hotel
Reston, Virginia
December 4, 2003

1:00 p.m.	**Welcome and Introductions**	Dr. Sheldon Sheps
	Status of the Working Group Report on Blood Pressure and Children	Dr. Bonita Falkner
	Clinical Trial Update	Dr. Jeffrey Cutler
	• ALLHAT	Dr. Jeffrey Cutler
	• Other Late-Breaking trials: CHARM, VALIANT, and INVEST	Dr. George Bakris
	• Discussion of Clinical Trials	
	Break	
	Report from the National Kidney Diseases Education Program and K/DOQI	Dr. Thomas Hostetter
	Discussion: Partnering With Existing and New Campaigns	
	Management of High Blood Pressure in Clinical Practice: Perceptible Qualitative Differences in Approaches Utilized by Clinicians	Mr. Chuke Nwachuku
	Mission Possible—National High Blood Pressure Education Month	Dr. Edward Roccella
	Reducing Sodium Intake—the United Kingdom Experience	Dr. Stephen Havas
	Closing the Disparity Gap by Translating Research Results to Practice	Dr. Claude Lenfant
6:00 p.m.	**Adjournment**	

Attachment C

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM
SUBCOMMITTEES JOINT MEETING

Sheraton Reston Hotel
Reston, Virginia
December 4, 2003

Subcommittee Members Present: Sheldon G. Sheps, M.D. (chair), George Bakris, M.D., Henry R. Black, M.D., Barry L. Carter, Pharm.D., Oscar Carretero, M.D., M.B.A., Jerome D. Cohen, M.D., Charles Curry, M.D., Mark J. Cziraky, Pharm.D., Keith C. Ferdinand, M.D., F.A.C.C., Michael Glick, D.M.D., Lee A. Green, M.D., M.P.H., Stephen Havas, M.D., M.P.H., M.S., Joseph L. Izzo, Jr., M.D., Daniel W. Jones, M.D., Kathryn M. Kolasa, Ph.D., R.D., Stuart Linas, M.D., Lynn Kirby, R.N., N.P., William Manger, M.D., Ph.D., C.O.H.N.-S., Edward Marshall, O.D., M.P.H., M.S., Nancy Houston Miller, R.N., B.S.N, Marvin Moser, M.D., William A. Nickey, D.O., Otelio S. Randall, M.D., F.A.C.C., Kevin Rebeck, P.A.-C., James W. Reed, M.D., F.A.C.E., Leonard M. Steiner, M.S., O.D., Ron Stout, M.D., M.P.H., Rita Strickland, Ed.D., R.N., Carlos Vallbona, M.D., Howard Weiss, M.D., Laurie Wiltshire, M.P.H., R.N., Jackson T. Wright, Jr., M.D., Ph.D.

Guest Speakers: Vicki Burt, R.N., Jeffrey Cutler, M.D., Bonita Falkner, M.D., Thomas Hostetter, M.D., Claude Lenfant, M.D., Mr. Chuke Nwachuku.

WELCOME AND INTRODUCTIONS
[Dr. Sheldon Sheps]

Dr. Sheps welcomed the Coordinating Committee (CC) members.

Status of the Working Group Report on Blood Pressure and Children [Dr. Bonita Falkner]

Dr. Falkner reported that the Working Group met to address an update of the "Guidelines on High Blood Pressure in Children and Adolescents." This will be the fourth iteration of the guidelines, following reports published in 1977, 1987, and 1996. The goal is to complete the report by April or May 2004. The draft report will be sent to the CC for review and comment.

The 1977 report generated the first set of blood pressure (BP) distribution curves based on data from more than 6,000 children. It showed, for the first time, the normal range of BP in children, using the 95th percentile as the cutpoint to define hypertension. The curves seemed somewhat high for adolescent boys and girls. The 1987 report included data on more than 50,000 children and refined the distribution curves with the 95th percentile considerably lower. The curve was fairly flat in adolescent girls when they reached their adult stature. For adolescent boys, the curve continued to rise, but at age 18, the 95th percentile for systolic blood pressure (SBP) was at 140 mmHg. All previous reports gave considerable attention to techniques for measuring BP, including measurement as part of routine health exams in children, with guidelines for evaluation.

The current Working Group will look again at the normative data and address the following new issues since 1996: BP measurement (especially with the inability to use mercury manometers); target organ damage (TOD) and childhood obesity; lifestyle and pharmacologic treatment; and sleep disorders.

Dr. Bernard Rosner, the statistician who worked on the previous reports, reevaluated the data, which included new data from the National Health and Examination Survey (NHANES, 1999–2000). The current height/weight percentiles from the Centers for Disease Control and Prevention (CDC) were used. The analysis showed virtually no change in the BP distribution curves by age, sex, or height. The new report will present the 90th and 95th percentiles for age, sex, and height, and will also include the 50th percentile.

Definitions. The report's definitions of hypertension and prehypertension will be congruent with the definition in the "Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure" (JNC 7). Normotension is SDB/diastolic blood pressure (DBP) <90th percentile; prehypertension (formerly called borderline hypertension or high normal) is the 90–95th percentile; and hypertension is SBP and/or DBP >95th percentile. Adolescents with SBP >120 mmHg will be considered prehypertensive, warranting recommendations for lifestyle modification.

BP measurement. The report will recommend auscultation using an aneroid device to measure BP in children. Other issues will include the use of standards for cuff sizes and indications for 24-hour ambulatory BP monitoring (ABPM) in children and adolescents.

TOD. An increase in left ventricular mass is associated with rising BP and/or body mass index (BMI). Left ventricular hypertrophy (LVH) is present in approximately 25–35 percent of children with hypertension. There are indications for echocardiography to ascertain the presence of LVH. There is no evidence for the role of proteinuria or microalbuminuria in children with elevated BP.

Evaluation. The report will update indications for further evaluation to identify causes of hypertension, other risk factors and comorbidities, and TOD.

Lifestyle therapies. The report will provide evidence for the efficacy of lifestyle therapies, including weight reduction when overweight, increased physical activity, and counseling on appropriate diet and avoidance of tobacco and alcohol.

Pharmacologic therapies. The report will review the available agents, including the historical background and the impact of the Food and Drug Administration Modernization Act (FDAMA) of 1997. Until 1996, there were relatively few clinical trials of drugs in children, and most approved drugs lacked pediatric labeling. Only 9 of 29 agents commonly prescribed for hypertension in the 2000 "Physicians' Desk Reference" had pediatric dosing information. The FDAMA gives the pharmaceutical industry a financial incentive to study drugs in children. The FDA issues written requests to manufacturers, and those that respond with data are given 6 months of additional patent protection for a completed pediatric study. The Blood Pressure in Children Act and the Pediatric Research Equity Act of 2003 extended this type of process. FDAMA has resulted in more than 220 written requests and dozens of pediatric trials since 1998.

For cardiovascular (CV) medications, 23 written requests were issued and 16 trials are completed or in progress.

Recommendations will include indications, general principles for using antihypertensive medications in children, choice of agents, and long-term issues. Dr. Falkner listed the drug categories, and number of drugs in each category that have pediatric data available: five angiotensin converting enzyme inhibitors (ACEIs), two angiotensin receptor blockers (ARBs), four beta-adrenergic blockers, and four calcium channel blockers (CCBs). (See attachment D for the listing of drugs and details on whether the data are published and trials under way.) The drug tables will be updated with information on dosing and treatment intervals. Guidelines on indications for drug therapy will be given for symptomatic hypertension, secondary hypertension, presence of other risk factors such as hyperlipidemia, chronic renal disease, diabetes types 1 and 2, and hypertensive TOD (LVH and retinal changes).

Sleep Disordered Breathing (SDB). An association between SDB and high BP has been established in adults, and there are some data in children. A recommendation will be to include a sleep history in the evaluation of hypertension in children and adolescents.

Discussion

During a question and answer session, Dr. Falkner made the following comments:

- The Working Group discussed sodium reduction. There is little evidence that changes in diet to lower sodium would lower BP in children. The literature search is not complete. Some members offered to provide more citations. The report will recommend that children receive nutrition counseling, and will discuss the Dietary Approaches to Stop Hypertension (DASH) diet.

- We do not have the results of all the drug efficacy trials. Felodipine had minimal efficacy in children, but the trial may lack the power to show this. Dr. Falkner is not aware of safety issues in children. Most of the trials were designed with multiple doses, and some trials may provide data for up to 1 year (the initial trials lasted 6–8 weeks).

- Asked if the SBP data in children hold up as well as the SBP data in adults, Dr. Falkner said that the emphasis is on SBP because of evidence from pediatric nephrology. The curves give the impression that BP tracks like height and weight, but it does not track that tightly. Children and adolescents with higher BP in childhood and adolescence are those that have hypertension as adults. Hypertension is defined as >95th percentile—a statistical definition in the absence of outcome data that are present for adults.

- The report will recommend increased physical activity in the context of changing lifestyles, but it may not recommend a specific program (such as 10,000 Steps). Participation in sports will be encouraged unless there are specific indications against this.

- There will be a statement that children with both hypertension and hyperlipidemia should have their BP lowered.

Clinical Trial Update [Dr. Jeffrey Cutler]

Dr. Cutler reviewed hypertension treatment trials, including some new findings published during the last year, as well as new perspectives on older data. The bottom line is that the data support the findings of "JNC 7 Express" and the ALLHAT study.

ALLHAT

Dr. Cutler reviewed the ALLHAT subgroups and secondary endpoints, including race, estimated glomerular filtration rate (GFR)/diabetes, heart failure (HF), and new diabetes, as well as comparisons across trials.

- In the comparison of amlodipine (CCB) versus chlorthalidone (diuretic), there was no difference in the prevalence of coronary heart disease (CHD), total mortality, or combined CHD. Amlodipine was somewhat better at preventing stroke, while chlorthalidone was better for preventing HF. Chlorthalidone was better at preventing HF in subgroups divided by age, sex, race, and diabetes.

- In the trial of lisinopril (ACEI) versus chlorthalidone, there was no difference in CHD, total mortality, or combined CHD. Chlorthalidone was better at preventing stroke, combined CVD, and HF. African Americans had a higher relative risk of combined CVD and stroke (significantly higher in the ACEI group), while non-African Americans had a significantly higher rate of combined CVD and HF. The results by race were due in part to differences in BP results. African Americans in the ACEI group had an 4 mmHg higher SBP.

- Prospective observation studies predict that the 4 mmHg difference in African Americans would lead to a 19 percent higher risk of stroke and a 14 percent higher risk of HF mortality (versus the 40 percent and 32 percent higher risk observed in ALLHAT). Thus, the BP difference explains about half of the observed event differences.

- In the ALLHAT study population as a whole, there was no difference in the risk of end stage renal disease (ESRD) with chlorthalidone compared with amlodipine and lisinopril. At the end of the study, estimated GFR was higher in patients randomized to amlodipine compared with chlorthalidone.

- A posthoc analysis was conducted to determine whether treatment with CCB or ACEI—each versus diuretic—lowers the incidence of ESRD in high-risk hypertensive patients stratified by baseline GFR. Differences by baseline GFR group were not statistically significant, even among diabetic participants.

- The strength of the data are the number of patients with moderate reduction in GFR, and the fact that the number of patients developing ESRD was higher in

ALLHAT than in other renal studies. However, data on proteinuria (an independent predictor of decline in renal function) were not available for ALLHAT participants. High-risk hypertensive patients are at higher risk for CVD than ESRD (30 percent versus 2 percent). Therefore, it is more important to prevent CVD than renal insufficiency. The risk of ESRD is higher in diabetic participants and those with reduced GFR at baseline.

- ALLHAT found that patients hospitalized for HF had a 25 percent increase in mortality at 2 years and a 50 percent increase at 5 years. A HF validation substudy (a central diagnostic review of HF hospitalizations of 2,000 patients) showed a high degree of agreement (71–83 percent) with diagnoses assigned by ALLHAT investigators.

- Relative risk calculated for several stringent definitions of HF confirm the superiority of a thiazide-type diuretic over a CCB, an ACEI, or an alpha-blocker in preventing the onset of symptomatic HF in hypertensive patients with at least one additional risk factor.

- Biochemical results include fasting glucose at baseline and at 4 years for patients in the chlorthalidone, amlodipine, and lisinopril groups—both in the overall cohort and those with diabetes at baseline. The fasting plasma glucose was 4 mg/dL higher with chlorthalidone compared with lisinopril (the value for amlodipine was in between). Incidence of new diabetes was 4 percent higher in the chlorthalidone group compared with the lisonipril group. Three of four cases of new diabetes were not related to group assignment.

- ALLHAT plans to determine the implications of differences in new diabetes by determining the morbidity/mortality consequences of thiazide-associated diabetes in observational studies and ALLHAT followup. It will also determine whether it is possible to prevent or reverse new diabetes by maintaining potassium balance, controlling weight, and increasing physical activity.

- ALLHAT needs to look at CVD differences in diabetics and nondiabetics. The study may also examine the potential of potassium-sparing agents and ACEI/diuretic combinations to prevent diabetes in the high-risk group with impaired fasting glucose (IFG).

Comparison With Other Trials

Dr. Cutler compared ALLHAT with other trials involving diuretic plus or minus beta-blocker (D/BB). He showed a table listing ALLHAT and six other large hypertension trials (CAPPP, NORDIL, CONVINCE, STOP-2, INSIGHT, and ANBP-2) comparing two or more regimens in terms of CVD or CV mortality. Alternative treatments have not been proven superior to D/BB treatment in any trials.

The Second Australian National Blood Pressure Study (ANBP-2) was published after ALLHAT in 2003, and considered by some to contradict ALLHAT. With 6,000 participants

(versus 24,309 in ALLHAT), ANBP-2 examined the use of the ACEI, enalapril, versus the diuretic, hydrochlorothyazide (HCTZ), and the primary outcome was all CV events or death from any cause. Dr. Cutler reviewed first BP, endpoints, results by gender, and baseline characteristics of the two studies and concluded that their results are not contradictory. However, he pointed out several differences in the studies. ALLHAT's randomized double-blind design protects against biases more effectively than ANBP-2's open-label probe design. In terms of sample size and number of events, ALLHAT has 4–10 times more data than ANBP-2. Treatment differences were consistent across genders in ALLHAT, while differences were noted only in men in ANBP-2.

Meta-Analyses

Dr. Cutler described and compared two meta-analyses.

The Blood Pressure Lowering Treatment Trialists' Collaboration ("Lancet," November 2003) was a prospective study including trials completed after 1995. The analysis separated the placebo/usual care control and direct comparator trials. There was no "standard regimen" in direct comparator trials where diuretics and BBs were combined. The Collaboration's second cycle included 29 trials (n=162,341). Dr. Cutler reviewed the results of comparisons of active treatments (ACE versus diuretic/BB; calcium antagonist versus diuretic/BB, ACE versus calcium antagonist) for CHD, stroke, HF, and major CV events. The Collaboration also examined whether differences in cardiovascular outcomes among randomized groups were related to observed differences in BP. The following conclusions were made:

- ACEIs, calcium antagonists, and diuretics/BBs have similar net effects on total CV events.
- ARBs are effective in reducing total CV events.
- ACEI and diuretic/BB-based regimens are more effective than calcium antagonists for preventing HF.
- Calcium antagonists may be more effective for stroke prevention.
- More intensive BP lowering produces larger reductions in stroke and total CV events.
- Size of BP difference between randomized groups is closely associated with reduction in risk (except for HF).
- Size of BP reduction appears to be an important determinant of outcome.

The Network Meta-analysis (Psaty et al., 2003) included all 42 post-1995 clinical trials (including ALLHAT) with a total of 192,478 patients who were randomized to diuretics, BBs, CCBs, ACEIs, alpha-blockers, ARBs, or placebo. A single analysis (no subgroup analysis) included direct comparisons of treatment strategies within randomized trials, as well as indirect comparisons constructed from two trials that have one treatment in common. The analysis

included CHD, stroke, HF, major CVD, CVD mortality, and total mortality. Low-dose diuretics were compared with CCBs and with ACEIs. The two main findings were:

- Compared with CCBs, low-dose diuretics resulted in a nonsignificant trend toward a lower rate of CHD and a significantly (25 percent) lower risk of HF.

- Compared with ACEIs, low-dose diuretics resulted in a 12 percent lower risk of HF and 14 percent lower risk of stroke.

Dr. Cutler said that findings from other large CVD endpoint trials are totally consistent with ALLHAT's conclusion that diuretic-based antihypertensive treatment is unsurpassed in preventing major CV morbidity and mortality. The findings offer some support for the treatment's superiority in reducing risk of HF.

Other Late-Breaking Trials: CHARM, VALIANT, and INVEST [Dr. George Bakris]

CHARM

Candesartan in Heart Failure Assessment of Reduction in Mortality and Morbidity (CHARM) compares the ARB, candesartan, to placebo in patients with systolic and diastolic HF in a three-component study: (1) alternative therapy to ACEI (patients ACEI intolerant); (2) adding an ARB to current ACEI-based therapy; and (3) preserved therapy (ACEI treated/not treated). The primary outcome for each trial was CV death or hospitalization for HF. Dr. Bakris reviewed the inclusion and exclusion criteria, study design, and baseline characteristics. All participants were receiving therapy for hypertension. He also reviewed the results for primary and secondary outcomes; secondary outcomes for each of the three components; and overall results for CV death, non-CV death, CV death or CHF hospitalization, and all-cause death.

Overall results of CHARM (7,601 patients, median followup 38 months) indicated that treatment of a broad spectrum of symptomatic HF patients with candesartan resulted in a 9 percent reduction in all-cause deaths (significant when adjusted), a 12 percent reduction in CV mortality, a 21 percent reduction in CHF hospitalizations, and a 16 percent reduction in CVD deaths or CHF hospitalization. Results for secondary outcomes were all significant.

VALIANT

Valsartan in Acute Myocardial Infarction Trial (VALIANT), the 2003 version of the Acute Infarction Reperfusion Efficacy (AIRE) study, was designed as a mortality trial in high-risk patients—who derived particular benefit from an ACEI—to determine whether the ARB, valsartan, post-myocardial infarction (MI) was superior to captopril in improving survival and, with equal statistical power, whether the addition of valsartan to captopril was superior to the proven dose of captopril in improving survival. If valsartan was not superior to captopril, a noninferiority analysis was prespecified to determine whether valsartan could be considered "as effective as" captopril.

VALIANT was conducted within 10 days in patients with acute MI who have either clinical/radiology signs of HF or LV systolic dysfunction. The double-blind, active-controlled study randomized the patients to captopril, valsartan, or captopril plus a lower dose of valsartan.

Median study duration was 25 months. The primary endpoint was all-cause mortality; secondary endpoints were CV death, MI, or HF. More than 14,000 patients were studied a median duration of 25 months. Dr. Bakris described the baseline characteristics and medications, the drug dose titration scheme, and study results. Valsartan was as effective as captopril in reducing all-cause mortality as well as CVD death, MI, and HF. It is a clinically effective alternative to ACEI with all standard post-MI therapies (Pfeffer et al., 2003). Furthermore, with valsartan, there were fewer discontinuations due to adverse events. Dr. Bakris concluded that in patients with MI complicated by HF, LV dysfunction, or both:

- Valsartan was as effective as a proven dose of captopril in reducing the risk of death, CV death, or hospital admission for nonfatal MI or HF.
- Combining valsartan with a proven dose of captopril produced no further reduction in mortality—and more adverse drug events.
- The implications are that valsartan is a clinically effective alternative to an ACEI.

INVEST

International Verapamil SR/trandolapril Study (INVEST), published December 3, 2003 in "JAMA," used a probe design to determine the effects on clinical outcomes of two BP treatment strategies in more than 22,000 hypertensive patients with coronary artery disease (CAD) and hypertension: calcium antagonist (verapamil SR) versus noncalcium antagonist (the BB atenolol). The hypothesis was that treatment strategies are equivalent in risk for adverse outcomes. The primary outcome in the intent-to-treat analysis was first occurrence of either death (all cause), nonfatal stroke, or nonfatal MI. The secondary and other outcomes were CV death, nonfatal MI, nonfatal stroke, CV hospitalization, and BP control.

Dr. Bakris described INVEST's entry and exclusion criteria, the study population, and the treatment strategies. Patients in the calcium antagonist strategy (CAS) received verapamil SR with the ACEI, trandolapril, added in steps 2, 3, and 4; the diuretic, HCTZ, was added in step 4. Patients in the noncalcium antagonist strategy (NCAS) received the BB, atenolol, in steps 1–4, with HCTZ added in steps 2–4, and trandolapril added in step 4. Results included the following:

- There was no difference in mean BP control. Overall control at 2 years was comparable to that achieved in other studies (ALLHAT and LIFE).
- There was also no difference in the primary outcome—being alive free of MI or stroke over the mean followup of 2.7 years.
- There was no difference in secondary outcomes, except that among patients with prior history of HF, those on BB/diuretic did better than those on CAS.
- New-onset diabetes was reduced in the verapamil arm compared with the BB arm. (Dr. Bakris said that he would lay the blame on the BB, not the diuretic.)

Discussion of Clinical Trials

- Asked why ALLHAT showed no difference in total mortality with the diagnosis of new-onset HF, Dr. Cutler said only a handful of deaths would be expected. A posttrial followup may show differences.

- Dr. Cutler said that relative risks as a function of baseline GFR were not adjusted for on-treatment BP. He agreed that a table to explain this would help.

- Asked for his opinion of the network analysis (the questioner did not think much of it), Dr. Cutler responded that it provides another piece of information.

- Asked why ALLHAT and ANBP-2 should be compared—considering the difference in the age of subjects in the two studies, the greater number of diabetics and African Americans in ALLHAT, and the use of a different diuretic—Dr. Cutler said that we can compare any trials and find many differences; the challenge is to tease out the influential ones. He thought that the racial differences are important but discounted the gender differences. He added that in ALLHAT, the effects were the same in diabetics and nondiabetics. The only reason we compare the two trials is that some felt that the ANBP-2 refuted ALLHAT. ANBP-2 was not a comparable study—it was small and had flaws.

- Diuretics and BBs are different pharmacologically but are similar in their ability to lower BP. One limit of the Controlled ONset Verapamil Investigation of Cardiovascular Endpoints (CONVINCE) trial is that the patients were not randomized to BBs or diuretics; they were assigned by physicians.

- Asked if ALLHAT will be examined for differences in subjects' use of drugs—such as aspirin and lipid-lowering medications—to detect what may have driven the rate of stroke and combined cardiac events in the African American cohort, Dr. Cutler said we can—and should—look at nonstudy ancillary treatments.

- A participant noted that BB use may account for the difference in event rates in ALLHAT versus ANBP-2. He asked whether the difference in ACEI use in the INVEST trial could account for differences in the study arms. Dr. Bakris said that the analysis has been done, but the data are not obvious and the analysis was murky. Dr. Sheps added that the INVEST study provided evidence that the ACEI, trandolapril, was protective with any of the regimens. Two factors appear related to dosage: increasing risk with diuretics and lower risk with trandolapril.

- A Finnish paper on new-onset diabetes (Hafner, "Circulation," 2001; 103:346) showed that patients with a BMI >30 had a much higher risk for new-onset diabetes if they were on a BB or diuretic—but it was primarily driven by the BB. At BMI <27, there was no increased risk. Dr. Sheps later said he does not think that the literature is robust enough to support the role of BBs in diabetes.

- There is often confounding evidence when observational studies look at diuretic use. People who are sicker get higher doses of diuretics. In ALLHAT, there is a definite difference in outcomes. The presumed effect of diabetes incidence on CV outcomes over time is not known. We don't know if changing hemoglobin A1c levels will affect these outcomes; the Action to Control Cardiac Risk in Diabetes (ACCORD) trial is addressing this.

- Lowering hemoglobin A1c in diabetics has a large effect on CV events, as shown in several trials, including the United Kingdom (U.K.) Prospective Diabetes Study.

- An analysis of the MRFIT data has examined the issue of thiazide diuretic-induced new diabetes. Vaccaro, 1998 published a paper based on these data, comparing patients with diabetes and no diabetes during 16 years of followup. The analysis separated the diabetics who had been on diuretics prior to developing diabetes from those who had not been on diuretics. Surprisingly, mortality was the same in both groups. We need to examine all the data for the diabetes outcome.

- Predicted differences in fasting glucose in the groups that received diuretics and ACEIs would predict a very low, 10–20 year difference in coronary outcomes (compared with a big increase in HF). Diuretics should be included in the regimen, especially for African Americans, who have a 40 percent increased risk of stroke or HF.

- Is diabetes related to potassium depletion? A paper in "Hypertension" looked at this issue and speculated that effects have not been seen yet because not enough time has elapsed. Dr. Bakris and Dr. Jim Sowers are writing an editorial on the potassium issue.

- Dr. Sheps said that overviews of ALLHAT and JNC 7 continue to support the use of diuretics. An unresolved issue is the impact of diuretics on diabetes. The studies have been relatively short; in people with diabetes or impaired glucose tolerance , the mortality curves tend to accelerate after 5–7 years.

- Asked if there has been "flak" regarding the conclusions of JNC 7, Dr. Roccella noted that he has taken flak on all of the JNC reports. Dr. Bakris said that JNC 7 was discussed at a meeting of the Spanish Hypertension Society; no one disagreed that diuretics should be part of the regimen, though there was some disagreement about their use as first-line therapy.

Report from the National Kidney Diseases Education Program (NKDEP) and Kidney Disease Outcomes Quality Initiative (K/DOQI) [Dr. Thomas Hostetter]

Dr. Hostetter thanked Dr. Roccella for his help in advising the NKDEP, which is run by the National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK). He listed three

reasons for the NKDEP: (1) kidney failure is a public health concern, (2) economical, effective testing and therapy exist, and (3) testing and therapy are inadequately applied.

The number of people developing kidney failure has doubled each decade since 1984. In 2000, 100,000 people developed kidney failure, leading to a total prevalence of 370,000. Most of the patients were on dialysis because kidney transplants have lagged behind the incidence of ESRD (also known as kidney failure). By 2010, 660,000 patients with ESRD are projected. Deaths from ESRD are second only to those from stroke and lung cancer. In 2000, there were 67,000 deaths from ESRD. By 2010, the number of people dying with treated uremia will be about 150,000.

The underlying causes of ESRD (in rank order) are diabetes, hypertension, glomerular nephritis, and polycystic kidney disease. Hypertension has not abated in recent years, though it is overshadowed by the growth of diabetic ESRD. In 1990, the highest incidence of kidney failure was found in the Stroke Belt, but in 2000, it has spread throughout the United States.

An analysis of data from 1978–91 (Munter et al., 2003) found that only 40 percent of the incidence was attributable to three factors: the increase in diabetes, patients who survived an MI or stroke, and the growth of the U.S. population. Later, Dr. Hostetter said that this analysis should be repeated with data from the 1990s to find out how much of the remaining 60 percent is the result of offering dialysis to patients who were considered marginal, particularly the elderly.

Using NHANES III data, Coresh et al. (2001) estimated that approximately 8 million people had a GFR that was half normal or less (59–30 ml/min/1.73 m^2), and about 10 million more have albuminuria.

Dr. Hostetter cited epidemiologic evidence linking CVD and chronic kidney disease (CKD), based on studies by Flack et al., 1993; Levey et al., 1998; Jenson et al., 2000, Rullope et al., 2001; Mann et al., 2001; and Collins et al., 2002.

- The risk of CVD is increased 1.4–2.05 times with creatinine >1.4–1.5 mg/dL.
- The risk of CVD is increased 1.5–3.5 times with microalbuminura.
- Annual mortality from CVD is increased 10–1000 times with ESRD.
- In the Medicare population, first-year CVD mortality (17 percent) is five times kidney failure incidence (3.5 percent) after diagnosis of CKD and diabetes. In analysis of younger patients, ESRD overshadows CVD.

Treatment to prevent progression of CKD to kidney failure includes the following:

- Intensive glycemic control lessens the progression from microalbuminuria in type 1 diabetes (DCCT, 1993).
- Antihypertensive therapy with ACEIs lessens proteinuria and disease progression in people with established kidney disease (meta-analyses by Giatras et al., 1997; Psait et al., 2000; and Jafar et al., 2001)

- Low-protein diets lessen disease progression in people with established kidney disease (meta-analyses by Fouque et al., 1992; Pedrini et al., 1996; Kasiske et al., 1998).

In the last 10 years there has been evidence that we can slow progression of CKD, but the disease is not being recognized or treated. Only 10 percent of Medicare beneficiaries with diabetes receive annual urine albumin tests (McClellan et al., 2000). Patients (especially African-American men) are referred late to a nephrologist (Kinchen, 2002). Less than one-third of people with identified CKD get an ACEI (McClellan et al., 1997).

With the goal of changing the incidence and prevalence of CKD, the NKDEP decided to focus on the high-risk populations. Compared with Whites, relative risks are 4.45 times greater for African Americans, 3.57 times greater in Native Americans, and 1.59 times greater in Asians/Pacific Islanders (Xue et al., 2000). The NKDEP's target audiences are African Americans with hypertension, diabetes, and/or a family history of kidney failure, as well as primary care providers (PCPs). PCPs must be engaged because there are an estimated seven new patients per day per nephrologist. (There are about 4,500 full-time nephrologists.)

Based on an NKDEP survey of 600 PCPs:

- Ninety-five percent believe that therapy for CKD is moderately to very effective for diabetic or hypertensive CKD.

- Seventy-seven percent said that a creatinine >1.6 mg/dL is the level at which a 65-year-old diabetic, hypertensive, White woman weighing 50 kilograms would have CKD.

Dr. Hostetter noted that is unreasonable to expect a PCP to do these calculations in practice. Therefore, along with other organizations, the NKDEP advocates that laboratories report GFR automatically with serum creatinine. The equation derived from the Modification of Diet in Renal Disease study is useful but has weaknesses. Work is ongoing to validate the equation in more diverse populations. Variation in the laboratory assay for creatinine is another problem.

Current NKDEP Activities

Pilot sites in Atlanta, Baltimore, Cleveland, and Jackson, Mississippi, are testing educational materials that include church kits, dialysis kits, public service announcements for radio and print, and patient brochures. A 4-minute video designed for dialysis units encourages relatives of ESRD patients to be tested. Results from the pilot sites will be available in May, with the hope of distributing the materials in June.

Other activities include the Laboratory Work Group, which will help standardize GFR measurement and establish a gold standard for the creatinine improving equation. The Quality Indicator Work Group is piloting with the Center for Medicare and Medicaid Services (CMS) and Emory University to look at 15 hospitals in Georgia, with the goal of identifying quality

indicators and proposing clinical performance measures for CKD to the CMS. In addition, industry partners help distribute materials and implement GFR reporting.

K/DOQI

The National Kidney Foundation (NKF) K/DOQI began with a dialysis quality indicator approach in the 1990s. This was then extended to pre-ESRD CKD. "The National Kidney Foundation Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification" was published in August 2003 in the "Annals of Internal Medicine" by a committee chaired by Dr. Andrew Levey. This document classifies kidney disease as five stages: (1) kidney damage with normal or increased GFR >90; (2) kidney damage with mild decreased GFR 60–89; (3) moderately decreased GFR 30–59; (4) severely decreased GFR 15–29, and (5) kidney failure, GFR <15. This classification agrees with JNC 7 with regard to special indications for defining CKD as albuminuria (GFR <60).

The NKDEP and the K/DOQI produced "Clinical Practice Guidelines on Blood Pressure Management and Use of Antihypertensive Agents in Chronic Kidney Disease," a document that recommends ACEIs and/or ARBs for CKD patients who are diabetic and for nondiabetics with proteinuria. In addition, diuretics are recognized as almost always essential in renal patients. The evidence was too slim to recommend agents for nondiabetic kidney disease with lower grades of proteinuria. There is no preference for a first-line agent in transplant patients.

Discussion

- What is the influence of Medicare reimbursement on increasing rates of treatment of older patients? A participant suggested presenting age-adjusted data. Dr. Hostetter agreed; he added that the median age of initiation of dialysis has not changed for 10 years (age 64 in Whites, 58 in African Americans).

- While hypertension and diabetes are both predominant causes of kidney damage, more emphasis should be given to hypertension. Controlling BP is more important than glycemic control. Dr. Hostetter said the listing of diabetes as the first cause of ESRD is arbitrary; he agreed that most diabetics with ESRD are hypertensive.

- PCPs and nephrologists need to recognize that modest elevations in creatinine levels (e.g., 1.5) represent moderate-to-advanced renal insufficiency, and that these patients should have a lower BP goal (requiring more than one drug in most cases).

- PCPs report high rates of testing diabetic patients, but the figures may be inflated. They know what to do but may not act on it. Providing GFR levels that warrant referrals to a nephrologist should help.

- The disk in the meeting packet contains 30 slides for PCPs. When these slides were presented to a group of PCPs in Chicago, the numbers shocked them. A paper by Krumholz showed that as stages of nephropathy increase, the use of

aspirin, ACEIs, and BBs decrease. When patients start dialysis, 50 percent of the ones who should be on these agents are no longer on them.

Management of High BP in Clinical Practice: Perceptible Qualitative Differences in Approaches Utilized by Clinicians [Mr. Chuke Nwachuku]

Mr. Nwachuku presented the results of a focus group study used to gain insight from clinicians who treat patients with high BP about management in relation to "JNC 6" guideline treatment recommendations. The study compared physicians who were more successful in achieving BP control (<140/90 mmHg) with those who were less successful. The advisory group that planned the study was formed with members from the Medicine Group, Boehringer Ingelheim, NHLBI, the ALLHAT Clinical Trials Center, and Migliara/Kaplan Associates.

Physicians were selected from the ALLHAT database, with two groups of physicians—a more successful group at achieving BP control and a less successful group—formed at each of four sites (New York, Atlanta, Chicago, and Los Angeles). There were four to eight participants in each of the eight groups. Limited focus groups were also conducted with office staff and non-ALLHAT patients.

Focus group sessions were approximately 90 minutes long and were tape recorded. At all sites, an experienced professional focus group facilitator (not a hypertension or clinical trials expert) led the discussions. The focus group study also looked at nonverbal factors, such as the length of time a physician spoke on a given question. Dr. David Morgan at Portland State University and Migliara/Kaplan Associates (which also wrote the report) conducted the data analyses.

Mr. Nwachuku reviewed the more successful and less successful groups' responses to the following questions:

Why are BP control rates low? The more successful group made the following points: Clinicians are not sufficiently aggressive with therapy and do not fully understand the risks associated with hypertension. Hypertension is no longer "in style" and needs to be made "more glamorous." There are no support groups for patients with hypertension; they do not understand that a SBP of 160 mmHg is unacceptable. Patients are looking for a quick fix. Physicians think BP is hard to control; there are too many classes of medications, and they don't know how to use them. Comorbid conditions present a bigger problem; physicians have too many patients and too little time. Patients do not have time to follow advice for lifestyle modification.

The less successful group agreed that physicians are not as aggressive and that hypertension needs to be "jazzed up." But they blamed lack of patient commitment and felt that "white coat hypertension" influenced measurement. They said that BP goals are not flexible, comorbid conditions have priority, and too many pills are needed to reach control (suggesting the need for different formulations).

What do you think about the 140/90 mmHg treatment goal in general? Both groups agreed with this goal for most patients and said they would modify it according to patient risk. The more successful group said they are more aggressive with younger patients and that they

inform patients about the goal. The less successful group thought that they could be less aggressive for geriatric patients (they considered an SBP of 170 mmHg acceptable).

What are diagnostic criteria for high BP? In both groups, physicians thought that at least two measurements were needed. Both groups also encourage patient self-measurement and more frequent clinic visits for newly diagnosed patients.

What patients are successful in reaching the recommended goal? Both groups said that successful patients are self-motivated and educated. The more successful group of physicians said that these patients are also cooperative, competitive, compliant with refills, tend to change lifestyle, and had a friend or family member with a clinical event. The less successful group said that the successful patients have cultural advantages and are compulsive and elderly.

What are barriers to successful treatment? Both groups mentioned asymptomatic disease as a barrier. The more successful group mentioned lack of a partnership with patients, patient stress, patients who are passive-aggressive, patient preoccupation with side effects, alternative medicine, difficulty modifying behavior, cultural issues, switching providers, and lack of time to counsel patients. Barriers mentioned by the less successful group included dislike of pharmacologic treatments, lack of trust, lack of acceptance of authority, lack of access to care, lack of health insurance, formularies, cost, inconducive home environments, multiple medications, and side effects.

What are the most important issues for improving BP? Both groups mentioned the need for tailored guidelines. The more successful group mentioned clinician adherence, clinical education, HMO accountability, diuretic treatment, public education, grassroots efforts, the uninsured population, and the need to keep it simple. The less successful group mentioned trust in physician, patient feedback, public education, and cost of medications.

Mr. Nwachuku said that the following key conclusions kept recurring:

- There is little appreciation of risk conferred by elevated SBP, especially in the elderly.
- Hypertension needs to be "jazzed up."
- Grassroots efforts for high BP are needed.
- Even before the end of ALLHAT and publication of the results, physicians who were more successful in controlling patient BP advocated the use of diuretics.
- The more successful physicians were more likely to engage in shared decision making with their patients.

Mr. Nwachuku said that these findings might be the basis for a more national survey. He also mentioned study limitations, including the fact that the study was done only in a group of selected ALLHAT physicians who would be expected to be better educated about hypertension. The issue of definition of SBP is probably more significant in the larger population of physicians.

Discussion

- In patient focus groups, patients said that the more successful physicians were those who partnered with their patients. This involves office staff as well as physicians.

- Less successful physicians seemed to blame someone else for failure to achieve BP control. They may not perceive what patients want.

- This study demonstrates the need for followup with multimethod, qualitative research methods and with a sampling group beyond ALLHAT.

- The first focus group report was issued in January 2000. Things have changed since then, and some of the questions may be obsolete. The message about SBP should be stronger today. The questions reflect some of the biases of the ALLHAT study. We do not yet have the answers we need. But the study does provide answers to the question of what makes a successful practitioner.

Mission Possible—National High Blood Pressure Education Month [Dr. Roccella]

Dr. Roccella reported that NHLBI will revise the theme for the month, "Mission Possible," which has been discussed previously by the CC. For National High Blood Pressure Month, the NHBPEP will provide articles that community organizations can use in local newspapers, radio spots in Spanish, coupons for discounts in grocery stores and pharmacies, and paycheck stuffers announcing National High Blood Pressure Month.

Dr. Joseph Izzo strongly suggested that the following statement be made: "Reduction in high BP is the most important thing one can do to achieve good, long-term cardiovascular health."

Reducing Sodium Intake—The United Kingdom Experience [Dr. Stephen Havas]

Dr. Havas provided an update on the U.K. approach to reducing sodium in its food supply and implications for the United States. Last summer, he went to the U.K. where he met with a leader on this issue, Dr. Graham McGregor, and participated in discussions with the Food Standards Agency (FSA).

"How Far Should Salt Intake Be Reduced," is the title of an article by Dr. McGregor that will appear in the December 2003 issue of "Hypertension." This article includes data on the effects of reducing sodium in hypertensives and normotensives. In both groups, the more sodium levels are reduced, the more SBP and DBP are reduced. There is a greater effect on SBP versus DBP, and a greater effect in hypertensives than in normotensives. The article includes data from a Finnish study (Tuomilehto et al., 2001) that collected urine samples from 2,500 men and women and followed them for 12 years to show the effects 6 gm/day increase in salt intake (about 1 teaspoon). Those with higher salt intake had increased risk of death from CHD, CVD, and all causes compared to those with lower salt intake. The study controlled for other CV risk factors, including BP.

The Consensus Action on Salt and Health (CASH) group was established in 1996 to bring pressure to adopt recommendations of a 1994 report that recommended substantial reduction of sodium in food. The U.K. government initially backed the report but withdrew its support after pressure from the food industry. "Salt and Health," a report published in 2003 by the Scientific Advisory Committee on Nutrition, reviewed the evidence on salt and sodium and confirmed the original recommendation to reduce sodium intake.

The FSA, which is responsible for food safety issues, is creating a model to determine how much sodium would need to be reduced. It will meet with the food industry to identify the goals for sodium reduction. If the industry does not meet these goals, the FSA may publish the names of the products in newspapers or label the products as unsafe. The FSA is also working with the restaurant and catering industries to reduce salt in food. An article on the FSA Web site discusses a big drop (20 percent) in salt levels in bread. Dr. Havas quoted from several articles about the FSA's efforts.

CASH believes the FSA is not working hard enough to put pressure on the food industry to lower salt in processed foods.

Dr. Havas showed samples from several CASH materials for public education. One points out that one serving of pizza contains 7 grams of salt while recommended daily consumption should not exceed 6 grams. A poster asks, "Do you know how much salt the average child consumes each year? Take a guess…nearly 4 kilos! Is this unhealthy? YES." Another gives low-salt recipes for children. CASH recommends that people consume no more than 0.1 gram of salt per 100 grams of food.

Dr. Havas also showed examples of articles in the U.K. press about the dangers of high levels of salt in food, such as "Salt Warning. We're eating twice as much salt as we should." A CASH press releases states, "100 people will die today because guidelines on salt have yet to be implemented. How long are we going to have to wait?" An article by Dr. McGregor is titled "Cost of Poor Blood Pressure Control in the U.K.: 62,000 Unnecessary Deaths Per Year."

Dr. Havas reminded the group that at its last meeting, he issued call for action to modify food processing and restaurant practices as the only way to achieve the NHBPEP recommendations for reducing sodium intake. He reviewed prior actions on sodium by the CC, including statements in 1993, 1996, and 1999. In December 2002, the CC voted to endorse the American Public Health Association (APHA) policy resolution for reducing sodium in the food supply by 50 percent over 10 years— this was included in JNC 7. There was some response in the U.S. media—but not as large as the response in the U.K.

Dr. Havas asked the following questions: How can we get the food industry to move aggressively on the issue? How do we generate more media interest in this issue? What should the role of the CC members be? Should the recommended level of sodium intake be lowered to <1,500 mg/day? Should we invite the food industry to the next CC meeting. The U.K. experience indicates that progress can be made if the Government and industry work together. Salt levels have been reduced progressively in Finland as well. The biggest success is working directly with food manufacturers to start lowering sodium in the food supply.

Discussion

- A participant noted that the NHBPEP previously made an enormous effort to influence the food industry. Some manufacturers did respond (Campbell Soup, Gortons, Gerbers). There was also an effort on the part of the media. We have done all the things that the U.K. has done, but we have a larger population with more diverse ethnic groups. We should do it again.

- Dr. Havas acknowledged previous efforts but said that we have not done enough. He noted that the Salt Institute's Web site attacked the science in the APHA's resolution. An article quoted a Salt Institute spokesperson as saying that people without high BP don't need to worry about salt; they need to eat more fruit and vegetables.

- The message should be simple. For example, it could list the 15 foods with the highest salt levels and tell people that if they use them moderately or not at all they will have a health benefit. A group at Stanford advised people to avoid 10 foods that have more than 150 mg/serving.

- More people are eating in restaurants. Because sodium intake is not labeled on the menu, they don't know how much salt they are ingesting.

- Two initiatives provide opportunities: almost every State is reviewing the criteria for foods to be sold in vending machines in schools (based on the childhood obesity pandemic), and the CDC has urged many States to look at healthy dining criteria. Partnerships with groups concerned with increasing physical activity and nutrition might make significant progress.

- We must continue to work at the industry level. Industry wants data that show that the public will accept the taste and consistency of low-salt foods.

Closing the Disparity Gap by Translating Research Results to Practice
[Dr. Claude Lenfant]

Dr. Lenfant, who retired as director of the NHLBI in August 2003, said that the number of scientific publications increased dramatically during his 33 years at the National Institutes of Health. A concern is that the translation of research results does not go far enough—all the way to the patient. During his tenure at NHLBI, many programs were established, including the NHBPEP, which is 31 years old. Since the creation of the NHBPEP, there have been 22,000 publications dealing with clinical research on treatment of hypertension. During the last 2–3 years, there have been about 1,200 publications a year. There are now 12 classes of medications and 68 brand names to treat hypertension. What is it we do not know? How can we increase control of BP across the population? The latest statistics show that 52 percent of hypertensive patients are treated. Of those patients on medications, 32 percent are controlled. Considering that there are 50 million people with hypertension in the United States, this is not a big success.

Dr. Lenfant said that he frequently hears that there is a failure in the health care system. He thinks this is wrong, because we are the system. He noted that one NHLBI program has focused on taking programs to communities—especially to minority communities such as American-Indian tribes. The NHLBI has trained people in these communities, who then trained others. Now there is a network for educating people in these communities about CV risk factors. Dr. Lenfant suggested that CC members could bring hypertension issues to the public in a similar way—e.g., by taking the message about salt to consumers.

Dr. Roccella said that he worked with Dr. Lenfant for 21 years. He noted that Dr. Lenfant has received 8 honorary degrees and 45 honors and awards, authored 230 papers, and served as editor of the Lung Biology and Health series. Expressing his deepest admiration and respect for Dr. Lenfant, Dr. Roccella presented him with the only copy of "JNC 7 Express" signed by the CC members.

Dr. Roccella thanked Dr. Lenfant for his contributions and adjourned the meeting.

Attachment D

NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM
COORDINATING COMMITTEE
ORGANIZATION ACTIVITIES UPDATE

Sheraton Reston Hotel
Reston, Virginia
December 4–5, 2003

AMERICAN ACADEMY OF FAMILY PHYSICIANS (AAFP)

Person Reporting: Lee Green, M.D., M.P.H.

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Please provide a brief summary of your organization's hypertension activities:

AAFP has featured three articles on hypertension and the JNC 7 in its flagship publication, *American Family Physician* (the most widely read journal in medicine): an editorial, a guideline summary, and a clinical article. The Academy scheduled me, as the AAFP representative to JNC, to present JNC VII in the Clinical Recommendations Update at the annual Scientific Assembly in September. That talk was standing-room-only, with over 2000 physicians, and was part of AAFP's new evidence-based CME project as well. Most state chapters have included JNC VII updates in their State CME activities as well. JNC VII has also been addressed in the Directors' Letter to the entire AAFP membership.

The greatest long-term impact however will likely stem from the AAFP and ABFP collaborating to make the new JNC VII-based hypertension module the first module of the new interactive case-based maintenance of certification process, soon to be required of all family physicians.

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ORGANIZATION ACTIVITIES UPDATE

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Reston, Virginia
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AMERICAN COLLEGE OF CHEST PHYSICIANS

Person Reporting: Sheldon G. Sheps, M.D.

Phone: 507-284-7570 **Fax:** 507-284-1161

E-mail: ssheps@mayo.edu

Please provide a brief summary of your organization's hypertension activities:

1. Presentations: ALLHAT (Dr. Steve Geraci of UW Madison and Dr. Richard Dart); BP in the ICU

2. Sheps SG, Dart R. JNC VII Express: New National Guidelines on Hypertension Released. ChestSoundings 2003;17:22

3. Richard A. Dart, James R. Gregoire, David D. Gutterman, and Steven H. Woolf. The Association of Hypertension and Secondary Cardiovascular Disease With Sleep-Disordered Breathing. Chest Jan 2003;123:244–260.

4. Richard A. Dart, Steve Gollub, Jason Lazar, Chandra Nair, David Schroeder, and Steven H. Woolf. Treatment of Systemic Hypertension in Patients With Pulmonary Disease: COPD and Asthma. Chest Jan 2003;123:222–243.

NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM
COORDINATING COMMITTEE
ORGANIZATION ACTIVITIES UPDATE

Sheraton Reston Hotel
Reston, Virginia
December 4–5, 2003

AMERICAN COLLEGE OF PREVENTIVE MEDICINE

Person Reporting: Carlos Vallbona, M.D.
(Information provided by Mr. Jud Richland, A.C.P.M.)

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Please provide a brief summary of your organization's hypertension activities:

1. We continue to address hypertension and heart disease each year at our annual meeting. For example, one session at our meeting earlier this year described a wide range of national cardiovascular disease programs with speakers from CDC, NHLBI, and MassPRO (a CMS-sponsored Quality Improvement Organization).

2. We actively participate in several Washington-based coalitions (such as the Coalition for Health Funding, the Research to Prevention coalition, and Research America) that advocate on Capitol Hill for greater funding for chronic disease programs, including those related to CVD and hypertension.

3. We have drafted position statements and/or collaborated with other organizations to develop policy statements on a wide range of CVD issues. For example:

    - We have advocated for a cholesterol screening benefit under Medicare. In fact, this was included in the recently passed Medicare reform legislation. See http://www.acpm.org/2003050H.htm.

    - We have collaborated with other organizations in developing principles for childhood obesity prevention for local policymakers. See http://www.acpm.org/2003015H.htm.

    - We have advocated for improvements in child nutrition program reauthorization proposals. See http://www.acpm.org/2003022H.htm.

- We recently submitted a resolution to the American Medical Association encouraging the AMA to support policies that encourage a physical activity-promoting "built environment." See http://www.acpm.org/2003-079(D).htm.

4. Our Prevention Practice Committee is in the process of developing two new position statements—one on counseling adolescents about weight management and one on counseling adults about this issue.

NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM
COORDINATING COMMITTEE
ORGANIZATION ACTIVITIES UPDATE

Sheraton Reston Hotel
Reston, Virginia
December 4–5, 2003

AMERICAN DIETETIC ASSOCIATION (ADA)

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Please provide a brief summary of your organization's hypertension activities:

Many current American Dietetic Association (ADA) activities focus on obesity, overweight, and/or diabetes and may also address the issue of hypertension. New publications include Managing Obesity: A Clinical Guide and Childhood and Adolescent Overweight.

The Health Professionals' Guide to Identification, Treatment and Prevention.

Scheduled for publication in Fall 2004, this is a new edition of Cardiovascular Nutrition: Strategies and Tools for Disease Management and Prevention.

As the lead partners of the Nutrition Screening Initiative, ADA and the American Academy of Family Physicians recently developed A Physician's Guide to Nutrition in Chronic Disease Management for Older Adults, available on the Web, in print, and as a CD–ROM.

ADA is also collaborating the National Dairy Council on the 3-A-Day of Dairy consumer campaign, which plans to expand the nutrition education messages in 2004 to include the importance of calcium in reducing hypertension.

NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM
COORDINATING COMMITTEE
ORGANIZATION ACTIVITIES UPDATE

Sheraton Reston Hotel
Reston, Virginia
December 4–5, 2003

AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS

Person Reporting: Barry L. Carter, Pharm.D.

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Please provide a brief summary of your organization's hypertension activities:

The Annual Midyear Clinical Meeting of The American Society of Health-System Pharmacists has programmed the following session that will be presented to approximately 500 participants on December 9, 2003:

A Landmark in Hypertension Research: ALLHAT Results and JNC 7

1. ALLHAT: Main Results and Clinical Implications: Jeffery Cutler, M.D.
2. ALLHAT: Cost-effectiveness Analysis and Societal Implications: Paul Heidenreich, M.D.
3. JNC George Bakris, M.D.
4. ALLHAT and JNC 7: Lessons for Health-System Pharmacists: Barry Carter, Pharm.D.
5. Panel Discussion: Paul Whelton, M.D.

NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM
COORDINATING COMMITTEE
ORGANIZATION ACTIVITIES UPDATE

Sheraton Reston Hotel
Reston, Virginia
December 4–5, 2003

DEPARTMENT OF VETERANS AFFAIRS (VA)

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Please provide a brief summary of your organization's hypertension activities:

As possibly the largest medical care system in the United States and with over 40 percent of the 4.5 million veterans seen at VA medical centers having hypertension, the VA has made considerable progress in BP control in recent years, due to a variety of activities and system changes, including the development of Primary Care and a fully electronic medical records system, that includes vital signs, progress notes, laboratory, ECG, radiology and other testing results, pharmacy records, etc. Blood pressure control rates in VA in the early 1990s were 25–30 percent, similar to the NHANES data, but in recent years control rates have been steadily improving to 55–60 percent in the most recent data.

Recent activities include the addition of several fixed-dose combination antihypertensive agents (lisinopril-HCTZ and atenolol-chlorthalidone) to the national VA formulary and widespread availability of home monitoring with automated sphygmomanometers. Blood pressure control has been part of VA medical center directors' quality performance profiles for several years. Much of this resulted from activities of the national VA Hypertension Field Advisory Committee, formerly chaired by the late H. Mitchell Perry, M.D., (now chaired by Dr. Cushman) and Cardiovascular and Medical Services in VA Central Office.

Following publication of the primary ALLHAT results in December, 2002, and then JNC 7 in May, 2003, The VA Hypertension Field Advisory Committee has conducted a series of three nationally broadcast (within VA) live teleconferences (with rebroadcasts) on (1) ALLHAT results and implications, (2) JNC 7 recommendations, and (3) Management of Hypertension in VA, Part 3: Effecting Change, which included discussion of the Hypertension Clinical Reminders electronic system; VA Pharmacy Benefits Management, including national VA data on antihypertensive drug use and blood pressure control rates, and the national VA formulary antihypertensive drugs and drug selection process; rational use of combination antihypertensive therapy as recommended in JNC 7; and example cases. In addition, a taping on "Hypertension"

was recently completed for "VA TV," which is intended for lay audiences both within VA medical centers and for broadcast on local television stations.

Dr. Cushman's office has submitted a proposal in collaboration with the Houston School of Public Health ALLHAT Clinical Trials Center to further disseminate the results of ALLHAT and the JNC 7 recommendations even more widely within VA. In collaboration with the VA Hypertension Field Advisory Committee and VA Pharmacy Benefits Management, VA will continue to monitor antihypertensive drug use patterns and BP control rates within VA.

NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM
COORDINATING COMMITTEE
ORGANIZATION ACTIVITIES UPDATE

Sheraton Reston Hotel
Reston, Virginia
December 4–5, 2003

NATIONAL HYPERTENSION ASSOCIATION (NHA)

Person Reporting: William M. Manger, M.D., Ph.D., Chairman

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Please provide a brief summary of your organization's hypertension activities:

- Editorial by Dr. Manger, "In Search of Pheochromocytoma," appeared in the September 2003 *Journal of Clinical Endocrinology and Metabolism*.
- Article on "Mechanism Whereby Potassium Prevents Stroke" by Manger et al., is in press in *The Journal of Hypertension*.
- Will present a 2-day symposium on hypertension, hyperlipidemia, and stroke at the New York Academy of Medicine on May 17 and 18, 2004. This is being coordinated by Dr. Manger with co-chairmen Dr. Jan Basile and Dr. Don Vidt.
- Talks on hypertension at:
  - Long Island College Hospital (State University of New York), December 2003
  - Presented one talk on hypertension at the Downtown Hospital, which is affiliated with NYU
  - Scheduled to present talk on hypertension at the University of Medicine and Dentistry of New Jersey
- Prepared a videotape on hypertension for NetCME for physicians in many hospitals throughout the nation to view and obtain CME credit
- Prepared a videotape on hypertension with Deacon Jones (Football Hall of Fame), sponsored by AstraZeneca, to be used in training and detection programs on hypertension throughout the nation

- Organized a workshop with Dr. James Watson (DNA Nobel Laureate), which was held at Cold Spring Harbor on November 16, 17, 18, 2003, to discuss pheochromocytoma and neuroblastoma: malignant versus benign molecular differentiation. About two dozen experts from the United States (Mayo Clinic, NIH, Sloan Kettering, Pennsylvania, Columbia Medical Center, Tufts Medical Center, etc.), Germany, and the Netherlands attended.

- The National Hypertension Association has developed a new program new program called VITAL (Values Initiative Teaching About Lifestyle). The program focuses on prevention of unhealthy lifestyles starting with introducing healthy nutrition and exercise in preschool and kindergarten children. We are in 17 schools (including New York City, Washington, DC, and Pittsburgh), and this program appears to be remarkably successful. We met with Senator Frist's office regarding VITAL on November 7, 2003. The administration in New York City is also working with NHA on advancing this program in New York schools. Representative on NHA marched in the African-American parade in Harlem on September 21, 2003, with young children wearing VITAL T-shirts. This was highly acclaimed.

- Newspaper article on hypertension has been prepared for publication in *The Southampton Press*. An article profiling Dr. Manger and NHA will also be published in *The Southampton Press*.

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COORDINATING COMMITTEE
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NATIONAL OPTOMETRIC ASSOCIATION

Person Reporting: Edwin C. Marshall, O.D., M.S., M.P.H.

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Please provide a brief summary of your organization's hypertension activities:

The National Optometric Association (NOA) has launched an office-based, community-focused program targeted at the three sight-threatening conditions that affect the minority community more than any other community. The NOA's "Three Silent Killers That Can Rob You Blind" program is designed to increase awareness and promote the prevention and control of glaucoma, diabetic eye disease, and high blood pressure within minority communities, and particularly the African-American community.

The August 2003 issue of *Primary Care Optometry* ran an article titled, "New hypertension guidelines released" in which I was quoted regarding the new "prehypertension" categories, the role of lifestyle in assessing lifetime risk for cardiovascular disease, and the role of optometrists in educating their patients and communities on the risk factors for hypertension, and the necessary interventions for prevention.

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COORDINATING COMMITTEE
ORGANIZATION ACTIVITIES UPDATE

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SOCIETY FOR NUTRITION EDUCATION (SNE)

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Please provide a brief summary of your organization's hypertension activities:

Kathy Kolasa presented a poster at the SNE annual meeting in Philadelphia, July 2003, highlighting the Coordinating Committee's work from the last year. This was information for the members and attendees of the Society. An abstract of the poster was published in the Annual Conference Proceedings. SNE and the High Blood Pressure Education Committee, 2001–2002. SNE Conference Proceedings, 2003;36(1):P42.

The editor of the *Journal of Nutrition Education and Behavior*, Sandra K Shepherd Ph.D., R.D. focused on JNC 7 in her September–October 2003 editorial (JNEB 35(5):225). The editorial was entitled "The JNC 7 Challenge." In the same issue, Kathy Kolasa authored a letter to the editor: "Summary of the JNC 7 Guidelines for the Prevention and Treatment of High Blood Pressure." JNEB 35(5):226–227

The members of SNE continue to include promotion of healthy eating (e.g., healthy weight, increasing consumption of fruits and vegetables, increasing calcium consumption) in their work.

NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM
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THE HYPERTENSION EDUCATION FOUNDATION INC. (HEF)

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Please provide a brief summary of your organization's hypertension activities:

The Hypertension Education Foundation (HEF) continues to organize and sponsor Hypertension Symposia in cooperation with the National Heart, Lung, and Blood Institute and the American Society of Hypertension. These meetings have been held periodically in more than 25 cities throughout the U.S. over the past 6–7 years. Approximately 75 hypertension experts have participated in these programs. Symposia are planned for Tucson, Tampa, and New York City within the next 2 months, and an additional 4–6 meetings are planned for 2004. The meeting in May 2004 will be telecast to approximately 230 medical facilities throughout the U.S. In 2003 the meeting in Baltimore was telecast to more than 1,700 physicians.

In addition, the HEF Web site has been an active one—with more than 25,000 hits per month and an average visiting time of more than 4–5 minutes. Patient education material and a booklet, "High Blood Pressure, What You Should Know About It and How You Can Help Your Doctor Treat It," are available and can be downloaded from the site. Shortly, a new booklet, "Diabetes and Hypertension: Control Them and Live Longer," will be available. The site also includes a discussion of the Seventh Joint National Committee Report on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, by Drs. Hill, Black, Izzo, and Moser. This was recorded at the Baltimore meeting in 2003. The HEF is exploring the possibilities of named lectureships in Yale and several other medical schools, and also may reinstitute a Fellowship Award in Hypertension. The HEF continues to get numerous requests for educational materials from individuals as well as medical facilities involved in the management in hypertension.