

## 12. Minority Activities

Throughout its history, the NHLBI has been a leader in conducting and supporting research to eliminate health disparities that exist between various segments of the U.S. population. The Institute has not only initiated research projects with significant minority participation in order to compare health status between various populations, but also given high priority to programs that focus exclusively on minority health issues.

Since FY 1991, the Institute has had procedures in place to ensure full compliance with the NIH Policy on Inclusion of Women and Minorities as Subjects in Clinical Research. As a result, all NHLBI-supported research that involves human subjects includes minorities, with the exception of a very few projects for which a compelling justification for limited diversity in the study population exists. Thus, all segments of the population, both minority and non-minority, stand to benefit from the Institute's research programs.

It has long been a goal of the NHLBI to increase the number of individuals from underrepresented groups in biomedical and behavioral research. Selected FY 2004 activities addressing this goal include:

- **Minority K–12 Initiative for Teachers and Students (MKITS):** Supports research, development, and evaluation of innovative science training programs to provide minority students in grades K–12 with the exposure, skills, and knowledge that will encourage them to pursue advanced studies in biomedical and behavioral sciences.
- **Historically Black Colleges and Universities (HBCU) Research Scientist Award:** Supports efforts by HBCU to recruit an established research scientist in cardiovascular, lung, or blood health and disease; transfusion medicine; or sleep disorders.
- **Sickle Cell Scholars Program:** Supports career development of young or new investigators in SCD research.
- **Summer for Sickle Cell Science Program:** As part of the Comprehensive Sickle Cell Centers program, supports research training and mentoring of individuals from high school to junior investigator level.
- **Student National Medical Association Externship in Sickle Cell Disease:** Supports an 8-week clinical rotation in SCD for third- and fourth-year medical students at an NHLBI-funded medical institution engaged in sickle cell research and patient care.
- **Research Scientist Award for Minority Institutions:** Strengthens the biomedical and behavioral research capabilities and resources of minority institutions by recruiting an established scientist with expertise in areas related to cardiovascular, lung, or blood health and disease; transfusion medicine; or sleep disorders.
- **Cultural Competence and Health Disparity Academic Award:** Enhances the ability of physicians and other health care professionals to reduce disparities—in a culturally sensitive manner—in cardiovascular, lung, and blood diseases, and sleep disorders among various population groups.
- **Partnership Programs To Reduce Cardiovascular Disparities:** Expand the capacity of research institutions to reduce health disparities, encourage more researchers to focus on minority health, and improve minority acceptance and community willingness to participate in research by pairing research-intensive medical centers that have a track record of NIH-supported research and patient care with minority health care serving institutions that lack a strong research program. Research will focus on the complex biological, behavioral, and

societal factors that result in cardiovascular health disparities in their target populations (e.g., African Americans, Hispanics, Native Hawaiians, and Pacific Islanders).

The Office of Minority Health Affairs (OMHA) within the OD provides oversight for, and coordinates, supports, and evaluates Institute programs related to minority health outcomes, including research, research training and career development, public outreach, and translation of research findings. The OMHA also coordinates activities to foster greater participation of underrepresented minorities in NHLBI research and research training programs. Selected FY 2004 activities include:

- Issuing four minority training and career development RFAs to increase the number of highly trained minority individuals conducting biomedical and behavioral research.
- Participating in HHS-Endorsed Minority Organization Internship Programs by providing positions in NHLBI extramural divisions to students from the National Association for Equal Opportunity in Higher Education, the Hispanic Association of Colleges and Universities, and the Washington Internships for Native Students programs.
- Cosponsoring with the NIH, the Cherokee Elementary School Project: Out of the Box, which is designed to create awareness and interest in the importance of science, medicine, and health; eliminate gaps in quality of health among minorities by encouraging health-related careers; and encourage youngsters to take responsibility for their own health.
- Supporting the African American, Hispanic, and Native American Youth Initiatives to bring minority students to the NIH campus for scientific presentations, an introduction to NHLBI research training and career development programs, and a tour of NHLBI laboratories.
- Providing undergraduate Tougaloo College Scholars the opportunity to observe biomedical research at the NHLBI during a 3-day tour of the NIH that included learning about the NIH and available research training opportunities.

See Chapter 13 for additional NHLBI-supported minority research training and career development programs.

The following text describes selected current projects that focus on minority populations and reflect the Institute's research portfolio related to minority health; additional information can be found in Chapters 9 through 11.

## **Heart and Vascular Diseases**

### **Risk Factors**

#### *Epidemiology*

Long-term epidemiologic studies are critical to uncovering risk factors that lead to disease. The Institute has initiated several major studies of heart disease focused significantly or completely on minority populations.

- **CARDIA** (see Chapter 10): To determine the evolution of CHD risk factors and lifestyle characteristics in young adults that may influence development of risk factors prior to middle age; 50 percent of the participants are black.
- **ARIC** (see Chapter 10): To investigate the association of CHD risk factors with development of atherosclerosis and CVD in an adult population; 30 percent of the participants are black.
- **CHS** (see Chapter 10): To examine risk factors for CHD and stroke in the elderly; 16 percent of the participants are minorities.

- Strong Heart Study (see Chapter 9): To compare risk factor levels and morbidity and mortality from CVD among American Indians from three different geographic locations.
- JHS (see Chapter 10): To identify environmental and genetic factors influencing evolution and progression of CVD in blacks.
- MESA (see Chapter 10): To examine the characteristics of subclinical CVD that predict progression to clinically overt CVD and related risk factors that predict subclinical disease in blacks, whites, Hispanics, and Asians; 62 percent of the participants are minorities.
- GOCADAN (see Chapter 9): To document CVD risk factors and measures of subclinical disease and to identify and characterize genes that contribute to CVD in approximately 40 extended Alaska Native families.
- HEIRS (see Chapter 10): To determine the prevalence of hereditary hemochromatosis; to identify genetic and environmental determinants and potential clinical, personal, and societal impacts of iron overload in an adult population consisting of 28 percent blacks, 13 percent Asians, and 13 percent Hispanics.

Several investigator-initiated epidemiologic studies are examining gene–environment interactions that increase CVD risk factors among various racial groups. Included among them are studies that compare gene–environment interactions in black populations in Africa, the Caribbean, and selected areas of the United States; determine the genes responsible for CVD risk factor response to dietary fat changes in blacks; investigate genes influencing changes in blood pressure in response to high- and low-salt diets in a rural Chinese population; and identify and map specific genes that contribute to CVD risk in Mexican Americans.

A study of the etiology of atherosclerosis focusing on diet and oxidative mechanisms is examining new risk factors that promote or inhibit LDL damage and inflammatory responses in the artery wall. Investigators seek to determine the relationship between longitudinal change in atherosclerosis and dietary antioxidants, antioxidant enzymes, and genetic polymorphisms; 43 percent of the participants are Hispanic.

The NHLBI supports research on the impact of adolescent lifestyle on the development of CVD. One project being conducted in youths, half of whom are black, is assessing the influences of diet and exercise on adiposity and regional fat distribution and the subsequent relationship between the two factors and development of CVD. Another is tracking the development of cardiovascular, behavioral, and physiological risk factors in Hispanic children and adolescents.

An ancillary study to MESA is seeking to determine whether impairment of myocardial perfusion reserve can serve as a marker of CHD. Scientists hypothesize that impaired myocardial perfusion reserve indicates the presence of subclinical coronary atherosclerosis and coronary microvascular disease. Developing a new measure of subclinical disease would enable early interventions and lifestyle modifications to prevent CHD. Fifty percent of the population will be Hispanic. Other ancillary studies to MESA are investigating progression of carotid atherosclerosis, association of risk factors with arteriosclerosis measured in retinal vessels, and the relationship of sex hormones to subclinical CVD and other risk factors in men and women.

Additional epidemiologic studies being supported include (1) a multicenter study to investigate cardiovascular and metabolic responses to endurance training, contribution of genetic factors to the accompanying response of CVD, and type 2 diabetes risk factors in a population that is 46 percent black; (2) a study of Chagas' disease a leading cause of heart disease throughout Latin America—to identify genetic determinants of susceptibility to infection and differential disease pathogenesis in a black population residing in rural Brazil; (3) a project to use pooled data from

nine existing U.S. studies to compare between blacks and whites, CHD incidence and mortality rates, exposure–outcome relationship, patterns of comorbidity, and population attributable risk; and (4) a project to examine the relationship between neighborhood socioeconomic characteristics and the prevalence and progression of subclinical atherosclerosis in an ethnically diverse population consisting of approximately 30 percent blacks, 10 percent Asians, and 20 percent Hispanics.

### ***Treatment and Prevention***

Many evidence-based guidelines for treatment of risk factors or disease have been developed, but they often are not adhered to by patients—especially minority populations—or adopted in routine clinical practice. The Institute has initiated the following activities to address this important problem:

- **Trials Assessing Innovative Strategies To Improve Clinical Practice Through Guidelines in Heart, Lung, and Blood Diseases:** To identify obstacles to implementing national evidence-based guidelines and test interventions to promote their use in clinical practice. Several approaches will be tested, including use of decision support tools; interactive seminars; internet learning; a computerized patient activation tool placed in the waiting room of primary care offices; and performance feedback and practice profiling.
- **Overcoming Barriers to Treatment Adherence in Minorities and Persons Living in Poverty:** To overcome barriers to treatment adherence for lifestyle changes and pharmacologic therapy in minorities and persons living in poverty. Studies are testing several approaches, such as telephone-based interventions, nurse case management and counseling, and patient and physician education intervention in clinical and community settings designed to overcome patient, provider, and medical systems barriers that impede treatment adherence. Urban and rural blacks, Hispanics, Asian Americans, and women are the targeted groups.

### ***Education***

The NHLBI, through its education programs (see Chapter 2), disseminates health information to physicians, health care professionals, patients, and the public on ways to prevent or treat diseases within the Institute’s mandate. It has developed the following programs to combat cardiovascular health disparities among four major cultural/ethnic groups: blacks, Hispanics, American Indians and Alaska Natives, and Asian Americans and Pacific Islanders. In addition, the NHLBI is exploring opportunities to reach residents of public housing communities nationally with science-based information on lifestyles and behaviors that can prevent, treat, and manage CVD.

- **Cardiovascular Health Outreach and Education in Public Housing Communities:** To empower blacks who reside in Baltimore City public housing developments to take charge of improving their cardiovascular health by adopting a heart healthy lifestyle.
- **Salud para su Corazón:** To disseminate information on CVD prevention, intervention, and treatment and promote heart healthy behaviors in Hispanic communities.
- **NHLBI-Indian Health Service Partnership to Strengthen the Heartbeat of American Indian and Alaska Native (AI/AN) Communities:** To develop and implement effective approaches to improve the cardiovascular health, including implementation of tailored heart health strategies, in three tribal communities and creation of a national cardiovascular health training program, “Honoring the Gift of Heart Health,” with the Indian Health Service.
- **NHLBI Asian American and Pacific Islanders Heart Health Outreach Project:** To develop culturally and linguistically appropriate outreach activities and tools (e.g., CVD risk factor fact sheets) to increase community awareness of heart disease and its associated risk factors

and to promote heart healthy lifestyles among a diverse Asian American and Pacific Islander population.

In addition to the activities mentioned above, the Institute has prepared publications on CVD prevention for minority populations. Examples include:

- Improving Cardiovascular Health in African Americans—Package of Seven Easy-To-Read Booklets
- Heart-Healthy Home Cooking African American Style
- Nine Easy-to-Read Booklets in Spanish and English on Heart Health
- Bringing Heart Health to Latinos: A Guide for Building Community Programs
- Filipinos Aspire for Healthy Hearts Fact Sheets in Tagalog and English
- Vietnamese Aspire for Healthy Hearts Fact Sheets in Vietnamese and English
- Filipinos Take It To Heart: A How-To Guide for Bringing Heart Health to Your Community
- Treat Your Heart to a Healthy Celebration.

The educational materials listed throughout this chapter may be obtained from the NHLBI public Web site or through the NHLBI online catalog.

## **High Blood Pressure**

### ***Etiology and Pathophysiology***

High blood pressure is a serious health problem that is especially prevalent and severe among minorities. Institute-initiated studies addressing the etiology and pathophysiology of high blood pressure include:

- Molecular Genetics of Hypertension (see Chapter 9): To determine the etiology and pathogenesis of hypertension and its complications in order to improve diagnosis and treatment of the disease. Many of the subprojects have a high percentage of minority participation; others target blacks or Hispanics exclusively.
- Family Blood Pressure Program (see Chapter 9): To use a network of investigators to identify genes associated with high blood pressure and to examine interactions between genetic and environmental determinants of hypertension in specific minority populations: blacks, Mexican Americans, and Asian Americans.

The Institute supports a number of investigator-initiated projects to examine antecedents of hypertension in children to determine racial differences in blood pressure regulation. One study is determining relationships between cardiovascular reactivity in adolescent normotensive blacks and development of pathobiologic markers of hypertension risk (i.e., increased resting blood pressure, left ventricular mass, and relative wall thickness) later in life. Another is investigating the genetics of cardiovascular reactivity in black youth.

Impaired sodium regulation also appears to be linked to the development of hypertension. Scientists are investigating the effects of stress on salt retention and measuring hormonal variables known to influence sodium regulation in a population of obese and nonobese black youths. They are seeking to determine whether the mechanisms regulating sodium retention differ between the two groups. Another group of scientists is examining the role of sodium and obesity in hypertension development among blacks living in three different environments: Nigeria, Jamaica, and Chicago.

Investigators have observed that blacks have an augmented blood pressure response to salt. A study has been initiated to improve understanding of the genetic basis and phenotypic characterization of salt-sensitive hypertension in blacks.

Researchers also are examining the influence of SES and ethnic discrimination on stress reactivity to determine if it provides a pathophysiologic link to CVD in blacks. One group is studying the combined influence of low SES and ethnicity on development of behavioral risk factors and testing the extent to which they mediate associations between sociodemographic factors, stress, and cardiovascular markers in adolescents. Another group is assessing the relationship between early life exposure to socioeconomic stressors such as adverse socioeconomic conditions, low levels of social integration, and racial discrimination, and development of hypertension in blacks.

Stress may be a major contributor to CVD among American Indians. Investigators are evaluating the long-term effects of posttraumatic stress disorder—a common disorder among reservation-dwelling Indians—on the cardiovascular system and the role of lifestyle, cultural, and biological mediators in the relationship of posttraumatic stress disorders with coronary flow reserve and heart rate variability.

The role of dietary factors, particularly macronutrients, in the etiology of high blood pressure is another area of investigation. Scientists are conducting epidemiologic studies among participants with diverse ethnicity, SES, and dietary habits in four countries to determine the impact of selected dietary components (proteins, lipids, carbohydrates, amino acids, calcium, magnesium, sodium, potassium, antioxidants, fiber, and caffeine) on blood pressure.

The NHLBI supports a number of studies to identify genes linked to hypertension in blacks, Mexican Americans, and whites to determine if part of the disparity in prevalence can be attributed to genetic differences among the groups. Genes under investigation include those associated with the renin-angiotensin system, the kallikrein-kinin system, and sodium transport.

### ***Treatment and Prevention***

Identifying effective treatment strategies for various populations requires large-scale studies with representative populations in sufficient numbers.

- ALLHAT (see Chapter 11): To compare the combined incidence of fatal CHD and nonfatal MI among patients receiving ACE inhibitors, calcium antagonists, or alpha-1 blockers and patients in a control group receiving a diuretic. Also, in a subset of these groups, to determine whether cholesterol-lowering therapy reduces mortality in moderately hypercholesterolemic individuals compared with a control group; 32 percent of the participants are black and 19 percent are Hispanic. Research findings demonstrated that the less expensive traditional diuretics are at least as effective as newer medicines in treating high blood pressure and preventing some forms of heart disease.

Although it is well known that reducing hypertension will reduce CVD rates, the implementation of evidence-based guidelines for hypertension treatment in clinical practice is not very high. To address this issue, the NHLBI initiated a program to improve hypertension control rates in blacks, a group with the highest prevalence and earliest onset of hypertension and disparately high premature cardiovascular mortality and morbidity:

- **Interventions To Improve Hypertension Control Rates in African Americans:** To evaluate the feasibility of clinical interventions directed at the medical care delivery system to increase the proportion of blacks who have their blood pressure controlled to levels specified by the JNC VII guidelines.

Understanding racial differences in blood pressure control is an area of major interest for the Institute. Scientists are examining whether variations in genes of the renin-angiotensin-aldosterone system predict differences in blood pressure response to diuretic therapy among hypertensive blacks and whites. Research also is being focused on variations in the ACE gene between blacks and whites to explain racial differences in the antihypertensive responsiveness to ACE inhibitors.

### ***Education***

The NHLBI (see Chapter 2) has developed a number of outreach activities to inform minority populations of the importance of blood pressure control. Included among them are a toll-free number that provides materials on hypertension in English or Spanish; mini telenovelas (*Más vale prevenir que lamentar*), “health moments” to reinforce CVD prevention for local Spanish-language television stations; a Spanish version of the High Blood Pressure Education Month Kit; and several publications for health professionals, patients, and the public. Below are some examples:

- *Sí se Puede: Prevenir y Controlar la Presión Arterial Alta con Actividad Física*
- *Plan de Alimentación Saludable Contra la Hipertensión: Prevenir y Controlar la Presión Arterial Alta Siguiendo el Plan de Alimentación Conocida Como DASH*
- *Sí se Puede: Prevenir y Controlar la Presión Arterial Alta. Lo Que Usted Debe Saber Sobre la Prevención y Control de la Presión Arterial Alta*
- *Sí se Puede: Prevenir y Controlar la Presión Arterial Alta. Lo Que los Médicos Deben Saber*
- *Take Steps To Prevent High Blood Pressure in English and Spanish*
- *Cut Down on Salt and Sodium in English and Spanish*
- *Churches as an Avenue to High Blood Pressure Control*
- *Working With Religious Congregations: A Guide for Health Professionals*
- *Protect Your Heart! Prevent High Blood Pressure*
- *Spice up Your Life! Eat Less Salt and Sodium*
- *Keep the Harmony Within You—Check Your Blood Pressure*
- *Keep Your Heart in Check—Know Your Blood Pressure Number in Tagalog and English and in Vietnamese and English.*

### ***NHBPEP Coordinating Committee Activities***

The organizations that belong to the NHBPEP coordinating committee have continuing education programs on the prevention and treatment of hypertension that are focused on their minority members. They also support hypertension prevention and awareness in community-based settings such as screening and church activities, community awareness campaigns, and media events.

## **High Serum Cholesterol**

### ***Etiology***

The Institute supports a number of investigator-initiated projects to identify genes that influence the lipoprotein profile within various racial and ethnic groups. Research findings could offer an

explanation for differences in susceptibility to CHD found between various racial and ethnic groups.

Scientists also are interested in the protective effect of HDL. One study is focusing on isolating and characterizing native HDL species to determine their structure and function. Research findings may lead to new strategies to prevent and treat arteriosclerotic heart disease. Thirty-eight percent of the participants are minorities.

Variation in hepatic lipase activity is associated with differences in plasma concentrations of HDL and LDL synthesis and catabolism. Researchers are investigating whether ethnic differences in hepatic lipase activity are responsible for the well-known differences in plasma HDL concentrations found in blacks and whites. Genetic studies are being conducted on a population that is 39 percent black.

### ***Prevention***

The NHLBI is supporting an investigator-initiated study among minority preschool children to track the long-term effectiveness of nutrition interventions on blood cholesterol and diet. Additional potential risk factors, such as increased blood pressure, obesity, and intention to smoke, also will be monitored.

### ***Education***

The NCEP (see Chapter 2) has prepared the following publications on blood cholesterol for minority audiences.

- Learn Your Cholesterol Number in Spanish and English
- Protect Your Heart—Lower Your Blood Cholesterol in Spanish and English
- Heart-Healthy Home Cooking African American Style
- Delicious Heart-Healthy Latino Recipes
- Cut Down on Fat—Not on Taste in Spanish and English
- Empower Yourself! Learn Your Cholesterol Number
- Be Heart Smart! Eat Foods Lower in Saturated Fats and Cholesterol
- American Indian and Alaska Native People: Treat Your Heart to a Healthy Celebration
- Serve Up a Healthy Life—Give the Gift of Good Nutrition in Tagalog and English
- Serve Up a Healthy Life With Good Nutrition in Vietnamese and English.

## **Obesity**

### ***Etiology***

The latest NHANES data show a continued rise in the proportion of Americans who are overweight; black women are especially at risk. To understand the reasons for the racial disparity among women, the Institute initiated a long-term program, the NHLBI Growth and Health Study (NGHS), to examine the development of obesity and CVD risk factors in a biracial cohort of young girls. The study, which ended in FY 2000, found black girls consumed more calories and a higher percentage of calories from fat and watched more television than white girls. An investigator-initiated study using the NGHS cohort, starting at ages 18 to 19 years, is examining the changes in cardiac output and total peripheral resistance that occur with developing obesity and their influence on ethnic difference in blood pressure regulation. Another project, using data



from the NGHS, is examining CHD risk factors in black and white girls to identify genes involved in black–white differences in lipid metabolism and obesity.

Pregnancy is often associated with excess weight gain and postpartum weight retention that can lead to obesity. Understanding the determinants of pregnancy-associated weight gain and retention is the focus of a project being conducted within a predominantly black and Hispanic population of pregnant adolescents.

### ***Prevention and Treatment***

The NHLBI has initiated a program to prevent obesity in high-risk children.

- GEMS (see Chapter 9): To test the effectiveness of weight-control interventions (involving diet, physical activity, and psychosocial and familial influences) administered during the critical transition period from prepuberty to puberty in black girls at high risk for obesity.

The Institute supports a number of investigator-initiated studies on the effectiveness of obesity prevention and control interventions among diverse populations. Black and Hispanic parents and children at Head Start sites are participating in a nutrition education and weight-control program; 70 percent of the participants will be minorities. Another study will test the effectiveness of a family-based intervention to prevent obesity in low-income Latino children.

A school-based study involving predominantly minority children is determining whether reducing the amount of time children spend watching television and videos and playing video games prevents obesity. A project with a subject population consisting of Asians, Hispanics, and whites is testing an integrated school- and community-based intervention involving physical activity and diet to reduce the prevalence of obesity. An ancillary study to an Institute-initiated program to reduce the decline in physical activity in adolescent girls (TAAG) is investigating the influence of community characteristics (e.g., street design, access to public transportation, facilities for physical activity, population mix, and socioeconomic mix of the neighborhood) on physical activity levels and body mass index; approximately 50 percent of the girls are minority.

The Institute is supporting a weight loss maintenance trial to test the effectiveness of two strategies to promote the long-term maintenance of weight loss in adults who recently lost weight; about 40 percent of the population will be black. Another study will evaluate the effectiveness of diets of different macronutrient compositions to promote and sustain weight loss in adults; approximately 25 percent of the population will be black.

Black women are the subjects of a weight management program specifically tailored to their psychosocial, sociocultural, and health perspectives and life circumstances. A study using data from the NHANES III is seeking to determine whether multiple perceptions and behaviors related to weight loss cluster according to sociodemographic characteristics. Research findings may lead to the design of culturally sensitive intervention strategies for minorities. Blacks and Mexican Americans at various SES levels constitute the major portion of the population surveyed.

### ***Education***

The NHLBI OEI (see Chapter 2) has prepared health information on losing excess weight for minorities.

- *Watch Your Weight* in English and Spanish

- Embrace Your Health! Lose Weight if You Are Overweight.

## **Physical Inactivity**

The Institute has initiated research on the effectiveness of intervention programs to encourage greater physical activity within selected groups.

- TAAG (see Chapter 11): To test the effectiveness of school–community-linked interventions to reduce the decline in physical activity in adolescent girls, from grades 6 through 8. Of 3,600 girls from 36 schools, approximately 30 percent will be minorities.

The NHLBI supports several investigator-initiated studies on strategies to increase physical activity among minority populations. Included among them are studies to examine the effect of vigorous exercise on reduction of childhood obesity in black girls. Adolescent girls are the focus of a number of projects to determine the optimal amount of exercise required for primary prevention of CHD, provide culturally relevant physical activities, enhance social support for exercise, and test the effects of different amounts and intensities of physical activity on CVD risk factors. Hispanic women and women with low SES and literacy skills are subjects in two intervention projects to encourage sustained increases in physical activity among sedentary and underserved groups. One of the projects also is seeking to determine the degree of generalization of activity from wife to husband and mother to child.

## ***Education***

The Institute has prepared for minorities the following publications on the importance of physical activity and ways to become more physically active.

- Stay Active and Feel Better in English and Spanish
- Energize Yourself! Stay Physically Active
- American Indian and Alaska Native People: Be Active for Your Heart!
- Be Active for a Healthy Heart in Tagalog and English
- Be Active for a Healthier Heart in Vietnamese and English.

The Institute also has developed a Web-based application on physical activity for lay health educators in English and Spanish, which can be found at <http://hin.nhlbi.nih.gov/salud/pa/index.htm>.

## **Smoking**

The Institute supports a number of investigator-initiated smoking intervention and follow-up cessation maintenance studies that specifically target minorities. Two studies are evaluating the effectiveness of two smoking cessation programs for smokers who seek treatment at the hospital emergency department. One study involves patients who suffer from acute respiratory illness; approximately 35 percent are minorities. The other targets Chinese American patients hospitalized with CVD, pulmonary disease, or diabetes mellitus.

Other projects being supported include a study to assess the extent of smoking onset and cessation in minority youths, identify determinants of smoking onset, and determine predictors of cessation; a study of elderly smokers (40 percent minority) to evaluate the effectiveness of three smoking cessation strategies; and an intervention study tailored to an underserved population at risk for smoking relapse, smoking onset, and smokeless tobacco use.

## ***Education***

The Institute has prepared the following publications on smoking cessation for minorities.

- *Kick the Smoking Habit* in English and Spanish
- Refresh Yourself! Stop Smoking
- American Indian and Alaska Native People: Help Your Heart
- *Don't Burn Your Life Away—Be Good to Your Heart* in Tagalog and English and in Vietnamese and English.

## **Psychosocial Factors**

The NHLBI has initiated research on the effect of depression, anxiety, and lack of social support on prognosis after a CHD event.

- ENRICHD (see Chapter 11): To determine the effects of psychosocial interventions on morbidity and mortality in post-MI patients who were depressed and socially isolated and/or who perceived themselves as lacking support from family and friends; 34 percent of the participants were minorities. Despite the treatment group's improvement in psychological and social functioning and quality of life, no difference in heart disease survival or second heart attack rate was demonstrated compared to the control group, who also reported improvement in their psychological well-being.

The Institute supports investigator-initiated research on the role of race and ethnicity, psychosocial and environmental factors, and low SES in the development of CHD. Scientists are investigating the contribution of biobehavioral factors in the etiology, pathogenesis, and course of CHD. Racial differences in stress-induced physiologic responses also are being examined.

Investigators are interested in the effects of race and psychosocial factors, such as hostility, on glucose metabolism. A study was initiated to determine how hostility is differentially related to glucose metabolism in blacks and whites. Research findings may increase understanding of the differences in the etiology of diabetes in the two groups.

Additional areas of focus include the genetic basis of aggression and the relationships between risk-promoting variables (psychosocial stress, smoking, poor diet, physical inactivity); presumed mediating variables (sympathetic nervous system activity and insulin metabolism); and CHD risk factors. Fifty to sixty percent of the participants are black or Hispanic.

## **Ischemic Heart Disease**

The NHLBI supports a major multicenter program involving basic and clinical research on ischemic heart disease in blacks.

- Ischemic Heart Disease in Blacks (see Chapter 9): To elucidate the pathophysiological basis for excess morbidity and mortality from ischemic heart disease in blacks, and subsequently to develop appropriate therapeutic strategies.

## Diabetes

Blacks, Hispanics, and American Indians have a high prevalence of diabetes. The NHLBI supports research to elucidate the pathogenic mechanisms involved in the relationship between diabetes and elevated risk for CVD.

Several investigator-initiated studies are examining the genetic relationships between noninsulin-dependent diabetes mellitus (NIDDM) and atherosclerosis. They include a study between two sets of Hispanic families with NIDDM, one with CHD and one without; a study in Mexican Americans to determine common genes linking insulin resistance and coronary artery disease; a project in Japanese American families to characterize the genetic epidemiology of CHD risk factors (high LDL, risk factors that characterize the insulin resistance syndrome and NIDDM, and lipoprotein(a) levels and apo-lipoprotein(a) phenotypes); and a project in blacks and Hispanics to examine genetic determinants of insulin resistance and visceral adiposity as intermediate components in the pathways that lead to type 2 diabetes and atherosclerosis.

In addition, the Institute supports research on the role of hyperglycemia and insulin resistance in the development of vascular disease. A study in American Indians with NIDDM is seeking to elucidate the underlying biological processes and their interaction in the acceleration of atherogenesis. A project in a diverse diabetic patient population of blacks, whites, and Hispanics with and without carotid atherosclerosis is seeking to understand the atherogenicity of hypertriglyceridemia in diabetes by focusing on the size and number of triglyceride-rich lipoproteins.

Hypertension and diabetes are major contributors to CVD and occur disproportionately in blacks. In particular, black women seem to have earlier disease onset and poorer outcomes. Scientists are investigating the link between hypertension and type 2 diabetes and the relative excess of androgen found in black women to determine whether insulin resistance, excess androgen, and endothelial dysfunction contribute to accelerated vascular injury in blacks.

Other investigator-initiated studies on diabetes and CVD risk among minority populations include a survey to compare the prevalence of diabetes and CVD risk factors among native Mexicans and Mexican Americans, and a study among blacks, whites, and Hispanics with existing insulin resistance, including impaired glucose tolerance and NIDDM, to identify dietary factors that may contribute to elevated CVD risk.

### *Treatment*

The NHLBI supports clinical trials to determine the benefits of various strategies to reduce CVD among patients with diabetes or treat patients with coronary artery disease and diabetes.

- ACCORD (see Chapter 11): To evaluate the benefits of different therapies to reduce CVD in type 2 diabetes; over one-third of the participants are minorities.
- BARI 2D (see Chapter 9): To evaluate whether urgent revascularization offers an advantage over medical therapy in patients with coronary artery disease and diabetes. In addition, for a given level of glycemic control, to determine whether insulin-providing drugs offer advantages or risks compared to insulin sensitizers (drugs that enhance insulin action); 33 percent of the participants are from minority populations.
- SANDS (see Chapter 9): To compare intensive treatment (pharmacologic agents, such as ACE inhibitors and simvastatin for high blood pressure and LDL cholesterol) to conventional

treatment in 488 American Indians with diabetes, ages 40 or older. The primary outcome measure is change in carotid intimal-medial thickness.

## **Lung Diseases**

The NHLBI supports research on a number of lung diseases, such as asthma, sarcoidosis, and TB, that disproportionately affect minorities. The following section provides examples of research to address health disparities in lung diseases.

### **Asthma**

#### ***Etiology and Pathophysiology***

Asthma is a chronic lung disease characterized by inflammation of the airways. Various genetic and environmental factors contribute to the severity of symptoms. The Institute has launched a collaborative program to investigate the mechanistic basis for severe asthma and to determine how it differs from mild-to-moderate asthma.

The NHLBI is supporting a number of investigator-initiated projects on the etiology and pathophysiology of asthma. Two studies are using genomic screening to search for the genetic basis of asthma, one in a large sample of Asian siblings who are already known to differ widely in their airway responsiveness (sensitivity to histamine) and lung function and another in a homogeneous Hispanic population in Costa Rica. A third study is identifying genes contributing to asthma severity in blacks, a population disproportionately affected in the United States.

Other projects are focusing on understanding the mechanisms by which environmental factors trigger the onset of asthma. One study is investigating the role of viruses in the exacerbation of asthma; 50 percent of the participants are minorities. Another is examining how pulmonary infection caused by mycoplasma pneumoniae exacerbates asthma and prolongs abnormalities in lung function; 40 percent of the participants are minority. A third study is seeking to understand the role of gene–environment interactions in the development of immune responses in a pediatric population that is genetically predisposed to asthma; 40 percent of the participants are Hispanic.

Occupational- or environmental-induced asthma is a major problem, especially among low-income, urban blacks and Hispanics. The NHLBI is supporting a project to examine work-related asthma in those populations.

Circadian change in airway function is an important aspect of asthma; more than 70 percent of deaths and 80 percent of respiratory arrests occur during sleep. Researchers are investigating the mechanisms that cause the changes in airway function in nocturnal asthma that lead to exacerbation of symptoms; 36 percent of the participants are minority.

#### ***Treatment and Control***

The Institute has initiated research to identify optimal drug strategies for treatment and management of asthma. Because the disorder disproportionately affects minority children, it is important for them to be well represented in clinical trials.

- ACRN (see Chapter 9): To establish an interactive network of asthma clinical research groups to conduct studies of new therapies for asthma and disseminate findings to the practicing community. Overall, 37 percent of the participants are from minority populations.

- CAMP (see Chapter 11): To determine whether inhaled corticosteroids are safe and effective for long-term treatment of children with mild-to-moderate asthma. The therapy proved more effective than nonsteroidal anti-inflammatory medication and significantly reduced airway hyperresponsiveness. The only side-effect was a transient slowing in growth rate during the first year of treatment; 31 percent of the participants were minorities.
- CARE (see Chapter 11): To establish a network of pediatric clinical care centers to determine optimal treatment and management strategies for children with asthma. The study will attempt to customize therapy based on specific asthma phenotypes and genotypes; 30 percent of the population will be minorities.
- Centers for Reducing Asthma Disparities (see Chapter 9): To establish partnerships between minority-serving institutions and research-intensive institutions to conduct studies on causes of and corrections for disparities in asthma among racial/ethnic and low SES populations. Reciprocal training is encouraged to ensure culturally sensitive projects and enhance research capabilities.

The Institute also is supporting an investigator-initiated study on the effect of steroids on enhanced alpha-adrenergic vascular responsiveness in asthma; 77 percent of the participants are minority.

### *Translational Activities*

Ensuring full use of modern asthma treatment strategies is an important goal of the NHLBI. An investigator-initiated study, conducted in black communities in Baltimore, is examining the effectiveness of two asthma interventions to reduce emergency room visits, improve adherence to medication schedules, and lower asthma morbidity. One strategy provides assistance to families in accessing medical care; the other combines this assistance with a family intervention to encourage consistent use of asthma medication. Another study is determining whether shared decisionmaking between patients and physicians in choosing asthma therapy improves adherence; 82 percent of the participants are minority.

Two studies are evaluating the benefits of administering drug treatment to children at school. One is a Birmingham-based study involving a predominately black population with moderate-to-severe asthma. The other is a New York City-based study that is establishing a collaboration between school nurses and primary care physicians to form a network to prevent asthma attacks. The project is identifying school children with asthma and working with their families and physicians to develop an asthma management plan that includes supervision of drug treatment at school. It refers children who lack continuing care to physicians who follow the NAEPP Guidelines.

In Detroit, investigators are developing and evaluating computer-based instructions and peer counseling for teens with asthma. All of the participants enrolled are black.

In San Diego, scientists are evaluating an intervention project to reduce tobacco-related morbidity among low SES Hispanic children with asthma. By collaborating with Hispanic counselors, researchers have developed a behavioral program that seeks to reduce environmental tobacco smoke (ETS) exposure in children with asthma.

In Ohio, investigators are testing the effects of reducing indoor ETS on asthma symptoms, pulmonary function, airway inflammation, and health services use; 44 percent of the participants are minorities.

Another ETS intervention program is being tested among predominately low SES black and Hispanic children in Los Angeles. Researchers are evaluating the effectiveness of two low-cost interventions (one involving counseling and booster telephone calls and the other involving a video and household reminder kit) to reduce asthma morbidity.

In St. Louis, a randomized controlled trial is being conducted among young black children recruited at the time of an emergency department visit for asthma exacerbation. Investigators are testing the effectiveness of an intervention strategy that includes case management, telephone contacts, and a monetary incentive to increase follow-up visits to primary care providers.

### ***Education***

The NAEPP (see Chapter 2) has developed easy-to-read materials on asthma treatment and control directed to audiences with low literacy.

- Facts About Controlling Your Asthma
- El asma: Cómo Controlar Esta Enfermedad.

## **Chronic Lung Disease in Premature Infants**

The NHLBI supports research on prevention of chronic lung disease (bronchopulmonary dysplasia) in preterm infants.

- Inhaled Nitric Oxide (NO) for the Prevention of Chronic Lung Disease (CLD) (see Chapter 9): To determine if low-dose inhaled NO will reduce CLD in premature newborns (gestational age less than 34 weeks and birth weight between 500 and 1,250 grams at birth) with respiratory failure that required mechanical ventilation in the first 48 hours of life; 27 percent of the infants will be from minority populations.
- Inhaled Nitric Oxide in Prevention of Chronic Lung Disease (see Chapter 9): To investigate whether low-dose inhaled NO administered to preterm infants between 500 and 1,250 grams birth weight who continue to require mechanical ventilation at 10 days of age increases survival without CLD at 36 weeks postmenstrual age; 55 percent of the infants will be from minority populations.

## **Sarcoidosis**

Sarcoidosis is an inflammatory disease of unknown etiology that affects the lungs. The Institute has initiated a study to elucidate the mechanism involved in the disease.

Investigator-initiated studies on the causes of sarcoidosis include a study to identify genes linked to sarcoidosis susceptibility in blacks and to determine if hereditary susceptibility predisposes blacks to sarcoidosis, and a project to elucidate the mechanisms involved in the immunologic and inflammatory processes that ultimately lead to end-stage fibrosis in progressive pulmonary sarcoidosis; 50 percent of the participants are black.

## **Sleep Disorders**

The NHLBI supports research on the etiology, pathophysiology, and consequences of sleep-disordered breathing (SDB), a condition characterized by repetitive interruptions in breathing. Sleep apnea, a common disorder that disproportionately affects blacks, is associated with an

increased risk of CVD, and is particularly prevalent in heart failure patients. An Institute-initiated program is assessing the interrelationship between sleep disorders and heart, lung, and blood diseases. Another study will examine the interrelationship between sleep apnea and heart failure and the mechanisms leading to cardiovascular stress when they occur together.

The Institute also supports a wide spectrum of investigator-initiated projects to elucidate cardiovascular and other health consequences of SDB. Ongoing studies in various community settings are assessing the health risks of SDB within specific ethnic populations, including blacks, Hispanics, Asians, and American Indians. A study of sleep in black families will investigate whether sleep problems contribute to diabetes, and the potential relationship to CVD. Characterization of how SDB occurs within family groups is helping to identify potential genetic risk factors that may allow early identification and treatment of high-risk individuals.

Treatment strategies for SDB are another area of interest. A multisite clinical trial was initiated to determine whether continuous positive airway pressure is an effective treatment for excessive daytime sleepiness and cognitive impairment associated with moderate-to-severe SDB; 30 percent of the participants are minority.

## **Tuberculosis**

Beginning in 1993, the NHLBI funded five annual competitions for Tuberculosis Academic Awards (TBAAAs). The goal of the TBAA program was to improve prevention, management, and control of TB by supporting increased opportunities for health care practitioners to learn modern principles and practices. The TBAA program promoted coordinated clinical approaches to the care of patients of various ethnic backgrounds who have TB; raised awareness among health care providers of unique ethnic, cultural, and socioeconomic dimensions of TB; focused educational efforts in areas where TB incidence is persistently high (e.g., immigrant communities, refugee centers, homeless shelters, correctional facilities); promoted development of minority faculty capable of providing appropriate instruction in diagnosis and management of TB; and enhanced TB education programs in minority medical schools and in the communities they serve. The program ended in 2002.

Building on the foundation laid by the TBAA program, the NHLBI funded a contract for a TB Curriculum Coordinating Center to provide access to the best TB educational and training opportunities in the United States. The program is directed at medical schools, nursing schools, and allied health schools—especially those that provide primary care to communities where TB is endemic and the population is at high risk.

In 2001, the Institute initiated a program on Genetic Aspects of Tuberculosis in the Lung. Four of the ten awards were to institutions conducting genetic studies in humans to characterize genes associated with TB susceptibility and host immune responses to infection. A large number of the participants being recruited are from minority populations.

The NHLBI supports a number of investigator-initiated studies focused on understanding the relationship of the immune system to TB. Most of the patients are from minority populations with HIV. One group is seeking to identify the correlates of protective immunity in a Mexican population in order to aid development of anti-TB vaccines. Another group will conduct a Phase I safety trial on a vaccine with a patient population consisting of 85 percent minorities. A third group is examining the role of interferon-gamma in the pathogenesis of TB among Hispanics



with and without HIV. A fourth group is identifying and characterizing host factors that predispose Asians to develop TB. In predominately minority populations in the United States and South Africa, a new study will compare the effectiveness of adding aerosolized interferon-gamma to the usual treatment regimen for advanced TB.

The NHLBI also supports research to improve TB control among minority populations. One project is evaluating educational strategies to improve adherence to medication regimens and regular clinic visits among TB-infected adolescents in California. The program, based in San Diego, is directed at Hispanic adolescents. Another study, located in the Harlem community of New York City, is testing a new strategy to promote adherence to therapy among inner-city TB patients. Both programs are outgrowths of behavioral research programs begun by the Institute in 1995.

## **Blood Diseases**

### **Sickle Cell Disease**

SCD is an inherited blood disorder that produces chronic anemia, end organ damage, and periodic episodes of pain. It affects about 1 in 500 blacks and 1 in 1,000 Hispanics. Since 1972, the NHLBI has supported an extensive research program to improve understanding of the pathophysiology of SCD and uncover better approaches for its diagnosis and treatment and for prevention of complications.

- Comprehensive Sickle Cell Centers Program (see Chapter 9): To provide a multidisciplinary and multilevel research approach to expedite development and application of new knowledge for improved diagnosis and treatment of SCD and prevention of its complications.
- Reference Laboratory to Evaluate Therapies for SCD (see Chapter 9): To use a battery of standardized tests for preclinical evaluation of potential new therapeutic agents for SCD.

#### ***Basic Research***

SCD is caused by hemoglobin polymerization that causes red blood cells to become hard, sticky, and shaped like sickles or crescents. When sickled cells go through small blood vessels, they tend to get stuck and block the flow of blood. This can cause pain, damage, and low blood count or anemia. Finding improved treatments and ultimately a cure for SCD is a major commitment of the Institute. NHLBI-supported scientists have learned a great deal about sickle cell anemia—what causes it, how it affects the patient, and how to treat some of its complications. They also have begun to have success in developing drugs to prevent the symptoms of sickle cell anemia and procedures that should ultimately provide a cure.

Advances in basic research include unraveling the molecular pathways that lead to sickling, thus allowing investigators to test compounds that might interrupt the sickling process; discovering the beneficial role of fetal hemoglobin in patients with SCD that prevents sickling and confirming the need to find fetal hemoglobin-enhancing drugs; developing the transgenic mouse model for SCD that allows investigators to study the effects of sickle cell anemia in a living organism and evaluate experimental treatments that cannot be done in humans; and curing a sickle mouse model through gene therapy, a significant achievement that brings us close to human gene therapy.

Basic research advances reported in FY 2004 include:

- Developing high-throughput robotic screening methods to identify active compounds for further mechanistic and preclinical evaluation as potential therapeutic agents for sickle cell anemia.
- Identifying nitrite as a major bioavailable pool of NO, a known vasodilator that could increase blood flow to oxygen-deprived tissue. Therapeutic application of nitrite could potentially be used to treat diseases associated with oxygen-starved tissue, such as SCD.
- Establishing the link between a candidate genetic modifier in an endothelial NO synthase gene and acute chest syndrome (ACS) in female patients with SCD. Identifying genetic modifiers of ACS will aid in choosing potential therapeutic targets and enable individualized treatment.
- Developing the first gene therapy cure of a hemoglobinopathy mouse model using purified hematopoietic stem cells.
- Treating transgenic SCD mice with vanillin, a food additive that binds with sickle hemoglobin, prolongs survival under hypoxia, and correlates with a reduced number of sickle red cells. Study results demonstrate the potential of vanillin to be a new and safe antisickling agent for SCD patients.

In 2004, the NHLBI participated in a trans-NIH conference on “New Directions for Sickle Cell Therapy in the Genome Era.” One of the recommendations from the conference was for the Institute to develop a joint initiative with the National Human Genome Research Institute to apply chemical genomics approaches to SCD pathophysiology and therapy.

### ***Clinical Research***

The NHLBI is committed to finding improved treatments and ultimately a cure for SCD and other hemoglobinopathies. Institute-initiated studies have begun to yield therapies that will alleviate the symptoms of sickle cell anemia and procedures that should ultimately provide a cure.

- Multicenter Study of Hydroxyurea (MSH) Patients’ Follow-up (see Chapter 11): To determine the toxic effects of long-term hydroxyurea use in the patients who participated in the adult hydroxyurea clinical trial that ended successfully in 1995; 100 percent of the participants are black. A significant finding of the study was that patients who took hydroxyurea for 9 years experienced a 40 percent reduction in deaths.
- BABY HUG (see Chapter 11): To assess the effectiveness of hydroxyurea in preventing onset of chronic organ damage in young black children with sickle cell anemia.
- STOP 2 (see Chapter 9): To determine the optimal primary prevention strategy for the transfusion treatment shown to be effective in STOP 1 in a minority pediatric population. The trial is designed to determine how long transfusions are needed for primary stroke prevention.

An article in the July 2004 issue of the journal *Blood* highlighted a stroke prevention outcome from the NHLBI-supported STOP 1 Trial on the efficacy of blood transfusion in primary stroke prevention. The study showed a strong causal relationship between the publication of the STOP 1 Clinical Alert by the NHLBI and a dramatic reduction in the the rate of first-time stroke in California children with SCD.

The NHLBI is supporting several transplant-related clinical studies that are seeking to reach minority populations. To ensure increased awareness and equitable opportunities for participation, the studies support bilingual transplant center personnel and provide public Web

pages, educational materials, and informed consent documents in Spanish, Japanese, Korean, Chinese, and Vietnamese. In addition, focus groups have been held to identify barriers to participation.

- Cord Blood Stem Cell Transplantation Study (COBLT) (see Chapter 11): To establish ethnically diverse cord blood banks and to determine the utility of umbilical cord blood cells as a hematopoietic stem cell source for patients diagnosed with malignant and nonmalignant blood diseases. The COBLT bank contains more than 8,000 cord blood units; approximately 57 percent are from minority donors. Approximately 30 percent of the patients are minority.
- Blood and Marrow Transplant Clinical Research Network (see Chapter 11): In collaboration with the NCI, to promote the efficient comparison of innovative treatments and management strategies for patients undergoing blood or marrow transplantation. It has developed strategies and implemented procedures to enroll patients from minority groups.

Each year in the United States approximately 1,500 children are diagnosed with sickle cell anemia, and 30 to 50 children with thalassemia. A recent retrospective analysis of 44 children who were transplanted with sibling cord blood for SCD or thalassemia showed that matched sibling cord blood transplantation offers the potential for a cure.

- Sibling Donor Cord Blood Banking and Transplantation Study (see Chapter 9): To establish a cord blood bank for collecting sibling donor cord blood in families that currently have a child with sickle cell anemia or thalassemia. Investigators will evaluate the safety and effectiveness of matched sibling cord blood transplantation for treatment of children with SCD or thalassemia. A majority of the participants are black.

Transplants for patients with sickle cell anemia are performed at many centers across the United States, with few performed at a single center. To promote a unified strategy for sharing data, the NHLBI, with support from the National Center for Minority Health and Health Disparities, awarded a grant supplement to the International Bone Marrow Transplant Registry (IBMTR) to collect data on demographics and outcomes of patients with sickle cell anemia who received a blood or marrow transplant. Recognizing that the registry by itself may not be sufficient to instill a sense of collaboration among investigators, the Institute, with support from the NIH Office of Rare Diseases, recently sponsored a meeting to bring together transplant investigators to review data collected by the IBMTR and to develop a systematic plan to sustain an infrastructure for collaboration among U.S. centers treating and transplanting patients with sickle cell anemia.

Although medical progress has increased the lifespan of patients with SCD, translating research advances to clinical practice remains a challenge. Adult patients continue to have difficulty receiving advanced care. To address this need, the NHLBI held a workshop in June 2004 to focus on the major unmet needs faced by adults with SCD and to develop strategies to address them. This fall, the Institute issued an initiative to establish a SCD Network that will develop and evaluate safe and effective therapies to treat and prevent complications of SCD.

### ***Education***

The NHLBI has developed a number of publications on SCD that target minorities.

- *Datos Sobre La Anemia Falciforme* (Facts About Sickle Cell Anemia)
- Fact Sheet: Hydroxyurea in Pediatric Patients With Sickle Cell Disease
- Facts About Sickle Cell Anemia
- Patient Fact Sheet: The Multicenter Study of Hydroxyurea in Sickle Cell Anemia (MSH)
- Management and Therapy of Sickle Cell Disease.

## **Cooley's Anemia**

Cooley's anemia is an inherited disorder of red blood cells that affects primarily people of Mediterranean, African, Southeast Asian, Chinese, and Asiatic Indian origin. In 2000, the Institute initiated a program to establish a network of clinical research centers to evaluate new therapeutic agents. Research efforts include developing oral chelators to remove iron overload caused by repetitive transfusion therapy, testing drugs to enhance fetal hemoglobin production, and examining gene therapy approaches to cure the disease.

- **Thalassemia (Cooley's Anemia) Clinical Research Network** (see Chapter 11): To establish a group of clinical centers to accelerate research in the management of thalassemia, standardize existing treatments, and evaluate new ones.

Investigator-initiated studies include efforts to develop oral chelators to remove the iron overload caused by repetitive transfusion therapy; exploration of hormone therapy for patients surviving into their teens; testing of drugs intended to enhance fetal hemoglobin production (hydroxyurea and butyrate); investigation of gene therapy approaches to cure the disease; prevention of bone diseases; optimum treatment of hepatitis; treatment of heart disease and iron overload; noninvasive ways of measuring iron burden; and efforts to improve the safety of the Nation's blood supply.

## **Women's Health Initiative**

Coronary heart disease, cancer, and osteoporosis are the most common causes of death, disability, and impaired quality of life in postmenopausal women. The WHI (see Chapters 2 and 11) is addressing the benefits and risks of HT, changes in dietary patterns, and calcium/vitamin D supplements in disease prevention. Several of the centers have recruited primarily minority populations: blacks, Hispanics, Asian Americans, Pacific Islanders, and American Indians. The Clinical Trial recruited 12,607 minorities and the Observational Study recruited 15,658. Overall, of the 161,809 postmenopausal women recruited into the WHI, 17 percent were minorities.